Republika e Kosovës
Republika Kosova-Republic of Kosova
Qeveria – Vlada – Government

MINISTRIA E SHËNDETËSISË - MINISTARSTVO ZDRAVSTVA - MINISTRY OF HEALTH

UDHËZIM ADMINISTRATIV (Shëndetësi) Nr. 07/2015. MBI KËRKESAT E PRAKTIKËS SË MIRË TË PRODHIMIT LËSHIMIT TË AUTORIZIM PRODHIMIT DHE ÇERTIFIKATËS PËR PRAKTIKEN E MIRË TË PRODHIMIT PËR PRODUKTET MEDICINALE

ADMINISTRATIVE INSTRUCTION (Health) No. 07/2015 ON LAYING DOWN THE REQUIEREMENTS OF GOOD MANUFACTURING PRACTICE, ISSUING MANUFACTURING AUTHORISATION AND CERTIFICATE OF GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS

ADMINISTRATIVNO UPUTSTVO (Zdravstvo) Br. 07/2015 O KOJIM SE UVRDUJE ZAHTEVI DOBRE PROIZVODNE PRAKSE , IZDVANJE PROIZVODNJA OVLASCENJA I SERTIFIKAT DOBRE PROIZVODNE PRAKSE ZA MEDICINSKE PROIZVODE

Ministri i Ministrisë së Shëndetësisë	**Minister of Ministry of Health**	**Ministar Ministarstva Zdravstva**
Në mbështetje të nenit 10, dhe nenit 41 pika 1 të Ligjit Nr.04/L-190 për Produkte dhe Pajisje Medicinale (Gazeta Zyrtare Nr. 27/2014Prill 2014), nenit 8 nënparagrafi 1.4 të Rregullores Nr.02/2011 për fushat e përgjegjësisë administrative të Zyrës së Kryeministrit dhe Ministrive si dhe nenit 38 paragrafit 6 të Rregullores së Punës së Qeverisë Nr.09/2011 (Gazeta Zyrtare Nr. 15, 12.09.2011),	Based on the article 10, and article 41 point 1 of Law Nr. 04/L-190 for Products and Medical Devices (Official Gazette No. 27/2014 April 2014), article 8 of Regulation subparagraph 1.4 Nr. 02/2011 the areas of administrative responsibility Office of the Prime Minister and Ministries and article 38 paragraph 6 of the Rules of Procedure of the Government Nr.09/2011 (Official Gazette No. 15, 12.09.2011),	Na osnovu člana 10,i člana 41 tacka 1 zakona 04/L-190 za Proizvodima i Medicinskim Sredstvima (Službeni Glasnik Br. 27/2014 April 2014), član 8 uredbe tačke 1.4 Br. 02/2011 Oblastima administrativne odgovornosti Kancelarija Premijera i Ministarstva i člana 38 stav 6 Poslovnika Vlade Br. 09/2011 (Službeni Glasnik Br. 15, 12.09.2011),
Nxjerr:	Issues:	Donosi:
UDHËZIM ADMINISTRATIV (Shëndetsi) Nr.07/2015 MBI KËRKESAT E PRAKTIKËS SË MIRË TË PRODHIMIT, LËSHIMIT TË AUTORIZIM PRODHIMIT DHE ÇERTIFIKATËS PËR PRAKTIKEN E MIRË TË PRODHIMIT PËR PRODUKTET MEDICINALE	**ADMINISTRATIVE INSTRUCTION (Health) No.07/2015 ON LAYING DOWN THE REQUIEREMENTS OF GOOD MANUFACTURING PRACTICE, ISSUING MANUFACTURING AUTHORISATION ANDCERTIFICATE OF GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS**	**ADMINISTRATIVNO UPUTSTVO (Zdravstvo) Br. 07/2015 O KOJIM SE UVRDUJE ZAHTEVI DOBRE PROIZVODNE PRAKSE , IZDVANJE PROIZVODNJA OVLASCENJA I SERTIFIKAT DOBRE PROIZVODNE PRAKSE ZA MEDICINSKE PROIZVODE**

Neni 1 Qëllimi	Article 1 Purpose	Član 1 Delokrug
1. Ky Udhëzim Administrativ vendos parimet dhe kërkesat për praktikën e mirë të prodhimit për produktet medicinale dhe produktet medicinale hulumtuese, për prodhimin e të cilave nevojitet autorizimi në Republikën e Kosovës, dhe kërkesat për lëshimin e autorizim prodhimit dhe çertifikatës për praktikën e mirë të prodhimit për produktet medicinale.	1. This Administrative Instructions lays down the principles and requirements of good manufacturing practice for medicinal and investigational products medicinal, whose manufacture requires authorization in Republic of Kosovo, and the requirements for manufacturing authorizations and certificates of good manufacturing practice for medicinal products.	1. Ovo Administrativno Uputsto odredjuje principe i zahteve dobre prakse proizvodnje medicinskih proizvda i medicinsko istraživačkih - testirajućih proizvoda, čija proizvodnja zahteva ovlašćenje u Republici Kosovo kao i zahteva za izdavanje ovlašćenja i sertifikata dobre prakse u proizvodnji.
2. Ky Udhëzim Administrativ është në përputhshmëri të pjesërishme me: Direktivën 2001/83/EC të Parlamentit Europian dhe Këshillit e 6 Nëntor 2001 mbi kodin e komunitetit lidhur me produktet medicinale për përdorim njerëzor; Direktivën 2004/27/EC të Parlamentit Europian dhe Këshillit e 31 Mars 2004 që amandamenton Direktivën 2001/83/EC mbi kodin e komunitetit lidhur me produktet medicinale për përdorim njerëzor; Direktivën 2011/62/EU të Parlamentit Europian dhe e Këshillit e 11 Mars	2. This Administrative Instruction is partially compliant with EU: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; Directive 2004/27 of the European Parliament and of the Council of 31 March 2004 on the Community code relating to medicinal products for human use; Directive 2011/62/EU of European Parliament and Council of March	2. Ovo Administrativno uputstvo delimično je u skladu sa: Direktivom 2001/83 EC Evropskog parlamenta i Saveta od 6 novembra 2001. o kodu zajednice u vezi sa medicinskim proizvodima za ljudsku upotrebu; Direktivom 2004/27/EC Evropskog parlamenta i Saveta od 31 Marta 2004. koji dopunjuje i izmenjuje Direktivu 2001/83/EC o kodu zajednice u vezi sa medicinskim proizvodima za ljudsku upotrebu; Direktivom 2011/62/EC Evropskog parlamenta i Saveta od 11 Marta

2008 që amandamenton Direktivën 2001/83/EC mbi kodin e komunitetit lidhur me produktet medicinale për përdorim njerëzor, lidhur me parandalimin e përfshirjes në zingjirin juridik furnizues të produkteve mjekësore të falsifikuara; Direktivën 2001/20/EC të Parlamentit Europian dhe Këshillit e 4 Prill 2001 mbi përafrimin e ligjeve, rregulloreve dhe dispozitave administrative të Shteteve Anëtare lidhur me implementimin e praktikës së mirë klinike në kryerjen e hulumtimeve klinike për produktet medicinale për përdorim njerëzor, dhe Direktivën e Komisionit 2003/94/EC të 8 Tetor 2003 që përcakton parimet dhe udhëzimet e praktikës së mirë të prodhimit lidhur me produktet medicinale për përdorim njerëzor dhe produktet medicinale hulumtuese për përdorim njerëzor.	2008 that amends the Directive 2001/83/EC for community code related to medical products for human use that delas with prevention of involvement in legal supply chain of falsified medical products; Directive 2001/20/EC of European Parliament and Council of April 4th 2001 related to approximation of laws, regulations and administrative dispositions of member States related to implementation of best practices in performing the clinical researches for medical products for human use and Commission Directive 2003/94/EC of 8 October that determines the principles and guidelines of best clinical practice of producing related to medical products for human use and medical research products for human use.	2008.koji dopunjuje i izmenjuje Direktivu 2001/83/EC o kodu zajednice u vezi sa medicinskim proizvodima za ljudsku upotrebu, u vezi sprečavanja uključivanja u pravnom lancu snabdevanja falsifikovanih medicinskih proizvoda; Direktivom 2001/20/EC Evropskog parlamenta i Saveta od 4. Aprila 2001. o usklađivanju zakona, pravilnika i admnistrativnih odredbi država članica u bezi sa sprovođenjem dobre kliničke prakse u obavljanju kliničkih istraživanja za medicinske proizvode koji su za ljudsku ipotrebu, i Direktivom Komisije 2003/94/EC od 8. oktobra 2003. koja propisuje načela i uputstva dobre proizvođačke prakse u vezi sa medicinskim proizvodima za ljudsku upotrebu i medicinske istraživačke proizvode za ljudsku upotrebu.

Neni 2 Definicionet	Article 2 Definitions	Član 2 Definicije
1. Për qëllimet e këtij Udhëzimi Administrativ, zbatohen përkufizimet e përcaktuara me Ligjin për Produkte dhe Pajisje Medicinale Nr.04/L-190 dhe përkufizimet e mëposhtme:	1. For the purposes of this administrative instruction shall be applieddefinitions as in Law on Medical Products and Devices 04 / L-190 including the following definitions:	1. Za potrebe ovog administrativnog uputstva upotrebljavaju se definicije iz Zakona o medicinskim proizvodima i opremi 04 / L- 190 kao i sledeće definicije.
1.1. Sigurimi i kualitetit farmacuetikë është numri i tërësishëm i aktiviteteve dhe procedurave të organizuara me qëllimtë sigurimit se produktet medicinale dhe produktet hulumtuese medicinale janë të kualitetit të kërkuar sipas qëllimit të përdorimit të tyre.	1.1. Pharnaceutical quality assurance means the total sum of organized activities and procedures with the objective of ensuring that medicinalproducts and investigational medicinal products are of the quality required for their intended use.	1.1. Bezbednost farmaceutskog kvaliteta podrazumeva celokupnu aktivnost obavljenih procedura kako bi seobezbedili medicinski proizvodi i medicinsko istraživački-testirajući proizvodi traženogkvaliteta za korišćenje u ovom cilju.
1.2. Verbim është maskimi i qëllimshëm i identitetit të produktit medicinal hulumtues në pajtueshmëri me udhëzimet e organizuesit.	1.2. Blinding means the deliberate disguising of the identity of an investigational medicinal product in accordance with the instructions of the sponsor.	1.2. Prikrivanje podrazumeva namerno maskiranje identiteta medicinsko istraživačko-testirajućeg proizvda u skladu sa uputstvima sponzora.
1.3. Demaskim i identitetit të produktit hulumtues medicinal është zbulim i identitetit të produktit të maskuar qëllimisht.	1.3. Unblinding of the identity of investigational medicinal product means the disclosure of the identity of a blinded product.	1.3. Neprikrivanje identiteta istraživačko-testirajućeg proizvoda podrazumeva otkrivanje identiteta prikrivenog proizvoda.
1.4. Pjesë individuale të prodhimit të produkteve medicinale përfshijnë	1.4. Individual parts of manufacturing of medicinal	1.4. Individualne delove medicinskih proizvoda

të gjitha operacionet nga furnizimi me materiale dhe produkte, prodhimit te prouktit medicinal në kuptim të ngushtë, paketimit immediat, paketimit të jashtëm, kontollit të kualitetit, lirimit të serisë, importit, deponimit dhe shpërndarjes në depo. Prodhimi i produktit medicinal në kuptim të ngushtë është ndarë sipas procedurave të prodhimit dhe fromave farmaceutike dhe përfshin të gjitha proceset e prodhimit nga pranimi i lëndëve të para, formulimit farmaceutik dhe teknologjik deri te paketimi i produktit medicinal. Kontrolli i kualitetit është i ndarë sipas llojit të testeve të kryera përfshire ato fizike, kimike, biologjike dhe testeve mikrobiologjike ku mund të perfshihen testet mikrobiologjike të produkteve jo sterile dhe sterile.	products include all operations from the supply of materials and products, the manufacture of medicinal products in the narrow sense, immediate packaging, outer packaging, quality control, batch release, import, storage and delivery to wholesale distributors. The manufacturing of medicinal products in the narrow sense is divided according to manufacturing procedures and pharmaceutical forms and includes all manufacturing procedures from receiving starting materials, pharmaceutical and technological forming to packaging of medicinal products. Quality control is divided according to types of conducted tests and includes physical and chemical, biological and microbiological tests that may include microbiological testing of non-sterile and sterile products.	obuhvataju sve operacije od snabdevanja materijalom i proizvodima, do proizvodnje medicinskih proizvoda u užem smislu, primarno pakovanje, spoljno pakovanje, kontrole kvaliteta, izdavanje serije, uvoza, čuvanja i predaje kod distributera na veliko. Porizvodnja medicinskih proizvoda u užem smislu podeljena je na bazi proizvodnih procedura i farmaceutskih oblika i obuhvata sve radnje proizvodnje od dobijanja početnih materijala, farmaceutskog i tehničkog formiranja za pakovanje medicinskih proizvoda. Kontrola kvaliteta je podeljena prema vrstama izvršenih testova i obuhvatafizičke testove, biološke i mikrobiološke koji mogu da obuhvataju mikrobiološkonesterilno i sterilno testiranje.
1.5. Çertifikata e praktikës së mire të prodhimit është çertifikatë me afat	1.5. Certificate of good manufacturing practice is a	1.5. Sertifikat dobre prakse proizvodnje je dokument

të kufizuar të vlefshmërisë që paraqet vlerësimin përfundimtarë të pajtueshmërisë së procesit të prodhimit ose pjesëve të tij me kërkesat e praktikës së mirë të prodhimit.	certificate with limited validity term which represents final evaluation of compliance of a manufacturing process or its parts with the requirements of good manufacturing practice.	ograničene važnosti koji predstavlja završnu procenu o uskladjenosti jednog procesa proizvodnje ili njenih delova sa zahtevima dobre prakse proizvodnje.
1.6. Vend prodhimi do të thotë hapsirë e definuar në të cilën kryhet procesi i integruar i prodhimit ose pjesë të veçanta.	1.6. Manufacturing site means a defined area on the address where an integral manufacturing process or its individual parts are carried out.	1.6. Lokacija proizvoda podrezumeva odredjenu zonu sa adresom na kojoj se vrši integralni proces proizvodnje ili njeni pojedini delovi.
1.7. Dokumentacion i Prodhuesit është dokument i zhvilluar nga prodhuesi i produkteve medicinale që përfshin informata për sistemin e menagjimit të kualitetit dhe të gjitha veprimeve qe kryhen në prodhues.	1.7. Documentation on the manufacturing site means a document developed by the manufacturer of the medicinal product which includes information on the quality management policy and all activities carried out on that manufacturing site.	1.7. Dokumentacija o zoni proizvodnje podrazumeva dokument pripremljen od proizvodjača medicinskog proizvoda koji obuhvata informacije o politikama menadžiranja, kvaliteta i svih izvršenih radnji u toj proizvodnoj lokaciji.
1.8. Kontaminim kryçëzor është kontaminim i lëndëve të para ose produkteve me material ose produkte tjera.	1.8. Cross-contamination means contamination of starting materials or products with other materials or products.	1.8. Podinfekcija podrazumeva infekciju početnih matareijala ili proizvoda sa drugim matreijalima i proizvodima.
1.9. Lirimi i serisë do të thotë kontroll i të gjitha dokumenteve relevante me qëllim të arritjes së pajtueshmërisë së serisë me autorizim marketingun për një produkt medicinal dhe kërkesat e	1.9. Batch release means inspection of all relevant documentation with the objective of establishing the compliance of a batch with the marketing authorisation for a medicinal	1.9. Izdavanje serije podrazumeva proveru celokupne dokumentacije sa ciljem stvaranja uskladenosti jedne serije sa ovlašćenjem o marketingu za medicinski

praktikës së mire të prodhimit dhe sigurimit të vlerësimit final të pajtueshmërise së series.	product and requirements of good manufacturing practice, and providing a final assessment of the batch compliance.	proizvod i sa zahtevima o dobroj praksi proizvodnje i obezbedjena uskladenosti serije.
1.10. Produkt medicinale hulumtues është një formë farmaceutike e substancës aktive ose placebo e testuar ose përdorur si një referencë në një hulumtim klinik, duke përfshirë produkte tashmë me autorizim të marketingut, por përdoret (formuluar ose të paketuara), në një mënyrë të ndryshme nga forma autorizuar, ose kur përdoret për një tregues të paautorizuar, ose kur përdoret për të fituar informacion të mëtejshëm në lidhje me formën e autorizuar.	1.10. Investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.	1.10. Ispitivani lek: farmaceutski oblik aktivne supstance ili placebo koji se ispituje ili koristi kao referenca u kliničkom ispitivanju, uključujući i proizvode već sa promet , ali se koristi ili montažni (formulisana ili upakovana) na način drugačiji od strane ovlašćenog obliku ili kada se koriste za neovlašćeno indikacije , ili kada se koristi da steknu dodatne informacije o ovlašćenog obliku.
1.11. AKPPM-Agjencia e Kosovës për Produkte dhe Pajisje Medicinale.	1.11. KMA- Kosovo Medicines Agency for Medicinale Products and Medical Devices.	1.11. KAMP- Kosovska agencija za medicinske proizvode i opreme.
1.12. LCK-Laboratoti zyrtare i kontrollit te kualitetit te produkteve dhe pajisjeve medicinale.	1.12. QCL-Official Laboratory for the Control of the Quality of Medicinal Products and Medical Devices.	1.12. LKK-Zvanični Laboratorija za kontrolu kvaliteta lekova IMedical Devices.
1.13. PMP-Praktika e Mirë e Prodhimit	1.13. GMP-Good Manufacturing Practice	1.13. DPP-Dobra Proizvodnja Praksa

Neni 3 **Prodhimi i produkteve medicinale**	**Article 3** **Manufacture of medicinal products**	**Član 3** **Proizvodnja medicinskih proizvoda**
Produktet medicinale dhe / ose produktet medicinale hulumtuese në Republikën e Kosovës mund të prodhohen nga personi juridik fizik i vendosur në Republikën e Kosovës në pajtueshmëri me autorizim prodhimin dhe permbushjes së kërkesave nga neni 3 paragrafi 1.29 dhe neni 10 i Ligjit 04/L-190 për Produkte dhe Pajisje Medicinale (më tej Ligji).	Medicinal products and/or investigational medicinal products in Republic of Kosovo, may be manufactured by legal or natural person established in Republic of Kosovo in accordance with manufacturing authorization and fulfillment of requirements form article 3 paragraph 1.29 and article 10 of Law Nr. 04/L - 190 on Medicinal Products and Medical Devices (hereinafter the Law).	Medicinski proizvodi i /ili istražiačko-testirajući medicinski proizvodi u Republici Kosovo, mogu da se proizvode od strane pravnog ili fizičkog lica nastanjenog na Kosovu na osnovu i u skladu sa ovlašćenjem za proizvodnju koje mora da popunjava obrazac zahteva po Članu 3, stav 1.29 i člana 10 Zakona Br.04/L – 190 o Medicinskim Proizvodima i Opremi (u daljem tekstu Zakon).
Neni 4	**Article 4**	**Član 4**
Prodhuesi i produkteve medicinale është i obliguar të përdorë substanca aktive të prodhuara në pajtueshmëri me kërkesat e praktikës së mire të prodhimit e që janë konfrom Farmakopesë Europiane.	The manufacturer of the medicinal products is required to use active substances manufactured in compliance with requirements of good manufacturing practices conform to the European Pharmacopoeia.	Proizvodjač medicinskih proizvoda mora da koristi aktivne supstance proizvedene u skladu sa zahtevima dobre prakse o proizvodnji koje su u skladu sa Evropskom Farmakopejom.
Neni 5 **Pajtueshmëria me Praktikën e Mirë të Prodhimit**	**Article 5** **Conformity with Good Manufacturing Practice**	**Član 5** **Srazmernost sa Dobrom praksom o proizvodnji**
Prodhuesi i produkteve medicinale duhet të sigurojë që të gjitha operacionet e prodhimit për produktet medicinale dhe /	The manufacturer of medicinal products shall ensure that all manufacturing operations for medicinal products and /	Proizvodjač medicinskih proizvoda mora da garantuje da su sve radnje o proizvodnji medicnskih proizvvoda i/ili

ose produktet medicinale hulumtuese janë kryer në pajtueshmëri me praktikën e mire të prodhimit dhe autorizim prodhimit, kjo aplikohet poashtu edhe për produktet medicinale që jane të dedikuara vetëm për eksport.	or investigational medicinal products are carried out in compliance with good manufacturing practice and the manufacturing authorization; this applies also to medicinal products intended for export only.	istraživačko-testirajućih proizvoda u skladu sa dobrom praksom o proizvodnji i sa ovlašćenjem o proizvodnji, ovo važi i za medicinske proizvode namenjene za izvoz.
Neni 6 **Pajtueshmëria me autorizimin për marketing**	**Article 6** **Conformity with marketing authorization**	**Član 6** **Saglasnost sa ovlašćenjem za marketing**
1. Prodhuesi siguron se të gjitha operacionet prodhuese për produkte medicinale, subjekt i autorizimit të marketingut, kryhen në pajtim me informatat e siguruara në aplikacionin për autorizim të marketingut siç janë pranuar nga AKPPM-ja.Në rastin e produkteve medicinale hulumtuese, prodhuesi siguron se të gjitha operacionet prodhuese kryhen në pajtim me informatat e siguruara nga organizatori siç janë pranuar nga autoriteti kompetent.	1. The manufacturer shall ensure that all manufacturing operations for medicinal products subject to a marketing authorization are carried out in accordance with the information provided in the application for marketing authorization as accepted by the KMA. In the case of investigational medicinal products, the manufacturer shall ensure that all manufacturing operations are carried out in accordance with the information provided by the sponsor to the competent authority in Republic of Kosovo.	1. Proizvodjać mora da garantuje da su proizvodnje radnje o medicinskim proizvodima kao objektu ovlašćenja za marketing izvršene u skladu sa informacijom datom u Ovlašćenju za Marketing prihvaćenih od KAMP. U slučaju medicinskih istraživačko-testirajućih proizvoda, proizvodjać mora da garantuje da su sve proizvodne radnje izvršene u skladu sa informacijom datom od sponzora za nadležni organ u Republici Kosovo.
2. Prodhuesi do t'i rishqyrtojë rregullisht metodat e tij prodhuese nga pikëpamja	2. The manufacturer shall regularly review his manufacturing methods	2. Proizvodjać mora stalno da pregleda svoje metode proizvodnje

e përparimit zhvillimit shkencor dhe teknik.	and quality control procedures in the light of their adjustment to scientific and technical progress.	i radnje kontrole kvaliteta imajući u obzir njihovu uskladjenost sa naučnim i tehničkim razvojem.
3. Në rast nevoje për modifikim të dosjes së produktit medicinal bazuar në të cilën është lëshuar autorizimi për marketing ose autorizimi i hulumtimeve klinike mbajtësi i autorizimit duhet të aplikoje për modifikim në AKPPM.	3. In case there is a necessity for modification of the dossier of the medicinal product, based on which marketing authorization or clinical trials authorization has been granted, the authorization holder shall submit the application for modification to the KMA	3. Ukoliko bude potrebe o modifikaciji dosijea o medicinskom proizvodu, na osnovu koga je izdato Ovlašćenje za Marketing ili ovlašćenje kliničkih istraživanja, nosilac ovlašćenja mora da podnosi zahtev za modifikaciju KAMP
Neni 7 **Pajtueshmëria me Autorizimin për Prodhim**	**Article 7** **Compliance with manufacturing authorization**	**Član 7** **Uskladjenost sa ovlašćenjem za proizvodnju**
1. Prodhuesi i produkteve medicinale duhet të prodhojë vetem produktet medicinale ose produktet medicinale hulumtuese për të cilat ai posedonë autorizim prodhimi valid.	1. The manufacturer of medicinal products shall manufacture only medicinal products or investigational medicinal products for which they hold valid manufacturing authorization.	1. Proizvodjač medicinskih proizvoda samo medicinskih ili istraživačko-testirajućih proizvoda za koje ima važeće ovlašćenje o proizvodnji.
2. Gjatë lëshimit ose modifikimit të autorizim prodhimmit prodhuesi i produkteve medicinale dhe / ose produkteve medicinale hulumtuese duhet të siguroi pajtueshmërine me të gjitha operacionet e prodhimit me të	2. During issuance or modification of manufacturing authorization, manufacturer of medicinal products and/or investigational medicinal products must ensure conformity of all manufacturing operations with	2. Prilikom dobijanja ili modifikacije ovlašćenja za proizvodnju, proizvodjać medicinskih i/ili istraživačko-testirajućih proizvoda mora obavezno da garantuje uskladjenost svih proizvodnjih radnji sa informacijom predatom

dhënat e dorëzuara te AKPPM-ja në Republikën e Kosovës ose autoriteti kompetent i vendeve tjera.	the information submitted to the KMA in Republic of Kosovo or competent authority of other countries.	kod KAMP u Republici Kosovo ili kod nadležnih organa drugih zemalja.
Neni 8 **Sistemi Farmaceutik i Sigurimit të Cilësisë**	**Article 8** **Pharmaceutical quality assurance system**	**Član 8** **Sistem garancije farmaceutskog kvaliteta**
Prodhuesi duhet të krijojë dhe zbatojë një sistem efikas të sigurimit të cilësisë farmaceutike, duke përfshirë pjesëmarrjen aktive të personelit udhëheqës dhe mbikëqyrës, si dhe personelit të departamenteve të ndryshme.	The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different departments.	Proizvodjač mora da stvori i da primeni efektivan farmaceutski sistem garancije kvaliteta, obuhvatajući aktivno učešće menadžmenta i osoblja raznih odeljenja.
Neni 9 **Personeli**	**Article 9** **Personnel**	**Član 9** **Osoblje**
1. Në çdo vend prodhimi, prodhuesi duhet të ketë në dispozicion një numër të mjaftueshëm të personelit kompetent dhe të kualifikuar, për të arritur objektivat e sigurimit të cilësisë farmaceutike. 2. Personeli kyç i prodhuesit përbëhet nga personi përgjegjës për prodhim, personi përgjegjës për kontroll të kualitetit dhe personi përgjegjës për	1. At each manufacturing site, the manufacturer shall have a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance objective. 2. Key personnel of the manufacturer consists of a person responsible for manufacture, a person responsible for quality control and a person	1. U svakoj koalicionoj proizvodnji, proizvodjač mora da ima na raspolaganju dovoljan broj nadležnog i kvalifikovanog osoblja kako bi postigao cilj zagarantovanog farmaceutskog proizvda. 2. Glavno osoblje proizvodjaća sesatoji se od jednog nadležnog lica za proizvodnju, jednog nadležnog lica za kontrolu kvaliteta i od

lirimin e serisë së produktit medicinal.	responsible for batch release of medicinal products.	jednog nadležnog lica za izdavanje serije medicinskih proizvoda.
3. Personi përgjegjës për prodhimin dhe personi përgjegjës për kontrollin e kualitetit duhet të veprojnë në mënyrë të pavarur nga njëri tjetri.	3. The person responsible for manufacturing and the person responsible for quality control shall act independently of each other.	3. Nadležno lice za proizvodnju i nadležno lice za kontrolu kvaliteta treba da rade nezavisno jedan od drugog.
4. Detyrat e stafit menaxherial dhe atij mbikqyrës duke përfshi personin e kualifikuar, përgjegjës për zbatimin dhe operimin me praktikën e mire të prodhimit duhet të jenë të definuara në përshkrimin e detyrave të punës. Marëdhënia e tyre sipas hierarkisë duhet të jetë e definuar në organogram. Organogrami dhe përshkrimi i detyrave të punës duhet të jenë aprovuar në pajtueshmëri me procedurat e mbrendeshme të prodhuesit.	4. The duties of the managerial and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.	4. Zadaci upravljačkog osoblja, računajući kvalifikovana lica, nadležna za primenu i za operaciju dobre prakse proizvodnje moraju da se odrede u opisu poslova. Njihovi hijerarhijski odnosi moraju da se odrede statutom organizacije. Statuti organizacija i opisi poslova moraju da se usvajaju u skladu sa unutrašnjim procedurama proizvodjača.
5. Personeli duhet të trajnohet në mënyrë të vazhdueshme ku efikasiteti duhet të verifikohet,si në teori dhe aplikimin e konceptit të sigurimit të kualitetit dhe praktikës së mire të prodhimit dhe ku vlerësohet kërkesa të veçanta për prodhimin e produkteve medicinale hulumtuese.	5. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice, and, where appropriate, the particular requirements for the manufacture of	5. Osoblje mora da ima početno i stalno podučavanje, čija efektnost mora da se proverava, posebno pokrivajući teoriju i primenu koncepta garancije kvaliteta i dobre prakse u proizvodnji i gde je to potrebno i posebne zahteve za proizvodnju istražiačko-testirajućih medicinskih proizvoda.

	investigational medicinal products.	
6. Programet e higjenës të adaptuara sipas aktiviteteve që kryhen duhet të krijohen dhe mbikqyren. Këto programe në përgjithsi përfshijne procedurat sa i përket shëndetit, praktikës së higjenës, dhe veshjes së personelit.	6. Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.	6. Prgrami higijene prilagodjeni aktivnostima koje će da se urade, moraju da se osnivaju i da se primenjuju. Posebno, ovi programi moraju da obuhvataju radnje o zdravlju, higijenskoj praksi i ovlačenju osoblja.
Neni 10	**Article 10**	**Član 10**
1. Personi përgjegjës për lirimin e serisë si në nenin 3 pragrafi 1.39 dhe neni 10 pragrafi 5 dhe 6 të Ligjit duhet të kenë njohuri të mjaftueshme, të fituara gjatë studimeve në lëndët e mëposhtme: 1.1. Fizikë eksperimentale, 1.2. Kimi të përgjithshme dhe inorganike, 1.3. Kimi organike, 1.4. Kimi analitike, 1.5. Kimi Framaceutike përfshi analizat e produkteve medicinale, 1.6. Biokimi (mjekësore) e përgjithshme dhe e aplikueshme , 1.7. Fiziologji,	1. The person responsible for the batch release as per article 3 paragraph 1.39 and article 10 paragraph 5 and 6 of the Law must have proficient knowledge, obtained through the course of studies, of following subjects: 1.1. Experimental physics, 1.2. General and inorganic chemistry , 1.3. Organic chemistry, 1.4. Analytical chemistry, 1.5. Pharmaceutical chemistry, including analysis of medicinal products, 1.6. General and applied biochemistry (medical), 1.7. Physiology,	1. Nadležno lice za izdavanje serije po Članu 3, stav 1.39 i Članu 10, stav 5 i 6 Zakona, mora imati znanja i sposobnosti stečene kursom studiranja za sledeće predmete: 1.1. Eksperimentalna fizika, 1.2. Opšta i neorganska hemija, 1.3. Organska hemija, 1.4. Analitička hemija, 1.5. Farmaceutska hemija, obuhatajući analizu medicinskih proizvoda, 1.6. Opšta i primenjena (medicinska) biohemija, 1.7. Fiziologija,

1.8. Mikrobiologji, 1.9. Farmakologji, 1.10. Teknologji farmaceutike, 1.11. Toksikologji, 1.12. Farmakognozi (studime të përbërjes dhe efekteve të të substancave aktive natyrore dhe atyre me origjinë shtazore). 2. Nëse programi i studimit nuk përfshin aftësimin në disa nga lëndët të referuara në pragrafin 1 të këtij neni, personi i kualifikuar duhet të posedojë dëshmi të zotësive adekute në lëndët e involvuara. 3. Personi i kualifikuar duhet të ketë përvojë praktike mbi dy vjeçare, në një ose më shumë ndërmarrje të cilat janë të autorizuara për prodhimin e produkteve medicinale sa i përket analizave të produkteve medicinale, analizës së substancave aktive dhe testimit e kontrollit të nevojshëm për të siguruar kualitetin e produkteve medicinale. Kohëzgjatja e përvojës praktike mund të reduktohet një vit në rast se studimet universitare zgjasin të paktën pesë vite, dhe mund te reduktohet për një vit e gjysmë kur	1.8. Microbiology, 1.9. Pharmacology, 1.10. Pharmaceutical technology, 1.11. Toxicology, 1.12. Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin). 2. If the study programme does not include proficiency in some of the subjects referred in paragraph 1 of this article, the qualified person shall provide evidence of adequate proficiency in subjects involved. 3. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products. The duration of practical experience may be reduced by one year where a university course lasts for at least	1.8. Mikrobiologija, 1.9. Farmakologija, 1.10. Farmaceutska tehnologija, 1.11. Toksikologija, 1.12. Farmakognozija (istraživanje sastava i efekata prirodnih aktivnih supstanci biljnog i životinjskog porekla). 2. Ako program studija ne obuhvata osposobljavanje u nekim od pomenutih predmeta u stavu 1 ovog člana, kvalifikovano lice mora da obezbedi dokaze adekvatnog poznavanja u obuhvaćenim predmetima. 3. Kvalifikovano osoblje mora da ima radno iskustvo stečeno, najmanje za dve godine, u jednom ili u više preduzeća ovlašćenih za proizvodnju medicinskih proizvoda, u aktivnostima kvalitetne analize medicinskih proizvoda, količinske analize aktivnih supstanci i testiranja i potrebnu kontrolu kako bi se garantovao kvalitet medicinskih proizvoda. Trajanje praktičnog iskustva može da se reduktira na godinu dana, tamo gde

studimet zgjasin gjashtë vite.	five years and by a year and a half where the course lasts for at least six years.	univerzitetski kurs traje najmanje pet godina i na godinu i po dana, kada kurs studija traje najmanje šest godina.
4. Personi përgjegjës për lirimin e serisë së produktit medicinal mund të jetë po ashtu person përgjegjës për kontrollin e kualitetit ose për prodhimin e produkteve medicinale.	4. The person responsible for batch release of medicinal products may also be the person responsible for quality control or for manufacturing of medicinal products.	4. Nadležno lice za izdavanje serije medicinskih proizvoda, može takodje de bude lice za kontrolu kaliteta ili za proizvodnju medicinskih proizvoda.
5. AKPPM duhet te ndërmarrë masat e nevojshme për të siguruar se personi i kualifikuar i referuar në Nenin 10, pavarsisht nga marëdhënia e tij me majtësin e autorizimit për prodhim, është përgjegjës ne kontekst të procedurave të referuara në Nenin 10 pragrafi 5 dhe 6, për të siguruar se:	5. KMA shall take all appropriate measures to ensure that the qualified person referred to in Article 10, without prejudice to his relationship with the holder of the manufacturing authorization, is responsible, in the context of the procedures referred to in Article 10 paragraph 5 and 6, for securing:	5. KAMP mora da preduzme sve potrebne mere da garantuje da kvalifikovano lice iz Člana 10, neugrožavajući njegove odnose sa nosiocem ovlašćenja proizvodnje, jeste nadležno u kontekstu radnji po članu 10 o garanciji:
5.1. Çdo seri e produktit medicinal është prodhuar dhe kontrolluar konform ligjeve në fuqi dhe në pajtueshmëri me kërkesat e autorizim marketingut,	5.1. That each batch of medicinal products has been manufactured and checked in compliance with the laws in force in and in accordance with the requirements of the marketing authorization,	5.1. Da je svaka serija medicinskih proizvoda proizvedena i kontrolisana u skladu sa postojećim zakonima i u skladu sa zahtevima ovlašćenja za marketing.
5.2. Në rast të produkteve medicinale me prejardhje nga vendet e treta, pavarsisht nëse produkti është prodhuar në Kosovë, që çdo seri prodhimi ka kaluar në Republikën	5.2. In the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in Kosovo, that	5.2. U slučaju kada medicinski proizvodi dolaze iz trećih zemalja, nezavisno od toga iako su proizvedeni u Republici Kosovvo,

e Kosovës analizat e plota kualitative, analizat kuantitative e të paktën të gjitha substancave aktive dhe të gjitha testet ose kontrollat tjera të nevojshme për te siguruar kualitetin e produktit medicinal në përputhje me kërkesat e marketing autorizimit.	each production batch has undergone in Republic of Kosovo full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.	podvrgavaju se potpunoj analizi kvaliteta, analizi količine, najmanje svih aktivnih supstanci i testovima ili ostalim kontrolama da bi se garantovao kvalitet medicinskih produkata u skladu sa zahtevima ovlašćenja za marketing.
6. Personi i kualifikuar i referuar në Nenin 10 duhet të sigurojë se produktet e dedikuara për treg kanë të vendosura në paketim të gjitha karakteristikat e sigurisë.	6. The qualified person referred to in Article 10 shall in the case of medicinal products intended to be placed on the market, ensure that the safety features have been affixed on the packaging.	6. Kvalifikovano lice pozivajući se na član 10, kada su proizvodi namenjeni tržištu, treba da obezbedi karakteristike garancije istaknute na pakovanju.
7. Në të gjitha rastet dhe veçanërisht për produktet medicinale të liruara, personi i kualifikuar duhet ti çertifikoj në një regjistër ose dokument ekuivalent të përgaditur për këtë qëllim, që çdo seri e prodhuar i përmbush dispozitat e këtij neni, ky regjistër apo dokument ekuivalent duhet të ruhet të jetë i përditsuar me operacionet e kryera, dhe duhet të jetë në dispozicion të pmp auditorëve të AKPPM-së dhe në çdo rast për të paktën pesë vjet.	7. In all cases and particularly where the medicinal products are released for sale, the qualified person must certify in a register or equivalent document provided for that purpose, that each production batch satisfies the provisions of this Article; the said register or equivalent document must be kept up to date as operations are carried out and must remain at the disposal of gmp auditors KMA for the period specified by competent authority	7. U svim slučajevima, ali posebno kada se medicinski proizvodi iznose na tržište, kvalifikovano lice mora da potvrdi na nekom spisku ili na nekom ekvivalentnom dokumentu predvidjenom za ovu svrhu, da svaka serija proizvoda ispunjava odredbe ovog Člana. Spisak ili ekvivalentni dokument mora da se vodi uredno dok se ne završe operacije i mora da bude na raspolaganje dpp revizora KAMP za period odredjen od nadležnog

8. AKPPM duhet të siguroi që detyrat e personit të kualifikuar i referuar në Nenin 10 janë përmbushur, ose me anë të masave të përshtatshme administrative, ose duke i bërë që këta persona t'i nënshtrohen një kodi profesional të sjelljes. 9. AKPPM mund të kryej pezullimin e përkohshëm të personit të tillë duke filluar procedurat administrative apo disiplinore kundër tij për dështimin e përmbushjes së detyrimet e tij.	and in any event for at least five years. 8. KMA shall ensure that the duties of qualified persons referred to in Article 10 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct. 9. KMA may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against him for failure to fulfill his obligations.	organa i za svaki slučaj, najmanje za pet godina. 8. Nadležni organ mora da garantuje da su zadaci kvalifikovanih lica po Članu 10 ispunjeni prikladnim administrativnim merama ili su podvrgnuti nekom stručnom kodu o ponašanju. 9. KAMP može da predvidi privremeno razrešenje takvog lica početkom administrativnog ili disciplinskog postupka za neispunjenje zadataka.
Neni 11 **Hapësirat dhe Pajisjet**	**Article 11** **Premises and Equipment**	**Član 11** **Objekti i oprema**
1. Hapësirat dhe pajisjet e prodhimit duhet të jenë shtrira, dizajnuara, konstruktuara, adaptuara dhe mirëmbajtura në mënyre qe i përshtaten operacioneve të synuara. 2. Hapësirat dhe pajisjet e prodhimit duhet të jenë shtrirë, dizajnuar per opreim në mënyrë të tillë për të minimizuar rrezikun e ndonjë gabimi dhe për të lejuar pastrimin efektiv dhe mirëmbajtjen për të shmangur	1. Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations. 2. Premises and manufacturing equipment shall be laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid	1. Proizvodni objekti i oprema moraju da budu postavljeni, projektovani, izgradjeni, prilagodjeni i održavani prema željenim operacijama. 2. Proizvodni objekti i oprema moraju da budu instalirani, projektovani i operativni tako da minimiziraju opasnost od grešaka i da dozvoljavaju efektivvno čišćenje i održavanje kako bi se izbeglo

kontaminimin ,kontaminimin kryçëzor dhe, në përgjithsi, çdo efekt negative në cilësinë e produktit. 3. Hapësirat dhe pajisjet që do të përdoren për operacionet e prodhimit, kritike për kualtitetin e produkteve, duhet ti nënshtrohen kualifikimit dhe validimit te përshtatshërshtatshëm.	contamination, cross contamination and, in general, any adverse effect on the quality of the product. 3. Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.	zagadjivanje, kontaminacija i uopšte bilo kakav negativni efekat na kvalitet proizvoda . 3. Objekti I oprema koja će da se koristi za operacije proizvodnje, koji su odlučujući za kvalitet proizvoda, moraju se podrvgnuti potrebnoj proveri o isprvnosti.
Neni 12 **Dokumentacioni**	**Article 12** **Documentation**	**Član 12** **Dokumentacija**
1. Prodhuesi duhet të krijojëdhe mirëmbajënjë sistemdokumentimitë bazuar në specifikat,formulate prodhimit, instruksionet e procesimit dhe paketimit, procedurat dhe të dhënat që mbulojnëoperacione të ndryshmeprodhimi të ndërmarra.Dokumentetdo të jenëtë qarta, pa gabime,dhe do të mbahen të përditësuara. Procedurat e parapërgatitura për operacionet dhe kushtet e përgjithshme të prodhimit duhet të jenë në dispozicion, së bashku me dokumentet specifike për secilën seri. Këto dokumente duhet të mundësojnë gjurmimin e historisë së prodhimit të secilës seri dhe	1. The manufacturer shall establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of	1. Proizvodjač mora da vodi i održava sistem dokumentacije baziran na specifikacijama, obrascima za proizvodnju i uputstvima preradjivanja i pakovanja, procedura i podataka koji pokrivaju izvršene proizvodne radnje. Dokumentacija mora da bude jasna, bez grešaka i ažurirana. Opšte procedure za opšte operacije i uslove proizvodnje moraju da budu na raspolaganju zajedno sa posebnim dokumentima za proizvodnju svake serije. Grupa dokumenata mora da omogući proizvodnju svake serije i prezentirane izmene tokom razvoja

ndryshimeve të bëra gjatë zhvillimit të produktit medicinal në hulumtim.	each batch and the changes introduced during the development of an investigational medicinal product to be traced.	jednog istraživačko-testirajućeg medicinskog proizvoda koji mora biti praćen.
2. Për një produkt medicinal, dokumentacioni i series duhet të mbahet për të paktën një vit pas datës së skadimit të serivetë cilëve iu referohet ose të paktën pesë vjet pas çertifikimit të referuar në Nenin 10 pragrafi 7, cilado që është periudhë më e gjatë.	2. For a medicinal product, the batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates or at least five years after the certification referred to in Article 10 paragraph 7, whichever is the longer period.	2. Dokumentacija serije jednog medicinskog proizvoda mora da se čuva najmanje godinu dana posle isteka roka serije za koju je namenjena ili najmanje pet godina, predvidjeno u Članu 10, stav 7, za bilo koji period koji je duži.
3. Kur përdoren sisteme elektronike, fotografike apo sisteme tjera të përpunimit të të dhënave, në vend të dokumentimit të shkruar, prodhuesi fillimisht duhet të validoj sistemet duke dëshmuar se të dhënat do të ruhen në mënyrë të përshtatshme për periudhën e parashikuar kohore. Të dhënat e ruajtura me këto sisteme duhet të jenë gjithnjë tëgatshme dhe do ti ofrohen auditoreve të pmp-së sipas kërkesës. Të dhënat e ruajtura në mënyrë elektronikeduhet të mbrohenme metodatë tilla si dublifikim ose mbajtja e kopjeve dhe transfere në sisteme tjera të ruajtjes, kundër humbjes apo dëmtimit të të	3. When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the gmp auditors at their request. The electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails	3. Kada se umesto pisane dokumentacije koriste elektronski, fotografski ili drugi sistemi za obradu podataka, proizvodjać prvenstveno mora da oroči takve sisteme kako bi pokazao da će podaci da se čuvaju na odgovarajući način za predvidjeni period čuvanja. Čuvani podaci u ovim sistemima moraju da budu na raspolaganju u čitljivoj formi i moraju da se daju dpp revizora KAMP na njihov zahtev. Elektronski čuvani podaci moraju da se zaštite takvim metodama koa što su duplikati ili rezervne kopije back-up i transfer na nekom

dhënave si dhe gjurmët për auditim duhet të vendosen dhe mirëmbahen.	shall be maintained.	drugom sistemu za čuvanje, da se ne izgube ili oštećuju podaci a i dokazi o reviziji se moraju čuvati.
Neni 13 **Prodhimi**	**Article 13** **Production**	**Član 13** **Proizvodnja**
1. Operacionet e ndryshme të prodhimit duhet të kryhen në përputhje me instruksionet dhe procedurat e paracaktuara dhe në pajtim me PMP. Resurse adekuate dhe të mjaftueshme duhet të jenë në dispozicion për kontrollin në proces. Të gjitha devijimet e procesit dhe defektet e produktit duhet të dokumentohen dhe të hetohen plotësisht	1. The different production operations shall be carried out in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the inprocess controls. All process deviations and product defects shall be documented and thoroughly investigated.	1. Razne operacije proizvodnje moraju da se obavljaju u skladu sa odredjenim uputstvima i procedurama u skladu sa dobrom praksom o proizvodnji. Potrebni i dovoljni izvori moraju da budu na raspolaganju za kontrole u toku procesa. Sve devijacije procesa i razni defekti proizvoda moraju da se proveravaju i da se u potpunosti istražuju.
2. Duhet të ndërmirren masa të duhura teknike apo organizative me qëllim parandalimi të kontaminimit të kryqëzuar dhe ngatërresave. Në rastin e produkteve medicinale në hulumtim, vëmendje e veçantë do t'i kushtohet manovrimit të produkteve gjatë dhe pas çdo operacioni verbues.	2. Appropriate technical or organizational measures shall be taken to avoid cross contamination and mix-ups. In the case of investigational medicinal products, particular attention shall be paid to the handling of products during and after any blinding operation.	2. Moraju da se predizimaju tehničke i organizacione mere kako bi se izbegla medjukontaminacija i zbunjenost. Prilikom istraživačko-testirajućih medicinskih proizvoda, posebna pažnja mora da se posveti tretmanu proizvoda tokom i posle svakog procesa sakrivanja
3. Për produkte medicinale secili ndryshim i ri apo i rendësishëm i	3. For medicinal products, any new manufacture or important	3. U medicinskim proizvodima svaki novi proizvod ili važna

procesit të prodhimit duhet të validohet. Fazat kritike të procesit të prodhimit duhet të ri-validohen rregullisht.	modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly re-validated.	modifikacija procesa proizvodnje mora da se odobri. Odlučujućefaze proizvodnih procesa proizvodnje moraju da se regulišu-re-odobravaju.
4. Për produktetmedicinalenë hulumtim, procesi i prodhimit duhet të validohet në tërësi, për aq sa është e përshtatshme, duke marrë në kosideratë etapën e zhvillimit të produktit. Të paktën hapat kritik të procesit, siç është sterilizimi, duhet të validohen. Të gjithë hapat në dizajnimin dhe zhvillimin e procesit të prodhimit duhet të dokumentohen.	4. For investigational medicinal products, the manufacturing process shall be validated in its entirety in so far as is appropriate, taking into account the stage of product development. At least the critical process steps, such as sterilization, shall be validated. All steps in the design and development of the manufacturing process shall be fully documented.	4. Za istraživačke medicinske proizvode, proces proizvodnje mora da se odobri u njegovoj celovitosti za onoliko koliko je pogodan, imajući u vidu fazu razvoja proizvoda. Treba najmanje preduzeti one odlučujuće korake kao što je sterilizacija, koja se mora odobriti. Svi koraci u procesu projekcije i razvoja procesa proizvodnje moraju u potpunosti biti dukumentovani.
5. Proceset e prodhimit të përdorura në prodhimin e produkteve imunobiologjike duhet të validohen plotësisht në mënyrë që të jetë e konsistente nga seria në seri.	5. The manufacturing processes used in the manufacture of immunological products should be properly validated in order to attain batch-to-batch consistency.	5. Korišćeni procesi u proizvodnji imunoloških proizvoda moraju da se odobre pravilno kako bi se postigla izdržljivot od serije do serije.
Neni 14 **Kontrolli i kualitetit**	**Article 14** **Quality control**	**Član 14** **Kontrola kvaliteta**
1. Prodhuesi duhet të krijojë dhe mirëmbajë një system të kontrollit të cilësisë të vendosur nën autoritetin e një personi që kakualifikimet e	1. The manufacturer shall establish and maintain a quality control system placed under the authority of a person who has the requisite	1. Proizvodjač mora da stvara i da održava sistem kontrole kvaliteta postavljen pod nadležnošću jednog lica koje ima potrebnu kvalifikaciju

përshtatshme dhe i cili është i pavarur nga prodhimi. Ky person duhet të ketë në dispozicion, ose do të ketë qasje në, një ose më shumë laboratorë të kontrollit të cilësisë, me pajisje dhe personel adekuat për të kryer ekzaminimet dhe testime te nevojshme të materialeve fillestare dhe paketuese, si dhe testimin e produktit të ndërmjetëm dhe atij final.	qualifications and is independent of production. That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and packaging materials and the testing of intermediate and finished products	i koje je nezavisno od proizvodnje. Ovo lice mora da ima na raspolaganju ili da ima dostupnost na jednoj ili na više laboratorija za kontrolu kavliteta sa kvalifikovanim osobljem i sa opremom za potreban pregled i za testiranje početnih materijala i materijala za pakovanje kao i za testiranje medjuproizvoda i gotovih proizvoda.
2. Mund të përdoret laboratori i kontraktuar nëse autorizohet sipas Nenit 15 të këtij udhëzimi administrative.	2. Contract laboratories may be used if authorized in accordance with Article 15 of this administrative instruction and if approved in manufacturing authorization procedure.	2. Laboratorije sa ugovorom mogu da se koriste ako su ovlašćene u skladu sa Članom 15 ovog administrativnog uputstva i ako se odobre u procedure ovlašćenja proizvodnje.
3. Për produktet medicinale hulumtuese, sponzori duhet të siguroi se laboratori i kontraktuar përshtatet me kërkesat e AKPPM-së	3. For investigational medicinal products, the sponsor shall ensure that the contract laboratory complies with the requirements of the KMA	3. Za istraživačko-testirajuće medicienske proizvode, sponzor mora da garantuje da je ugovorena laboratorija u skladu sa zahtevima KAMP.
4. Gjatë kontrollitfinal të produktit përfundimtar, para lirimit të tij për shitje ose shpërndarje, ose për përdorim në hulumtime klinike, sistemi i kontrollit të cilësisë duhet të marë parasysh, përveç rezultateve analitike, informacione thelbësore, sikurse kushtet e prodhimit, rezultatet	4. During the final control of the finished product before its release for sale or distribution or for use in clinical trials, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of	4. Prilikom završne kontrole gotovog prozvoda, pre njegovog puštanja na prodaju, na distribuiranje ili na korišćenje za klinička testiranja, sistem kontrole kvaliteta mora da ima u vidu, osim rezultata o analizi i suštinske informacije kao što su uslovi proizvodnje, rezultati o

e kontrolleve në-proces, ekzaminimin e dokumenteve të prodhimit dhe konformiteti ne produktit ndaj specifikave të tij, duke përfshirë edhe paketimin final.	in-process controls, the examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack.	kontrolama u toku procesa, pregledi dokumentacije i srazmernosti proizvoda sa njegovim specifičnostima, računajući i završno finalno pakovanje.
5. Mostrat e çdo serie të produktit medicinal të përfunduar duhet të mbahen për të paktën një vit pas datës së skadimit të serisë.	5. Samples of each batch of finished medicinal product shall be retained for at least one year after the expiry date.	5. Uzorci svake serije gotovog medicinskog proizvoda moraju da se čuvaju najmanje godinu dana posle isteka roka.
6. Për produktet medicinale hulumtuese, duhet të ruhen mostra të mjaftueshme nga çdo seri e balkut për formulim të produktit dhe komponentet kyçe të paketimit të përdoruara për seri të produktit final, për të paktën dy vite pas përfundimit ose ndërprerjes formale të hulumtimit të fundit klinike në të cilin është përdorur kjo seri.	6. For an investigational medicinal product, sufficient samples of each batch of bulk formulated product and of key packaging components used for each finished product batch shall be retained for at least two years after completion or formal discontinuation of the last clinical trial in which the batch was used, whichever period is the longer.	6. Za jedan istraživačko-testirajući medicinski proizvod, dovoljni uzorci svake serije u masi formiranog proizvoda i glavnih komponenti korišćenog pakovanja za svaku seriju gotovog proizvoda moraju da se čuvaju najmanje dve godine nakon završetka ili formalnog prekida zadnjeg kliničkog istraživanja-testiranja u kome je korišena serija, zavisno koji je priod duži.
7. Mostrat e materialeve fillestare, me përjashtim të tretësve, gazrave oseujit, të përdorura në procesin e prodhimit do të mbahen për të paktën dy vjet pas lirimit të produktit. Kjo periudhë mund të shkurtohet në qoftë se periudha e stabilitetit të materialit, e indikuar në specifikimet përkatëse, është më e	7. Samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained for at least two years after the release of product. That period may be shortened if the period of stability of the material, as indicated in the relevant	7. Uzorci početnih materijala, osim rastvarača, gasova ili vode, korišćeni u procesu proizvodnje, moraju da se čuvaju najmanje dve godine nakon izdavanja proizvoda. Ovaj period može da se skrati ako je period stabilizacije materijala kraći kako je zapisan na

shkurtër. Të gjitha këto mostra, duhet të mbahen në dispozicion të pmp auditoreve AKPPM. Kushtc të tjera mund të përcaktohen, në marrëveshje me AKPPM-në, për marrjen e mostrave dhe ruajtjen e materialeve fillestare dhe të produkteve të caktuara të prodhuara individualisht ose në sasi të vogla, apo kur ruajtja e tyre mund të nxitë probleme të veçanta.	specification, is shorter. All those samples shall be maintained at the disposal of the gmp auditor KMA. Other conditions may be defined, by agreement with the KMA, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities, or when their storage could raise special problems.	odgovarajućim specifikacijama. Svi ovi uzorci moraju da budu na raspolaganju dpp revizora KAMP. Ostali uslovi se mogu odrediti u dogovoru sa KAMP o uzimanju uzoraka i čuvanju početnih materijala i nekih prozvoda proizvedenih individualno ili u malim količinama ili kada njihovo čuvanje može da izazove posebne probleme.
Neni 15 **Puna e kontraktuar**	**Article 15** **Work contracted out**	**Član 15** **Posao ugovoren od druge strane**
1. Çdo operacion prodhues ose operacione të lidhura me të, që kryhen nën kontraktim duhet të jenëobjekt i një kontrate me shkrim.	1. Any manufacturing operation or operation linked thereto which is carried out under contract shall be the subject of a written contract.	1. Svaka operacija proizvodnje ili operacija vezana za nju, koja se vrši na osnovu ugovora mora da bude subjekt nekog pismenog ugovora.
2. Kontrata duhet të përcaktojë qartë përgjegjësitë e secilës pale dhe duhet të përcaktojë, në veçanti, respektimin e PMPqë do të ndiqet nga ana e pranuesit të kontratës dhe mënyrën në të cilën personi i kualifikuar përgjegjës për çertifikimin e çdo serie do të kryej përgjegjësitë e tij.	2. The contract shall clearly define the responsibilities of each party and shall define, in particular, the observance of good manufacturing practice to be followed by the contract acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities.	2. Ugovor mora jasno da odredi nadležnosti svake strane i posebno mora da odredi primenu dobre prakse u proizvodnji koja se mora primeniti od primaoca ugovora i način na koji će nadležno kvalifikovano lice za sertifikovanje da vrši svoje nadležnosti.
3. Pranuesi i kontratës nuk duhet të	3. The contract-acceptor shall not	3. Primalac ugovora ne može da

nënkontraktojë ndonjë punë që i është besuar atij sipas kontratës pa autorizimin me shkrim nga kontratëdhënësi. 4. Pranuesi i kontratës duhet të respektojë parimet dhe udhëzimet e PMP dhe i nënshtrohetauditimeve të kryera nga pmp auditorët e AKPPM-së.	subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver. 4. The contract-acceptor shall comply with the principles and guidelines of good manufacturing practice and shall submit to audits carried out by gmp auditors KMA.	podugovora nijadan posao koji je njemu po ugooru poveren bez pismenog ovlašćenja davaoca ugovora. 4. Primaoc ugovora mora da bude u skladu sa principima dobre prakse o proizvodnji i mora da prihvati revizije kontrole izvršene od dpp revizora KAMP.
Neni 16 **Ankesat, tërheqja e produktit dhe demaskimi emergjent**	**Article 16** **Complaints, product recall and emergency unblinding**	**Član 16** **Žalbe, povlačenje proizvoda i hitna otkrivanja**
1. Prodhuesi duhet të implementoj një sistem të pranimit dhe regjistrimit të ankesave së bashku me një sistem efikas për tërheqje, të menjëhershme dhe në çdo kohë, të produkteve medicinale përmes rrjetit të distributorëve. Çdo ankesë sa i përket defektit duhet të regjistrohet dhe hulutohet nga prodhuesi. Prodhuesi duhet ta njoftojë AKPPM-në për çdo defekt që mund të rezultoje me tërheqje jo normale kufizim në furnizim dhe, aq sa është e mundur, tregojne vendet e destinacionit. Çdo tërheqje duhet bërë në përputhje me rregullat e AKPPM-së.	1. Manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and at any time, medicinal products in the distribution network. Any complaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall inform the KMA of any defect that could result in a recall or abnormal restriction on supply and, in so far as is possible, indicate the countries of destination.Any recall shall be made in accordance with the KMA	1. Proizvodjač mora da primeni sistem registracije i razmatranja žalbi zajedno sa efektivnim sistemom za momentalno povlačenje i u svako doba, medicinskih prioizvoda sa distributivne mreže. Svaka žalba oko nekog defekta mora da se evidentira i da se istražuje od proizvodjača. Proizvodjać mora da obavesti KAMP za svaki defekt koji može biti u nekom povlačenju ili neobičnom ograničenju u snabdevanju i koliko je to moguće, da pokaže mesto destinacije . Svako povlačenje mora da se radi u

2. Në rastin e produkteve medicinale hulumtuese, prodhuesi në bashkëpunim me sponzorin, zbaton një system për regjistrimin dhe shqyrtimin e ankesave, së bashku me një system efikas për tërheqje nga tregu, menjëherë dhe në çdo kohë, të produkteve medicinale hulumtuese të cilat tanimë kanë hyrë në rrjetin e shpërndarjes. Prodhuesi duhet të regjistrojë dhe të hulumtojë çdo ankesë në lidhje menjë defekt, dhe duhet të informojë autoritetet kompetente për çdo defekt që mund të rezultojë me tërheqje nga tregu apo kufizim të jashtëzakonshëm në furnizim. Në rast se produktet medicinale hulumtuese të gjitha vendet e hulumtimit duhet të identifikohen dhe për aq sa është e mundur vendet e destinimit duhet të tregohen. Në rast të produktit medicinal hulumtues, duhet të identifikohen të gjitha qendrat e testimit, dhe nëse është e mundur, të indikohen shtetet e destinimit.Në rast të produktit medicinal hulumtues për të cilin është lëshuar AM, prodhuesi i produktit medicinal hulumtues, në bashkëpunim me sponzorin, duhet të	regulations. 2. In the case of investigational medicinal products, the manufacturer shall, in cooperation with the sponsor, implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time investigational medicinal products which have already entered the distribution network. The manufacturer shall record and investigate any complaint concerning a defect and shall inform the competent authority of any defect that could result in a recall or abnormal restriction on supply. In the case of investigational medicinal products, all trial sites shall be identified and, in so far as is possible, the countries of destination shall be indicated. In the case of an investigational medicinal product for which a marketing authorization has been issued, the manufacturer of the investigational medicinal product shall, in cooperation with the sponsor, inform the marketing authorization holder of any defect	skladu sa pravilnikom KAMP. 2. U slučaju istraživačko-testirajućih proizvoda, proizvodjać mora da u sardnji sa sponzorom primeni sistem registracije i razmatranja žalbi zajedno sa efektivnim sistemom za momentalno povlačenje i u svako vreme, medicinskih proizvoda koji su već ušli u distributivnu mrežu. Proizvodjač mora da registruje i da istražuje svaku žalbu u vezi sa svakim defektom i da obavesti nadležni organ o svakom defektu koji može nastati nekim povlačenjem ili neobičnim ograničanjem snabdevanja. U slučaju istraživačko-testirajućih medicinskih proizvoda, sve lokacije testiranja moraju da se identifikuju i koliko je to moguće da se pokažu mesta destinacije. U slučaju kada je za jedan istraživačko-testirajući proizvod izdato ovlašćenje za marketing, proizvodjač istraživačko-testirajućeg medicinskog proizvoda mora da u saradnji sa sponzorom obavesti nosioca ovlašćenja za marketing za svaki defekt koji

informoj mbajtësin e AM për çdo defekt i cili mund të jetë i ndërlidhur me produktin medicinal të autorizuar. 3. Sponzori duhet të implementoj procedure për ç'verbërimin e shpejtë të produkteve të verbëruara, kur kërkohet një tërheqje e menjëhershme siç është referuar në pragrafin 2.. Sponzori i hulumtimit duhet të siguroj që procedura zbulon indentitetin e produktit të verbëruar vetëm në atë masë sa është e nevojshme.	that could be related to the authorized medicinal product. 3. The sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 2. The sponsor shall ensure that the procedure discloses the identity of the blinded product only in so far as is necessary.	može da bude povezan sa ovlašćenim medicinskim proizvodom. 3. Sponzor mora da primeni proceduru za brzo otkrivanje skrivenih proizvoda tamo gde je potrebno i za hitno povlačenje kao što je naglašeno u stavu 2. Sponzor mora da garantuje da procedura otkriva identitete skrivenog proizvoda samo za onoliko koliko je to potrebno.
Neni 17 **Vetë-inspektimi**	**Article 17** **Self-inspection**	**Član 17** **Samo-kontrola**
Prodhuesi duhet të kryejë vetë-inspektime të përsëritura si pjesë e sistemit të sigurimit të cilësisë, në mënyrë që të monitorojë zbatimin dhe respektimin e praktikës së mire të prodhimit dhe të propozojë masat e nevojshme korrigjuese. Duhet ruajtur të gjitha të dhënat nga vetë-inspektime e tilla si dhe masat korrigjuese që ndërmerren.	The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures. Records shall be maintained of such self-inspections and any corrective action subsequently taken.	Proizvodjač mora da vrši stalnu samokontrolu, kao deo sistema garancije kvaliteta kako bi pratio primenu i poštovanje dobre prakse o proizvodnji i da predlaže neku potrebnu meru korekcije. Mora da se vodi evididencija o samokontroli i svakom korektivnom postupku preduzetom kasnije.
Neni 18 **Etiketimi**	**Article 18** **Labelling**	**Član 18** **Etiketiranje**
Në rastin e një produkti mjekësor	In the case of an investigational	Za istraživačko-testirajuće medicinske

hulumtues, etiketimi duhet të jetë i tillë si për të siguruar mbrojtjen e subjektit dhe gjurmueshmërisë, për të mundësuar identifikimin e produktit dhe provën, dhe për të lehtësuar përdorimin e duhur të produkteve medicinale hulumtuese.	medicinal product, labelling shall be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the investigational medicinal product.	proizvode etiketiranje mora da bude takvo da garantuje zaštitu subjekta i otkrivanja, da bi omogućio identifikaciju proizvoda i testiranje i da bi olakšalo potrebno korišćenje istraživačko-testirajućeg proizvoda.
Neni 19 **Kërkesat dhe udhërrefyesit e praktikës së mirë të prodhimit**	**Article 19** **Requirements and guidelines of good manufacturing practice**	**Član 19** **Zahtevi i uputstva dobre prakse u proizvodnji**
Përveç dispozitave të përcaktuara në Ligj dhe udhëzim administrative prodhimi i produkteve medicinale kryhet sipas kerkesave dhe udherrefyesve të praktikës së mire të prodhimit për produktet medicinale dhe specifikave sa i përket procedurave individuale dhe formave të produktit medicinal "Praktika e mire e prodhimit për produktet medicinale për përdorim human dhe veterinary" duke përfshi të gjitha amandamentet, e të cilat jane të disponueshme në website të Eudralex.	In addition to provisions laid down in the Law and this administrative instruction, manufacture of medicinal products is governed by the requirements and guidelines of good manufacturing practice for medicinal products and by specifics concerning individual procedures and forms of medicinal products "Good Manufacturing Practices, medicinal products for human and veterinary use", including all amendments, and they are available on the Eudralex website.	Osim odredaba Zakona i ovog administrativnog uputstva, proizvodnja medicinskih proizvoda rukovodi se i zahtevima i uputstvima dobre prakse o proizvodnji medicinskih proizvoda i specifičnosti oko individualnih procedura i obblika medicinskih proizvoda „Dobre Prakse o Proizvodnji medicinskih proizvoda za ljudsku upotrebu i u veterinarstvu "računajući sve izmene koje se nalaze u prilogu ovom administrativnom uputstvu.

Neni 20 Lëshimi i autorizim prodhimit	Article 20 Issuing of manufacturing authorization	Član 20 Izdavanje odobrenja za proizvodnju
1. Për marrjen e autorizimit për prodhim, personi fizik ose juridik i vendosur në Republikën e Kosovës duhet të paraqesë: 1.1. kërkesë me aplikacion pranë AKPPM-së. 1.2. Specifikimet për produktin medicinal dhe formën farmaceutike që do të prodhohet. 1.3. Dokumentimi i hollësishëm i prodhuesit hapësira të përshtatshme dhe të majftueshme, pajisje teknike dhe hapsirat për kontrol në pajtueshmëri me kërkesat ligjore. 1.4. Deklartë me shkrim nga aplikuesi ku deklaron se do ti mundësojë personit përgjegjës për lirimin e serisë ti kryej punët në mënyrë të pavaruar dhe ti siguroi të gjitha burimet e nevojshme. 1.5. Deklaratë me shkrim nga aplikuesi që ai do të kryejë aktivitetet e prodhimit në	1. For the purpose of issuing manufacturing authorization, natural or legal person established in Republic of Kosovo shall submit: 1.1. application to KMA 1.2. Specification of the medicinal products and pharmaceutical forms which are to be manufactured 1.3. Manufacturing site particulars documenting suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements. 1.4. A written statement by the applicant declaring that he shall enable the person responsible for batch release to carry out his activities independently and ensure all requisite resources. 1.5. A written statement by the applicant that he shall carry out the manufacturing activities in	1. Fizičko ili pravno lice nastanjeno u Republici Kosovo za dobijanje ovlašćenja za proizvodnju mora da podnese: 1.1. zahtev u KAMP 1.2. Specifikaciju medicinskih proizvoda i farmaciutskih oblika koji će da se proizvode. 1.3. Podatke o lokaciji proizvodnje koji pokazuju pogodne i dovoljne objekte, tehničku opremu u skladu sa zakonskim zahtevima. 1.4. Pismenu izjavu podnosioca zahteva kojom izjavljuje da će omogučiti nadležnom licu za izdavanje serije da vrši svoje aktivnosti nezavisno i da će da obezbedi sve moguće izvore. 1.5. Pismenu izjavu podnosioca zahteva da će za da vrši aktivnosti proizvodnje u

përputhje me praktikën e mirë të prodhimit.	compliance with good manufacturing practice.	skladu sa dobrom praksom za proizvodnju.
1.6. Deklaratë me shkrim nga aplikuesi se për prodhimin e produkteve medicinale do të përdoren vetem substancat aktive në linje me praktikën e mire të prodhimit.	1.6. A written statement by the applicant that for manufacture of medicinal products, only active substances which are produced in line with good manufacturing practice, will be used.	1.6. Pismenu izjavu podnosioca zahteva da će se za proizvodnju medicinskih proizvoda koristiti samo aktivne supstance koje su proizvedene u skladu sa dobrom praksom o proizvodnji.
1.7. Deklaratë me shkrim nga aplikuesi se ai do të prodhoi vetem produkte medicinale për të cilat posedon autorizim prodhimi valid.	1.7. A written statement by the applicant declaring that he shall manufacture only medicinal products for which he holds a valid manufacturing authorization.	1.7. Pismena izjava podnosioca zahteva kojom izjavljuje da će proizvoditi samo medicinske proizvode za koje poseduje važeće ovlašćenje za proizvodnju.
1.8. Dëshmia e pagesës sipas udhëzimit administrative nr.01/2014 AKPPM.	1.8. Proof of payment as per administrative instruction nr. 01/2014 KMA.	1.8. Dokaz o uplati prema Administrativnom Uputstvu Br. 01/2014 KAMP.
Neni 21 **Auditorët e Pmp-së Akppm**	**Article 21** **Kma Gmp Audits**	**Član 21** **Kamp Dpp Revizija**
1. AKPPM-ja do të sigurojë që se kërkesat ligjore mbi produktet medicinale janë në pajtueshmëri me të, me anë të auditimeve nga pmp auditorët e AKPPM-së.	1. KMA shall ensure that that the legal requirement governing medicinal products are complied with, by means of audits by KMAgmp auditors.	1. KAMP će osigurati da je zakonski uslov upravljanjem medicinskim proizvodima se poštuju. putem reviziju od strane KAMP dpp revizora.
2. Auditimet mund të jenë të pa	2. Audits can be unannounced and	2. Revizija može biti bez najave i

paralajmëruara dhe sipas nevojës mund ti kërkohet LCK-së ose laboratorit të caktuar që të bëje kryerjen e testeve të mostrave.	where appropriate, by asking QCL or a designated laboratory to carry out tests on samples.	kada je to potrebno , postavljanjem LKK ili određen laboratoriju za vršenje ispitivanja na uzorcima
3. Prodhuesit e vendosur në Republikën e Kosovës dhe vendet tjera do ti nënshtrohen auditimeve të përsëritura.	3. Manufacturers located in Republic of Kosova and in other countries shall be subject to repeated audits.	3. Proizvođači nalazi u Republici Kosova iu drugim zemljama podleže ponovljenih revizija.
4. Me kërkesë specifike nga prodhuesit AKPPM-ja mund të kryejë auditime të lëndës së parë të prodhimit.	4. By specific request of the manufacturers KMA may carry out audits of starting material manufacturers.	4. Po konkretan zahtev proizvođača KAMP može obavljati inspekcije počevši proizvođači materijala.
5. Për interpretimin e parimeve dhe udhëzimeve të praktikës së mirë të prodhimit, AKPPM-ja do të marrë parasysh udhëzimet e detajuara të referuara në Nenin 19 të këtij udhëzimi administrative.	5. For interpretation of the principles and guidelines of good manufacturing practice, KMA shall take into account the detailed guidelines refferred to in article 19 of this administrative instruction.	5. Tumačenje načela i smernice dobre proizvođačke prakse, KAMP će uzeti u obzir detaljna uputstva prosleđeni u članu 19. ovog administrativnog uputstva .
Neni 22	**Article 22**	**Član 22**
1. Për lëshimin e autorizim prodhimit AKPPM- ja do të bëjë auditime për rregullsinë e aplikacionit dhe auditorët e pmp-së AKPPM do të japin opinionin e tyre për pajtueshmërinë me praktikën e mire të prodhimit.	1. For issuing manufacturing authorization KMA will conduct audits of the regularity of the application and KMA gmp auditor shall give his opinion on compliance with good manufacturing practice.	1. Za izdavanje ovlašćenja za proizvodnju KAMP mora da izvrši reviziju pregled o urednosti zahteva a dpprevizora KAMP treba da da mišljenje u skladu sa dobrom praksom o proizvodnji.
2. Për qërllim të përcaktimit të pajtueshmërise me praktikën e mire të	2. For the purpose of determining the compliance with good	2. Za odredjivanje uskladjenosti sa zahtevima dobre prakse o

prodhimit auditoreve të pmp-së AKPPM mund t'iu bashakangjiten në vlerësim komisioni i aprovuar nga AKPPM, ku mund të përfshihen ekspert të fushave të caktuara.	manufacturing practice requirements, KMA gmp auditor can be joined by commission appointed by KMA, which may include experts from individual fields	proizvodnji, revizor dpp KAMP može da se udruži prema komisiji odredjenoj od KAMP koji može da obuhvati stručnjake iz posebnih oblasti.
3. Gjatë përcaktimit të përputhshmërisë me kërkesat e praktikës së mire të prodhimit, një shënim do të përpilohet duke paraqitur gjendjen faktike dhe të nënshkruar nga AKPPM pmpauditorët, anëtarët e komisionit dhe përfasuesit e aplikuesit.	3. When determining the compliance with good manufacturing practice requirements, a record shall be compiled presenting factual state and signed by KMA gmpauditor, members of the commission and representative of the applicant.	3. Prilikom odredjivanja uskladjenosti sa dobrim zahtevima proizvodnje mora da se sačini zapisnik u kome se prikazuje faktičko stanje, potpisan od revizora dpp KAMP, od članova komisije i od predstavnika podnosioca zahteva.
Neni 23	**Article 23**	**Član 23**
1. Brenda 30 ditëve nga data e auditimit për praktikën e mire të prodhimit, auditorët e pmp -së AKPPM duhet të hartojnë një raport mbi përmbushjen e kërkesave të praktikës së mirë të prodhimit dhe t'ia dërgojnë atë aplikuesit.	1. Within 30 days of the date of the audit of good manufacturing practice, the KMA gmp auditor shall compile a report on the fulfilment of requirements of good manufacturing practice and submit it to the applicant.	1. U roku od 30 dana od dana revizijskog pregleda dobre prakse o proizvodnji, revizor dpp KAMP mora da sačini izveštaj o ispunjenju zahteva dobre prakse o proizvodnji i da dostavi podnosiocu zahteva.
2. Në të metat që janë identifikuar gjatë auditimit të referuara në paragrafin 1 të këtij neni, aplikuesi është i detyruar të paraqesë një shpjegim me shkrim mbi mangësitë e përcaktuara nga auditorët e pmp-së AKPM brenda 30	2. In the event shortcomings are identified during audit referred to in paragraph 1 of this Article, the applicant is obliged to submit a written explanation on the established shortcomings to the	2. Ako su prilikom inspekcijskog pregleda ustanovljeni nedostaci prema stavu 1 ovog Člana, podnosilac zahteva je dužan da u roku od 30 dana od inspekcijskog pregleda, revizoru dpp KAMP

ditëve nga data e auditimit.	KMA gmp auditor within 30 days of the audit.	podnosi pismeno objašnjenje o utvrdjenim nedostacima.
3. Auditorët e pmp-së AKPPM duhet ta japin opinionin e tyre me shkrim mbi përmbushejen e kushteve të praktikës së mire të prodhimit për aktivitetin e prodhimit të produkteve medicinale në bazë të raportit të auditimit,dhe në të metat e identifikuara , në bazë të deklaratës me shkrim të aplikuesit.	3. The KMA gmp auditor shall give his written opinion on the fulfilment of the requirements of good manufacturing practice for the activity of manufacturing medicinal products on the basis of the audit report, and in the event shortcomings are identified, on the basis of the written statement of the applicant.	3. Revizoradpp KAMP mora pismeno dati svoje mišljenje o ispunjenosti zahteva dobre prakse o proizvodnji za aktivnosti o proizvodnji medicinskih proizvda na bazi izveštaja o revizijskom pregledu, a ako su ustanovljeni nedostaci, na bazi pismene izjave podnosioca zahteva.
4. Autorizim prodhimi do të lëshohet nëse janë përmbushur kërkesat jo më largë se 90 ditë nga kërkesa e bërë.	4. Manufacturing authorization will be granted, if requirements are met, not later than 90 days from request submission.	4. Ovlašćenje za proizvodnju se izdaje ako su ispunjeni svi zahtevi, najkasnije u roku od 90 dana od podnošenja zahteva.
5. Nëse auditorët e pmp-së AKPPM kërkojnë të dhëna shtesë atëherë limitet kohore të parapara në nenin 23 paragrafi 4 dhe 24 paragrafi 2 ndalohen deri sa të dhënat shtesë të kërkuara janë dërguar.	5. If additional data is required by KMA gmp auditors application of the time-limits referred to in Article 23 paragraph 4 and 24 paragraph 2, shall be suspended until the additional data required have been supplied.	5. Ako su traženi dodatni podaci od dpp revizora KAMP, vremesnki rokovi odredjeni u Članu 22, stav 4 i Članu 24, stav 2, se suspenduju dok se ne obezbede traženi podaci.

Neni 24 **Autorizimi i përkohshëm prodhimi**	**Article 24** **Temporary manufacturing authorization**	**Član 24** **Privremeno ovlašćenje za proizvodnju**
1. Në qoftë se gjatë procedurës për lëshimin e autorizimit të prodhimit është konstatuar se aplikuesi nuk i përmbush plotësisht të gjitha kërkesat e përcaktuara e praktikës së mirë të prodhimit, AKPPM-ja mund të lëshojë një autorizim të prodhimit të përkohshme duke vendosur afatet për eliminimin e mangësive të identifikuara.	1. If during the procedure for the issuance of manufacturing authorisation it is ascertained that the applicant does not fully meet all the prescribed requirements of good manufacturing practice, KMA may issue a temporary manufacturing authorisation and set the deadlines for the elimination of identified shortcomings.	1. Ako je u toku postupka za izdavanje ovlašćenja za proizvodnju konstatovano da podnosilac zahteva ne ispunjava sve odredjene zahteve dobre prakse o proizvodnji, KAMP može da izda privremeno ovlašćenje o proizvodnji i da odredi rokove za otklanjanje identifikovanih nedostataka.
2. Autorizimi i përmendur në paragrafin 1 të këtij neni do të jetë valid deri në skadencën e afatit për përmirsimin e mangësive të identifikuara, nëse këto mangësi nuk janë eliminuar brenda afatit të specifikuar.	2. The authorisation referred to in paragraph 1 of this article shall cease to be valid upon the expiry of the deadline set for the elimination of identified shortcomings, if such shortcomings have not been eliminated within the specified deadline.	2. Pomenuto ovlašćenje u stavu 1 ovog člana prestaje da važi posle isteka ostavljenog roka za otklanjanje identifikovanih nedostataka, ako takvi nedostaci nisu otklonjeni u odredjenom roku.
Neni 25 **Aprovimi i Ndryshimeve**	**Article 25** **Change approval**	**Član 25** **Odobrenje o promeni**
1. Prodhuesi i produkteve medicinale duhet të bëjë kërkesë në AKPPM për aprovimin e çdo ndryshimi në	1. The manufacturer of medicinal products shall submit to the KMA a request for the approval of any	1. Proizvodjač Medicinskih Proizvoda mora da podnosi zahtev u KAMP za odobrenje o svakoj promeni u dokumentaciji ili u podacima i na

dokumentacion, ose në të dhënat dhe dokumentet në bazë të cilën është dhënë autorizimi prodhimit.	change in documentation, or in the data and documents based on which the manufacturing authorisation was granted.	dokumentima na osnovu kojih je izdato ovlašćenje za proizvodnju.
2. Në procedurën e aprovimit të ndryshimit të përmendur në paragrafin 1 të këtij neni, auditorët e pmp-së AKPPM duhet të japin mendimin e tyre në përputhje me kërkesat e praktikës së mirë të prodhimit nëse ndryshimi ndikon në përmbushjen e kërkesave të praktikës së mirë të prodhimit.Auditorë duhet të japin brenda 30 ditëve nga pranimi i kërkesës, në raste të veçanta jo më shumë se 90 ditë.	2. In the procedure of the change approval referred to in paragraph 1 of this Article, the KMA gmp auditors shall give they opinion on the compliance with the requirements of good manufacturing practice if the change affects the fulfilment of the requirements of good manufacturing practice. The Auditors shall give them opinion in 30 days from submission of the request, in exceptional cases not more than 90 days.	2. U postupku odobrenja pomenutih promena u stavu 1 ovog Člana, dpp revizora KAMP mora dati mišljenje o uskladjenosti sa zahtevima dobre prakse u proizvodnji ako promena utiče na ispunjenje zahteva dobre prakse u proizvodnji. Revizora mora dati mišljenje u roku od 30 dana od podnošenja zahteva, a u izuzetnim slučajevima ne kasnije od 90 dana.
3. Aplikuesi duhet të bashkangjes dokumentacionin për ndryshimin së bashku me kërkesën me shkrim për aprovim të ndryshimit të përmendur në paragrafin 1 të këtij neni, konfirmimin e pagesës së taksës administrative dhe shpenzimet e procedures.	3. The applicant shall enclose the documentation on the change to the written application for change approval referred to in paragraph 1 of this Article, confirmation of the payment of administrative fee and of the costs of procedure.	3. Podnsilac zahteva mora da priloži pismenu dokumentaciju za promenu zahteva za odobrenje po stavu 1 ovog Člana, potvrdu o uplati administrativne takse i troškova postupka.
4. Dispozitat e neneve 22 dhe 23 të këtij udhëzimi administrativ do të zbatohen në mënyrë adekuate për procedurën e miratimit të ndryshimeve, ku auditimi i praktikës së mirë të prodhimit është	4. The provisions of Articles 22 and 23 of this administrative instruction shall adequately apply to the procedure for change approval, where the audit of good	4. Odredbe Člana 26 i 27 ovog Administrativnog Uputstva moraju da se primenjuju adekvatno u postupku o odobrenju promene za koje je izvršen revizijski pregled

kryer.	manufacturing practice is conducted.	dobre prakse u proizvodnji.
5. Nëse aprovimi i ndryshimit nuk amadamenton asnjë të dhënë në autorizim prodhimin, AKPPM-ja do ta aprovojë ndryshimin përmes njoftimit me shkrim.	5. If an approved change does not require any data amendment in the manufacturing authorisation, the KMA shall approve the change by means of a written notification	5. Ako neka promena ne zahteva neku izmenu podataka u ovlašćenju za proizvodnju, KAMP treba da odobri takvu promenu putem pismenog obaveštanja.
Neni 26 **Çertifikata e praktikës së mirë të prodhimit**	**Article 26** **Certificate of good manufacturing practice**	**Član 26** **Sertifikat o dobroj praksi u proizvodnj**
1. Auditorët e pmp-së AKPPM nga auditimi duhet ta lëshojnë çertifikatën e praktikës së mire të prodhimit (me tutje çertifikatën) brenda 90 ditë e pas auditimit të praktikës së mire të prodhimit dhe kërkesës së prodhuesit.	1. The KMA audit by gmp auditors shall issue a certificate of good manufacturing practice (hereinafter: the certificate) within 90 days after the audit of good manufacturing practice and at the request of the manufacturer.	1. Revizija KAMP od dpp revizora treba da izda sertifikat dobre prakse u proizvodnji (u daljem tekstu: sertifikat) u roku od 90 dana nakon revizijskog pregleda dobre prakse u proizvodnji, na zahtev proizvodjaća ili uvoznika.
2. Kërkesë për lëshimin e certifikatës gjithashtu mund të paraqitet edhe nga prodhues nga vendi i tretë me anë të përfaqësuesit të tij në Republikën e Kosovës.	2. The application for the issuance of the certificate may also be submitted by the manufacturer from the third country through his representative in the Republic of Kosovo.	2. Zahtev za izdavanje sertifikata može da se podnese od proizvodjaća iz trećih zemalja preko svog predstavnika u Republici Kosovo.
3. Certifikata lëshohet nëse kërkesat e praktikës së mirë të prodhimit janë siç përcaktohet në procedurën e autorizimit të prodhimit apo të auditimit të kryer nga auditorët e pmp-	3. The certificate shall be issued if requirements of good manufacturing practice have been observed as established during the manufacturing authorisation	3. Sertifikat se izdaje ako su primenjeni zahtevi dobre prakse u proizvodnji odredjeni u postupku ovlašćenja u proizvodnji ili na osnovu revizijskog pregleda

së AKPPM.	procedure or audit conducted by the KMA gmp auditors.	izvršenog od dpp revizora KAMP.
Neni 27	**Article 27**	**Član 27**
Autorizim prodhimi lëshohet për prodhuesin, pjesë prodhimi, proceset e prodhimit që kryhen, dhe format farmaceutike të prodhuara në vend të prodhimit të referuara nga data e auditimit.	The certificate shall be issued for the manufacturing site, manufacturing parts, manufacturing processes carried out and pharmaceutical forms manufactured at the production site concerned, with mention of the date of audit.	Sertifikat se izdaje za lokaciju proizvodnje, za delove proizvodnje, za izvršene procese u proizvodnji u pomenutoj lokaciji za proizvodnju sa naznačenjem datuma revizijkog pregleda.
Neni 28	**Article 28**	**Član 28**
1. Çertifikata dëshmon përmbushjen e kërkesave për praktikën e mire të prodhimit në kohën e auditmit, dhe pajtueshmërine me praktikën e mire të prodhimit për një periudhë tri vjeçare nga dita e auditimit.	1. The certificate testifies to the fulfilment of the requirements of good manufacturing practice for the manufacturing site at the time of audit, and to the conformity with good manufacturing practice for the period of three years following the day of audit.	1. Sertifikat potvrdjuje ispunjenje zahteva dobre prakse u proizvodnji, o lokaciji proizvodnje u vreme revizijske kontrole, u skladu sa dobrom praksom o proizvodnji u periodu od tri godine od dana ravizijskog pregleda.
2. Periudha e validitetit mund të shtohet ose reduktohet në bazë të menaxhimit të riskut aplikuar nga auditimi i Agjencisë.	2. The period of validity may be extended or reduced on the basis of the risk management applied by the Agency audit	2. Period važenja može da se produži ili da se skrati na osnovu menadžiranja rizikom primenjenim od revizijskog Agencije.

Neni 29	Article 29	Član 29
Nëse gjatë auditimit është vënë re se mbajtësi i autorizim prodhimit ka dështuar në kryerjen e veprimeve në pajtueshmëri me praktikën e mire të prodhimit auditimi nga pmp auditorët e AKPPM mund të tërheq Çertifikaten.	If during audit supervision it is established that the holder of manufacturing authorisation has failed to carry out his activities in conformity with good manufacturing practice, the audit from gmp KMA auditors may revoke the certificate.	Ukoliko je prilikom revizijskog nadzora utvrdjeno da nosilac ovlašćenja o proizvodnji nije izvršio radnje u skladu sa dobrom praksom o proizvodnji, revizija dpp KAMP može da poništi sertifikat.
Neni 30 **Formularët e aplikimit dhe udhërrëfyesit**	**Article 30** **Application forms and guidelines**	**Član 30** **Prijave i smernice**
1. Aplikacionet dhe udhërrëfyesit janë pjesë përbërëse e këtij udhëzimi administrativ përditësohen nga AKPM dhe qasja do të mundësohet përmes webfaqes se AKPPM.	1. Applications and guidelines are part of this Administrative instruction will be updated from KMA and can be accessed through web page of KMA.	1. Aplikacije i smernice deo ovog administrativnog uputstva se prepreme od strane kalimsa sa pristup obezbeđen na web KALIMS-a.
2. Lista e udhërrëfyesve per PMP janë: 2.1. Pjesa I - Kërkesat themelore për Produkte Medicinale 2.1.1. Kapitulli 1 - Sistemi Farmaceutik i Cilësisë 2.1.2. Kapitulli 2 -- Personeli 2.1.3. Kapitulli 3 dhe Premisat dhe Pajisjet 2.1.3.1. marrëveshje	2. List of Guidelines for GMP are: 2.1. Part I - Basic Requirements for Medicinal Products 2.1.1. Chapter 1 Pharmaceutical Quality System 2.1.2. Chapter 2 Personnel 2.1.3. Chapter 3 Premise and Equipment 2.1.3.1. transitional	2. Lista smernice za DPP su: 2.1. Deo I - Osnovni zahtevi za medicinske proizvode 2.1.1. Poglavlje 1 Farmaceutski Sistem kvaliteta 2.1.2. Poglavlje 2 Osoblje 2.1.3. Poglavlje 3 i Premise i oprema 2.1.3.1. prelazni

kalimtare për vlerësimin toksikologjik në faqen 1 të Kapitullit 3	arrangement for toxicological evaluation on page 1 of Chapter 3	aranžmani za toksikološka evaluacija na strani 1. Poglavlja 3
2.1.3.2. I mëparshëm	2.1.3.2. Previous	2.1.3.2. Prethodna
2.1.4. Kapitulli 4 Dokumentacioni (janar 2011)	2.1.4. Chapter 4 Documentation (January 2011)	2.1.4. Poglavlje 4 Dokumentacija (januar 2011)
2.1.5. Kapitulli 5 Prodhimi	2.1.5. Chapter 5 Production	2.1.5. Poglavlje 5 Proizvodnja
2.1.5.1. Shih marrëveshjet kalimtare për vlerësimin toksikologjik në faqet 1-2 te Kapitullit 5	2.1.5.1. See transitional arrangement for toxicological evaluation on pages 1-2 of Chapter 5	2.1.5.1. Pogledajte prelazni aranžman za toksikološka evaluacija na stranicama 1-2 iz Glave 5
2.1.5.2. I mëparshëm	2 1.5.2. Previous	2.1.5.2. Prethodna
2.1.6. Kapitulli 6 Kontrolli i cilësisë	2.1.6. Chapter 6 Quality Control	2.1.6. Poglavlje 6 - Kontrola kvaliteta
2.1.7. Kapitulli 7 mbi Aktivitetet te cilat jepen me kontrate te jashtme "outsource"	2.1.7. Chapter 7 on Outsourced activities	2.1.7. Poglavlje 7 outsourced Aktivnosti
2.1.8. Kapitulli 8 Ankesat dhe terheqja e produkteve	2.1.8. Chapter 8 Complaints and Product Recall	2.1.8. Poglavlje 8 Žalbe i Recall medicinskih proizvoda.
2.1.9. Kapitulli 9 Vetë Inspektimit	2.1.9. Chapter 9 Self Inspection	2.1.9. Poglavlje 9 Samo inspekcija
2.2. Pjesa II - Kërkesat themelore për substancat aktive te perdorura si duke filluar Materiale	2.2. Part II - Basic Requirements for Active Substances used as Starting Materials	2.2. Deo II - Osnovni uslovi za aktivne supstance koje se koriste kao početni materijali

2.2.1. Kërkesat themelore për substancat aktive të përdorura si lëndë fillestare	2.2.1. Basic requirements for active substances used as starting materials	2.2.1. Osnovni zahtevi za aktivne supstance koristi kao početni material
2.3. Pjesa III - Dokumentet PMP lidhura	2.3. Part III - GMP related documents	2.3. Deo III - GMP srodnih dokumenata
2.3.1. Site Master File	2.3.1. Site Master File	2.3.1. Sajt Master File
2.3.2. Q9 Menaxhimi i rrezikut të Cilësisë	2.3.2. Q9 Quality Risk Management	2.3.2. K9 Kvalitetni Management rizika
2.3.3. Q10 Shënim për udhëzime mbi Farmaceutike Quality System	2.3.3. Q10 Note for Guidance on Pharmaceutical Quality System	2.3.3. K10 Napomena za vaspitanje na farmaceutski sistem kvaliteta
2.3.4. Certifikata Serisë MRA	2.3.4. MRA Batch Certificate	2.3.4. MRA Serijski Sertifikat
2.3.5. Forma për "konfirmim me shkrim" për substancat aktive eksportuar në Bashkimin Evropian për produktet mjekësore për përdorim njerëzor	2.3.5. Template for the 'written confirmation' for active substances exported to the European Union for medicinal products for human use	2.3.5. Šablon za " pisanu potvrdu za aktivne supstance izvozi u Evropsku uniju za medicinske proizvode za ljudsku upotrebu
2.3.6. Udhëzimi për përcaktimin e kufinjve te ekspozimit të bazuar në shëndetit për përdorim në identifikimin e rrezikut në prodhimin e produkteve të ndryshme mjekësore në objektet e përbashkëta.	2.3.6. Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities.	2.3.6. Uputstvo o postavljanju granice izloženosti zdravstvenih zasnovane za upotrebu u identifikaciji rizika u proizvodnji različitih lekova u zajedničkim objektima.
2.3.7. Udhëzimet e 19 mars 2015 mbi vlerësimin rrezikut për konstatimin e duhur te	2.3.7. Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining	2.3.7. Smernice 19. Marta 2015 godine na formalizovanom procenu

praktikës se mirë të prodhimit për ekscipientët të produkteve medicinale për përdorim njerëzor. Vlerësimi i rrezikut siç përcaktohet në tezën e udhëzimeve duhet të kryhet për mbushesit për produkte medicinale të autorizuara për përdorim njerëzor nga 21 mars 2016.	the appropriate good manufacturing practice for excipients of medicinal products for human use. A risk assessment as set out in these guidelines should be carried out for excipients for authorised medicinal products for human use by 21 March 2016.	rizika radi utvrđivanja dobre proizvodne prakse za ekscipijense medicinskih proizvoda za ljudsku upotrebu. Procena rizika kao što je navedeno u tezi smernica treba da se vrši za ekscipijenti za ovlašćenim medicinskih proizvoda za ljudsku upotrebu od strane 21. marta 2016.
2.4. Shtojcat	2.4. Annexes	2.4. Prilozi
2.4.1. Shtojca 1 - Prodhimi i Produkteve Medicinale sterile	2.4.1. Annex 1 - Manufacture of Sterile Medicinal Products	2.4.1. Aneks 1 - Proizvodnja sterilnih lekova
2.4.2. Shtojca 2 - Prodhimi i substancave aktive biologjike dhe produkteve mjekësore për përdorim njerëzor	2.4.2. Annex 2 - Manufacture of Biological active substances and Medicinal Products for Human Use	2.4.2. Aneks 2 - Proizvodnja biološki aktivnih supstanci i lekova za humanu upotrebu
2.4.3. Shtojca 3 - Prodhimi i preparateve radiofarmaceutike	2.4.3. Annex 3 - Manufacture of Radiopharmaceuticals	2.4.3. Aneks 3 - Proizvodnja radiofarmaceutika
2.4.4. Shtojca 4 - Prodhimi i Produkteve Medicinale Veterinare te ndryshme nga produktet veterinare imunologjike	2.4.4. Annex 4 - Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products	2.4.4. Aneks 4 - Proizvodnja veterinarskih medicinskih proizvoda osim imunoloških veterinarskih lekova
2.4.5. Shtojca 5 - Prodhimi i Produkteve Medicinale	2.4.5. Annex 5 - Manufacture of Immunological	2.4.5. Aneks 5 - Proizvodnja imunoloških veterinarskih

veterinare imunologjike	Veterinary Medicinal Products	lekova
2.4.6. Shtojca 6 - Prodhimi i gazrave mjekësore	2.4.6. Annex 6 - Manufacture of Medicinal Gases	2.4.6. Aneks 6 - Proizvodnja Medicinskih gasova
2.4.7. Aneksi 7 - Prodhimi i Produkte bimore Medicinale	2.4.7. Annex 7 - Manufacture of Herbal Medicinal Products	2.4.7. Aneks 7 - Proizvodnja biljnih lekova
2.4.8. Aneksi 8 - Marrja e mostrave të materialit filelstar dhe te paketimit	2.4.8. Annex 8 - Sampling of Starting and Packaging Materials	2.4.8. Aneks 8 - Uzorkovanje pocetnih materijala i ambalaže
2.4.9. Shtojca 9 - Prodhimi i lëngjeve, kremave dhe pomadave	2.4.9. Annex 9 - Manufacture of Liquids, Creams and Ointments	2.4.9. Aneks 9 - Proizvodnja tečnosti, kreme i masti
2.4.10. Shtojca 10 - Prodhimi i aerosoleve per inhalim me dozim te caktuar	2.4.10. Annex 10 - Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation	2.4.10. Aneks 10 - Proizvodnja pod pritiskom Metered Dose Aerosol preparati za inhalaciju
2.4.11. Shtojca 11 – Sistemet e Kompjuterizura	2.4.11. Annex 11 - Computerised Systems	2.4.11. Aneks 11 - Kompjuterizovani sistemi
2.4.12. Shtojca 12 - Përdorimi i Rrezatimit jonizues në prodhimin e produkteve medicinale	2.4.12. Annex 12 - Use of Ionising Radiation in the Manufacture of Medicinal Products	2.4.12. Aneks 12 - Upotreba jonizujućeg zračenja u proizvodnji lekova
2.4.13. Shtojca 13 - Prodhimi i Produkteve Medicinale investigative	2.4.13. Annex 13 - Manufacture of Investigational Medicinal Products	2.4.13. Aneks 13 - Proizvodnja Investigational lekova
2.4.14. Shtojca 14 - Prodhimi i produkteve të derivuara nga gjaku apo plazma e njeriut	2.4.14. Annex 14 - Manufacture of Products derived from Human Blood or Human Plasma	2.4.14. Aneks 14 - Proizvodnja proizvodi dobijeni od krvi ili od ljudske plazme

2.4.15. Shtojca 15 - Kualifikimi dhe va;idimi	2.4.15. Annex 15 - Qualification and validation	2.4.15. Aneks 15 - Kvalifikacije i validacija
2.4.16. Shtojca 16 - Vërtetimi – certifikimi nga person ii kualifikuar dhe leshimi i serise	2.4.16. Annex 16 - Certification by a Qualified person and Batch Release	2.4.16. Aneks 16 - Potvrda od strane stručnog lica i puštanje serije
2.4.17. Shtojca 17 - leshimi parametrik	2.4.17. Annex 17 - Parametric Release	2.4.17. Aneks 17 - Parametarska obrade
2.4.18. X	2.4.18. X	2.4.18. X
2.4.19. Shtojca 19 – mostrat referente dhe ato qe mbahen	2.4.19. Annex 19 - Reference and Retention Samples	2.4.19. Aneks 19 - Referentne i zadržavajuci Uzorci
2.5. Fjalor	2.5. Glossary	2.5. Rečnik
2.5.1. Fjalor	2.5.1. Glossary	2.5.1. Rečnik
2.6. Dokumentet tjera që lidhen me PMP	2.6. Other documents related to GMP	2.6. Ostali dokumenti u vezi sa GMP
2.6.1. Hartimi i procedurave të Komunitetit mbi inspektimet dhe shkëmbimin e informacionit të përditësuar për të përfshirë formate të reja të BE-së dhe Procedurave	2.6.1. Compilation of Community Procedures on Inspections and Exchange of Information updated to include new EU formats and procedures	2.6.1. Kompilacija procedura Zajednice o inspekcijama i razmeni informacija da bi uključilo nove formate i procedurama EU
2.6.2. Një version i rishikuar i "Udhëzuesit mbi Praktikën e Mirë të shpërndarjes së produkteve mjekësore për përdorim njerëzor	2.6.2. A revised version of the "Guidelines on Good Distribution Practice of Medicinal Products for Human Use	2.6.2. Revidirana verzija "Smernice o Dobre prakse u distribuciji medicinskih proizvoda za ljudsku upotrebu
2.6.3. Udhëzimet e 19 mars 2015 mbi Parimet e Praktikës së Mirë të shpërndarjes së	2.6.3. Guidelines of 19 March 2015 on principles of Good Distribution Practice of	2.6.3. Smernice od 19. marta 2015. o principima dobre prakse u distribuciji

substancave aktive për produktet mjekësore për përdorim njerëzor.	active substances for medicinal products for human use.	aktivnih supstanci za medicinske proizvode za ljudsku upotrebu.
Neni 31 **Dispozitat kalimtare**	**Article 31** **Transitional Provisions**	**Član 31** **Prelazne odredbe**
1. Të gjitha kërkesat e regjistruara për vlerësimin e kushteve të GMP në AKPPM deri në datën e nënshkrimit të këtij udhëzimi do të procedohen sipas UA 16/2013, përveç në rastet kur bëhet kërkesë nga pala që të bëhet ndryshimi i procedurave në bazë të këtij Udhëzimi Administrativ.	1. All registered requests for fulfilling GMP criterias made in KMA, until the date of signing of this administrative instruction will be procesed according to AI 16/2013, unless a request is made by the party to amend the procedures under this Administrative Instruction.	1. Svi registrovani zahtevi za DPP u okviru KALIMS-a do datuma potpisa ovog administrativnog upustva biće obrađeni po AI 16/2013, osim ako je zahtev podnet od strane stranke da izmeni procedure po ovom Administrativnom Upustvom.
2. Autorizimi për Prodhim jepet për të gjitha kërkesat e prodhuesve në bazë të këtij udhzëzimi administrativ.	2. Manufacturer Authorization is given for all requests of manufacturers according to this Administrative Instruction.	2. Ovlašćenje za proizvodnju za svi zahtevi od proizvodjaca izdaju se po ovom Administrativnom Uputstvom.
3. Ndryshimi i procedurave me kërkesë të palës mund të bëhet pas përmbushjes së obligimeve dokumentare e financiare ndaj AKPPM sipas këtij UA pa e dëmtuar buxhetin e Republikës së Kosovës dhe shëndetin publik.	3. Changing of the procedures due to the request of a party shall be made after the completion of the financial and documentary obligations to KMA by this AI without any financial loss for the budget of the Republic of Kosovo.	3. Promena procedure na zahtev stranke vrši se nakon ispunjenja dokumentarnog i finansijskih obaveza prema KALIMS pod ovim AU ako to ne utice na gubitak budzeta

Neni 32 **Dispozitat shfuqizuese**	**Article 32** **Abrogation provisions**	**Article 32** **Odredbe stavljanja van snage**
Me hyrjen në fuqi të këtij udhëzimi administrativ, shfuqizohet udhëzimi administrativ Nr. UA 16/2013,	Upon entry into force of this administrative instruction, the administrative instruction no.16/2013	Stupanjem na snagu ovog Administrtivnog Uputstva, stavljaju se van snage Administrativno Uputstvo 16/2013
Neni 33 **Hyrja në fuqi**	**Article 33** **Entry in force**	**Article 33** **Entry in force**
Ky Udhëzim Administrativ hyn në fuqi ditën e nënshkrimit nga Ministri i Shëndetësisë.	This Administrative Instuction enteries into force on the day of signing by Minister of Health.	Ovo Administrataivno Uputstvo stupa na snagu na dan potpisivanja od strane Ministra Zdravlja Republike Kosova.
Prishtinë **Dt:** 23/07/2015 **Ministri i Shëndetsisë** **Dr. Imet Rrahmani**	**Pristina** **Dt:** 23/07/2015 **Minister of Health** **Dr. Imet Rrahmani**	**Pristina** **Dt:** 23/07/2015 **Minister of Health** **Dr. Imet Rrahmani**

Republika e Kosovës
RepublikaKosova - Republic of Kosovo
Qeveria - Vlada - Government

Ministria e Sh]ndetësisë
MinistarstvoZdravstva– Ministry of Health

1. Title of the normative act: DIRECTIVE 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinalproducts for human use
2. Proposing body: European Commission
3. Table: 22/06/2015
4. List of relevant national legislation (full title of the act and number) with which the normative act of the Republic of Kosovo is compliant: - Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products. - Law on Medicinal Products and Medical Devices no.04/L-190Administrative instruction (Health) No .01/2015 Marketing Authorization for Medicinal Products
5. The level of compliance (fully compliant, partially compliant, not compliant or not applicable) of the normative act with EU legislation: Partially compliant

European Union – Republic of Kosovo

a)	b)	c)	d)
EU normative act (Article, paragraph, sub-paragraph, etc.)	Provisions of normative act of Kosovo (Article, paragraph, sub-paragraph, etc.)	Compliance of EU legislation with Kosovo legislation (fully compliant, partially compliant, non-compliant or not applicable)	Comments on reasons for partial compliance or non-compliance and the period foreseen for achieving full compliance

Article 1 ***Scope*** This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use whose manufacture requires the authorization referred to in Article 40 of Directive 2001/83/EC and in respect of investigational medicinal products for human use whose manufacture requires the authorisation referred to in Article 13 of Directive 2001/20/EC.	***Title of the Administrative Instruction*** ***Article 1*** ***Scope*** This Administrative Instructions lays down the principles and requirements of good manufacturing practice for medicinal products and investigational medicinal products, whose manufacture requires authorization, in Republic of Kosovo, and the requirements for issuing manufacturing authorizations and certificates of good manufacturing practice.	Fully compliant	
Article 2 *Definitions* For the purposes of this Directive, the following definitions shall apply: 1. 'medicinal product' means any product as defined in Article 1(2) of Directive 2001/83/EC;	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.1** **Medicinal product-** any substance or combination of substances that has properties for treatingor preventing disease in human beings which may be used in human beings or administered to them either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.	Fully Compliant	
2. 'investigational medicinal product' means any product as defined in Article 2(d) of Directive 2001/20/EC;	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good**	Fully compliant	

	Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products. **Article 2 paragraph 1 subparagraph 1.10** Investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form.		
3. 'manufacturer' means any person engaged in activities for which the authorization referred to in Article 40(1) and (3) of Directive 2001/83/EC or the authorization referred to in Article 13(1) of Directive 2001/20/EC is required;	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.29** 1**Manufacturer of medicinal products** - a legal entity or natural person responsible for the development, manufacture, quality control, packaging and labeling of medicinal products as well as their safety and efficacy irrespective of whether medicinal products where manufactured by themselves or on their behalf by a third party and possess a manufacturing	Partially compliant	National Legislation doesn't foresee all these issues. Amendment of the law 3-4 years

	authorizationwhich undergoes regular inspections from the Competent Authority.		
4. 'qualified person' means the person referred to in Article 48 of Directive 2001/83/EC or in Article 13(2) of Directive 2001/20/EC;	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.39** **Qualified Person of manufacturer or importer** - employed person responsible for quality assurance. He possess diploma, certificate or other evidence of official qualification, gained after the completion of university studies in duration of at least four (4) year, of theoretical studies and practical studies in one of the following scientific fields: pharmacy, human medicine, chemistry, biology, chemical-pharmaceutical technology.	Partially compliant	National Legislation doesn't foresee all these issues. Amendment of the law 3-4 years
5. 'pharmaceutical quality assurance' means the total sum of the organized arrangements made with the object of ensuring that medicinal products or investigational medicinal products are of the quality required for their intended use;	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 2 paragraph 1subparagraph 1.1** Pharmaceutical quality assurance means the total sum of organized activities and procedures with the	Fully compliant	

	objective of ensuring that medicinal products and investigational medicinal products are of the quality required for their intended use.		
6. 'good manufacturing practice' means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use;	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.28** **Good Manufacturing Practice GMP** - that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use.	Fully compliant	
7. 'blinding' means the deliberate disguising of the identity of an investigational medicinal product in accordance with the instructions of the sponsor;	2. Blinding means the deliberate disguising of the identity of an investigational medicinal product in accordance with the instructions of the sponsor.	Fully compliant	
8. 'Unblinding' means the disclosure of the identity of a blinded product.	3. Unbinding of the identity of investigational medicinal product means the disclosure of the identity of a blinded product.	Fully compliant	
Article 3 *Inspections* 1. By means of the repeated inspections referred to in Article 111(1) of Directive 2001/83/EC and by means of the inspections referred to in Article 15(1) of Directive 2001/20/ EC, the Member States shall ensure	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.**	Partially compliant	Article 15 (1) of Directive 2001/20 Verification of compliance of Investigational Medicinal Products with Good Clinical Practice will be regulated by law. ? Amendment of the law 3-4 years

that manufacturers respect the principles and guidelines of good manufacturing practice laid down by this Directive. Member States shall also take into account the compilation, published by the Commission, of Community procedures on inspections and exchange of information.	***Article 21*** ***KmaGmp Audits*** 1. KMA shall ensure that that the legal requirement governing medicinal products are complied with, by means of audits by KMA gmp auditors. 2. Audits can be unannounced and where appropriate, by asking QCL or a designated laboratory to carry out tests on samples. 3. Manufacturers located in Republic of Kosova and in other countries shall be subject to repeated audits. 4. By specific request of the manufacturers KMA may carry out audits of starting material manufacturers. **Administrative instruction (Health) no 01/2015 Marketing Authorization for Medicinal Products** ***Article 16 paragraph 8*** The KMA can make auditing of manufacturing sites at any time, there where the medicinal product in question is manufactured. Such auditing is conducted by auditors of KMA,and if needed in collaboration of departments of DMA dhe LQC in KMA for evaluation of conditions of manufacturing medicinal products according to the Good		

	Manufacturing Practice.		
2. For the interpretation of the principles and guidelines of good manufacturing practice, the manufacturers and the competent authorities shall take into account the detailed guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC, published by the Commission in the 'Guide to good manufacturing practice for medicinal products and for investigational medicinal products'.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 21 paragraph 5*** For interpretation of the principles and guidelines of good manufacturing practice , KMA shall take into account the detailed guidelines referred to in article 19 of this administrative Instruction.	Fully compliant	
Article 4 ***Conformity with good manufacturing practice*** 1. The manufacturer shall ensure that manufacturing operations are carried out in accordance with good manufacturing practice and with the manufacturing authorization. This provision shall also apply to medicinal products intended only for export.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 5*** ***Conformity with Good Manufacturing Practice*** The manufacturer of medicinal products shall ensure that all manufacturing operations for medicinal products and / or investigational medicinal products are carried out in	Fully compliant	

	compliance with good manufacturing practice and the manufacturing authorization; this applies also to medicinal products intended for export only.		
2. For medicinal products and investigational medicinal products imported from third countries, the importer shall ensure that the products have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down by the Community. In addition, an importer of medicinal products shall ensure that such products have been manufactured by manufacturers dulyauthorized to do so. An importer of investigational medicinal products shall ensure that such products have been manufactured by a manufacturer notified to the competent authorities and accepted by them for that purpose.		Not compliant	Import is going to be regulated by another administrative instruction Amendment of the law 3-4 years
Article 5 ***Compliance with marketing authorization*** 1. The manufacturer shall ensure that all manufacturing operations for medicinal products subject to a marketing authorization are carried out in accordance with the information provided in the application for marketing authorization as accepted by the competent authorities. In the case of investigational	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 6*** ***Conformity with marketing authorization***	Partially compliant	Clinical trials will be regulated by law under article 84 paragraph 2 of the Health Law - Law for clinical trials in legislation framework for 2015

medicinal products, the manufacturer shall ensure that all manufacturing operations are carried out in accordance with the information provided by the sponsor pursuant to Article 9(2) of Directive 2001/20/EC as accepted by the competent authorities.	1. The manufacturer shall ensure that all manufacturing operations for medicinal products subject to a marketing authorization are carried out in accordance with the information provided in the application for marketing authorization as accepted by the competent authorities. In the case of investigational medicinal products, the manufacturer shall ensure that all manufacturing operations are carried out in accordance with the information provided by the sponsor to the competent authority in Republic of Kosovo.		
2. The manufacturer shall regularly review his manufacturing methods in the light of scientific and technical progress and the development of the investigational medicinal product. If a variation to the marketing authorization dossier or an amendment to the request referred to in Article 9(2) of Directive 2001/20/EC is necessary, the application for modification shall be submitted to the competent authorities.	The manufacturer shall regularly review his manufacturing methods and quality control procedures in the light of their adjustment to scientific and technical progress.	Partiallycompliant	Second part of paragraph is Not compliant because will be regulated by law under article 84 paragraph 2 of the Health Law Amendment of the law 3-4 years
Article 6 ***Quality assurance system*** The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.**	Fully compliant	

departments.	***Article 8*** ***Pharmaceutical quality assurance system*** The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different departments.		
Article 7 ***Personnel*** 1. At each manufacturing site, the manufacturer shall have sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance objective.	***Article 9*** ***Personnel*** 1. At each manufacturing site, the manufacturer shall have a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance objective.	Fully compliant	
2. The duties of the managerial and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organization chart. Organization charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 9 paragraph 4** 4. The duties of the managerial	Fully compliant	

	and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organization chart. Organization charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.		
3. The staff referred to in paragraph 2 shall be given sufficient authority to discharge their responsibility correctly.	3. The person responsible for manufacturing and the person responsible for quality control shall act independently of each other.	Fully compliant	
4. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice, and, where appropriate, the particular requirements for the manufacture of investigational medicinal products.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 9 paragraph** 5. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice, and, where appropriate, the particular requirements for the manufacture of investigational medicinal	Fully compliant	

	products.		
5. Hygiene programs adapted to the activities to be carried out shall be established and observed. These programs shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 9 paragraph** 6. 6. Hygieneprograms adapted to the activities to be carried out shall be established and observed. These programs shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.	Fully compliant	
Article 8 ***Premises and equipment*** 1. Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 11 paragraph 1*** Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations	Fully compliant	
2. Premises and manufacturing equipment shall be laid out,	**Draft Administrative Instruction (Health) NO.**	Fully compliant	

designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.	**XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 11paragraph 2*** Premises and manufacturing equipment shall be laid out, designed and operated in such a way as to minimize the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.		
3. Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products,shall be subjected to appropriate qualification and validation.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 11 paragraph 3*** Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.	Fully compliant	
Article 9 Documentation	**Draft Administrative Instruction (Health) NO.**	Partially compliant	Second part of paragraph is Not compliant because this will be

1. The manufacturer shall establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of each batch and the changes introduced during the development of an investigational medicinal product to be traced. For a medicinal product, the batch documentation shall be retained for at least one year after the expiry date of thebatches to which it relates or at least five years after the certification referred to in Article 51(3) of Directive 2001/83/EC, whichever is the longer period. For an investigational medicinal product, the batch documentation shall be retained for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used. The sponsor or marketing authorization holder, if different,	**XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 12*** ***Documentation*** 1.The manufacturer shall establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of each batch and the changes introduced during the development of an investigational medicinal product to be traced. 2.For a medicinal product, the batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates or at least five years after the certification		regulated by law under article 84 paragraph 2 of the Health Law Amendment of the law 3-4 years

shall be responsible for ensuring that records are retained as required for marketing authorisation in accordance with the Annex I to Directive 2001/83/EC, if required for a subsequent marketing authorisation	referred to in Article 10 paragraph 7, whichever is the longer period.		
2. When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the competent authorities at their request. The electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 12 paragraph 3*** When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the competent authorities at their request. The electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.	Fully compliant	
Article 10 Production	**Draft Administrative Instruction (Health) NO.**	Fully compliant	

1.The different production operations shall be carried out in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the in process controls. All process deviations and product defects shall be documented and thoroughly investigated.	**XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 13 paragraph 1*** The different production operations shall be carried out in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the inprocess controls. All process deviations and product defects shall be documented and thoroughly investigated.		
2. Appropriate technical or organisational measures shall be taken to avoid cross contamination and mix-ups. In the case of investigational medicinal products, particular attention shall be paid to the handling of products during and after any blinding operation.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 13 paragraph 2*** Appropriate technical or organizational measures shall be taken to avoid cross contamination and mix-ups. In the case of investigational medicinal	Fully compliant	

	products, particular attention shall be paid to the handling of products during and after any blinding operation.		
3. For medicinal products, any new manufacture or importantmodification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly re-validated.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 13 paragraph 3*** For medicinal products, any new manufacture or important modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly re-validated.	Fully compliant	
4. For investigational medicinal products, the manufacturingprocess shall be validated in its entirety in so far as is appropriate, taking into account the stage of product development. At least the critical process steps, such as sterilisation, shall be validated. All steps in the design and development of the manufacturing process shall be fully documented.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 13 paragraph 4*** For investigational medicinal products, the manufacturing process shall be validated in its entirety in so far as is appropriate, taking into account the stage of	Fully compliant	

	product development. At least the critical process steps, such as sterilization, shall be validated. All steps in the design and development of the manufacturing process shall be fully documented.		
Article 11 *Quality control* 1. The manufacturer shall establish and maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production. That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and packaging materials and the testing of intermediate and finished products.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** *Article 14 paragraph 1* The manufacturer shall establish and maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production. That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and packaging materials and the testing of intermediate and finished products	Fully compliant	
2. For medicinal products, including those imported from third countries, contract laboratories may be used if authorized in accordance with Article 12 of this Directive and point	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice,**	Partially compliant	Content of the request referred to in Article 9 (2) of Directive 2001/20/EC will be regulated by law under article 84 paragraph 2 of the Health Law

(b) of Article 20 of Directive 2001/83/EC. For investigational medicinal products, the sponsor shall ensure that the contract laboratory complies with the content of the request referred to in Article 9(2) of Directive 2001/20/EC, as accepted by the competent authority. When the products are imported from third countries, analytical control shall not be mandatory.	**Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 14 paragraph 2 and 3*** 2.Contract laboratories may be used if authorized in accordance with Article 15 of this administrative instruction and if approved in manufacturing authorization procedure. 3.For investigational medicinal products, the sponsor shall ensure that the contract laboratory complies with the requirements of the KMA		Amendment of the law 3-4 years
3. During the final control of the finished product before its release for sale or distribution or for use in clinical trials, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 14 paragraph*** 4.During the final control of the finished product before its release for sale or distribution or for use in clinical trials, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of in-process controls, the	Fully compliant	

	examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack.		
4. Samples of each batch of finished medicinal product shall be retained for at least one year after the expiry date. For an investigational medicinal product, sufficient samples of each batch of bulk formulated product and of key packaging components used for each finished product batch shall beretained for at least two years after completion or formaldiscontinuation of the last clinical trial in which the batch was used, whichever period is the longer. Unless a longer period is required under the law of the Member State of manufacture, samples of starting materials, other thansolvents, gases or water, used in the manufacturing processshall be retained for at least two years after the release ofproduct. That period may be shortened if the period of stability of the material, as indicated in the relevant specification, is shorter. All those samples shall be maintained at the disposal of the competent authorities.Other conditions may be defined, by agreement with the competent authority, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities,	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 14 paragraph 5,6 and 7*** 5.Samples of each batch of finished medicinal product shall be retained for at least one year after the expiry date. 6.For an investigational medicinal product, sufficient samples of each batch of bulk formulated product and of key packaging components used for each finished product batch shall be retained for at least two years after completion or formal discontinuation of the last clinical trial in which the batch was used, whichever period is the longer. 7.Samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained for at least two years after the release of product. That period may be	Fully compliant	

or when their storage could raise specialproblems.	shortened if the period of stability of the material, as indicated in the relevant specification, is shorter. All those samples shall be maintained at the disposal of the gmp auditor KMA. Other conditions may be defined, by agreement with the KMA, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities, or when their storage could raise special problems.		
Article 12 **Work contracted out** 1 Any manufacturing operation or operation linked thereto which is carried out under contract shall be the subject of a written contract.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 15 paragraph 1** Any manufacturing operation or operation linked thereto which is carried out under contract shall be the subject of a written contract.	Fully compliant	
2. The contract shall clearly define the responsibilities ofeach party and shall define, in particular, the observance ofgood manufacturing practice to be followed by the contract acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.**	Fully compliant	

	Article 15 paragraph 2 The contract shall clearly define the responsibilities of each party and shall define, in particular, the observance of good manufacturing practice to be followed by the contract acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities.		
3. The contract-acceptor shall not subcontract any of thework entrusted to him under the contract without written authorisation from the contract-giver.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 15 paragraph 3** 3.The contract-acceptor shall not subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver.	Fully compliant	
4. The contract-acceptor shall comply with the principlesand guidelines of good manufacturing practice and shall submit to inspections carried out by the competent authorities pursuant to Article 111 of Directive 2001/83/EC and Article 15 of Directive 2001/20/EC.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.**	Fully compliant	

	Article 15 paragraph 4 4.The contract-acceptor shall comply with the principles and guidelines of good manufacturing practice and shall submit to audits carried out by gmp auditors KMA.		
Article 13 **Complaints, product recall and emergency unblinding** 1. In the case of medicinal products, the manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and atany time, medicinal products in the distribution network. Anycomplaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall inform thecompetent authority of any defect that could result in a recall or abnormal restriction on supply and, in so far as is possible, indicate the countries of destination. Any recall shall be made in accordance with the requirements referred to in Article 123 of Directive 2001/83/EC.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** ***Article 16 paragraph 1*** Manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and at any time, medicinal products in the distribution network. Any complaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall inform the KMA of any defect that could result in a recall or abnormal restriction on supply and, in so far as is possible, indicate the countries of destination.Any recall shall be made in accordance with the KMA regulations.	Fully compliant	
2. In the case of investigational medicinal products, the	**Draft Administrative Instruction (Health) NO.**	Fully compliant	

manufacturer shall, in cooperation with the sponsor, implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time investigational medicinal products which have already entered the distribution network. The manufacturer shall record and investigate any complaint concerning a defect and shall informthe competent authority of any defect that could result in a recall or abnormal restriction on supply.In the case of investigational medicinal products, all trial sites shall be identified and, in so far as is possible, the countries of destination shall be indicated. In the case of an investigational medicinal product for which amarketingauthorisation has been issued, the manufacturer of the investigational medicinal product shall, in cooperation with the sponsor, inform the marketing authorisation holder of any defect that could be related to the authorisedmedicinalproduct.	**XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** *Article 16 paragraph 2* In the case of investigational medicinal products, the manufacturer shall, in cooperation with the sponsor, implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time investigational medicinal products which have already entered the distribution network. The manufacturer shall record and investigate any complaint concerning a defect and shall inform the competent authority of any defect that could result in a recall or abnormal restriction on supply. In the case of investigational medicinal products, all trial sites shall be identified and, in so far as is possible, the countries of destination shall be indicated. In the case of an investigational medicinal product for which a marketing authorization has been issued, the manufacturer of the investigational medicinal product shall, in cooperation with the sponsor, inform the marketing		

	authorization holder of any defect that could be related to the authorized medicinal product.		
3. The sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 2. The sponsor shall ensure that the procedure discloses the identity of the blinded product only in so far as is necessary.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** *Article 16 paragraph 3* 3.The sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 2. The sponsor shall ensure that the procedure discloses the identity	Fully compliant	
Article 14 **Self-inspection** The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures. Records shall be maintained of such self-inspections and any corrective action subsequently taken.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** *Article 17* The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of	Fully compliant	

	good manufacturing practice and to propose any necessary corrective measures. Records shall be maintained of such self-inspections and any corrective action subsequently taken.		
Article 15 ***Labelling*** In the case of an investigational medicinal product, labeling shall be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the investigational medicinal product.	***Article 18*** ***Labelling*** In the case of an investigational medicinal product, labelling shall be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the investigational medicinal product.	Fully compliant	
Article 16 ***Repeal of Directive* 91/356/EEC** Directive 91/356/EEC is repealed. References to the repealed Directive shall be construed as references to this Directive.		Not applicable	
Article 17 **Transposition** 1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2004 at the latest. They shall forthwith communicate to the Commission the text of the provisions and correlation table between those provisions and the provisions of this Directive.		Not applicable	

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The Member States shall determine how such reference is to be made. 2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.			
Article 18 **Entry into force** This Directive shall enter into force on the 20th day followingthat of its publication in the Official Journal of the EuropeanUnion.		Not applicable	
Article 19 Addressees This Directive is addressed to the Member States.		Not applicable	

Republika e Kosovës
RepublikaKosova - Republic of Kosovo
Qeveria - Vlada - Government

Ministria e Shëndetësisë
MinistarstvoZdravstva– Ministry of Health

1. Title of the normative act: DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version)
2. Proposing body: European Commission
3. Table: 22/06/2015
4. List of relevant national legislation (full title of the act and number) with which the normative act of the Republic of Kosovo is compliant: - Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products, - Administrative Instruction (Health) No. 01/2015 Marketing Authorization for Medicinal Products - Law no.04/L-190 On Medicinal and Medical Devices, - Lawno. 02/L-128 OnNarcoticMedicaments , Psycho-TropesandPrecusors.
5. The level of compliance (fully compliant, partially compliant, not compliant or not applicable) of the normative act with EU legislation: Partially compliant

European Union – Republic of Kosovo

a)	b)	c)	d)
EU normative act (Article, paragraph, sub-paragraph, etc.)	Provisions of normative act of Kosovo (Article, paragraph, sub-paragraph, etc.)	Compliance of EU legislation with Kosovo legislation (fully compliant, partially compliant, non-compliant or not applicable)	Comments on reasons for partial compliance or non-compliance and the period foreseen for achieving full compliance

DEFINITIONS *Article 1* For the purposes of this Directive, the followingterms shall bear the following meanings:1. (point deleted) 2. *Medicinal product:* (a) Any substance or combination ofsubstances presented as having properties fortreating or preventing disease in human beings;or (b) Any substance or combination ofsubstances which may be used in or administeredto human beings either with a view to restoring, correcting or modifying physiological functionsby exerting a pharmacological, immunological or metabolic action, or to making a medicaldiagnosis.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.1** **Medicinal product**- any substance or combination of substances that has properties for treatingor preventing disease in human beings which may be used in human beings or administered to themeither with a view to restoring, correcting or modifying physiological functions by exerting apharmacological, immunological or metabolic action, or to making a medical diagnosis.	Fully Compliant	
3. *Substance:* Any matter irrespective of origin which may be: - human, e.g.human blood and human blood products; - animal, e.g.micro-organisms, whole animals, partsof organs, animal secretions, toxins,extracts, blood products; - vegetable, e.g.micro-organisms, plants, parts of plants,vegetable secretions, extracts; - chemical, e.g.elements, naturally occurring chemicalmaterials and chemical productsobtained by chemical change orsynthesis.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.2.** **Substance** - any matter irrespective of origin which may be: human, human blood and humanblood products; animal, micro-organisms, whole animals, parts of organs, animal secretions, toxins,extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions,extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products;obtained by chemical change or synthesis.	Fully Compliant	

3a. *Active substance:* Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.3.** **Active substance (Active pharmaceutical ingredient)** - any substance ormixture of substances that when used in production of a medicinal product,becomes an active ingredient of that product intended to exert apharmacological, immunological or metabolic action with a view to restoring,correcting or modifying physiological functions or to make a medical diagnosis.	Fully Compliant	
3b. *Excipient:* Any constituent of a medicinal product other than the active substance and the packaging material.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.4.** **Excipient** - any constituent of a medicinal product other than the activesubstance and the packaging material.	Fully Compliant	
4. *Immunological medicinal product:* Any medicinal product consisting of vaccines,toxins, serums or allergen products: (a) vaccines, toxins and serums shall cover inparticular: (i) agents used to produce active immunity, such as cholera vaccine,BCG, polio vaccines, smallpox vaccine; (ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin; (iii) agents used to produce passive	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.5.** **Immunological medicinal product** - any medicinal product consisting of vaccines, toxins, serumsor allergen products:vaccines, toxins and serums shall cover in particular:agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;agents used to diagnose the state of immunity, including in particular	Fully Compliant	

immunity, such as diphtheria antitoxin,anti-smallpox globulin, antilymphocytic globulin;	tuberculinand tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;agents used to produce passive immunity, such as diphtheria globulin, antismallpoxglobulin, antilymphocytic globulin.		
(b) 'allergen product' shall mean any medicinalproduct which is intended to identify or induce a specificacquired alteration in the immunological response to an allergizing agent.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.6.** **Allergen product** - any medicinal product which is intended to identify orinduce a specific acquired alteration in the immunological response to an allergizing agent	Fully Compliant	
4a. *Advanced therapy medicinal product:* A product as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products (1).	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.7.** **Advanced therapy medicinal product** - any following medicinal productsfor human use: a gene therapy medicinal product; a somatic cell therapy medicinal product;a tissue engineered product.	Fully Compliant	
5. *Homeopathic medicinal product:* Any medicinal product prepared from substancescalled homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. Ahomeopathic medicinal product may contain a number of principles.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.13** **Homeopathic medicinal product** - any medicinal product prepared from substances calledprimary homeopathic materials in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used in	Fully Compliant	

	the Republic of Kosovo. A homeopathic medicinal product may contain a number of principles.		
6. *Radiopharmaceutical:* Any medicinal product which, when ready foruse, contains one or more radionuclides(radioactive isotopes) included for a medicinal purpose.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
7. *Radionuclide generator:* Any system incorporating a fixed parentradionuclide from which is produced a daughterradionuclide which is to be obtained by elution or by any other method and used in radiopharmaceutical.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
8. *Kit* Any preparation to be reconstituted or combinedwith radionuclides in the finalradiopharmaceutical, usually prior to itsadministration.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
9. *Radionuclide precursor:* Any other radionuclide produced for the radiolabelling of another substance prior to administration.	**Lawon Narcotic Medicaments, Psycho-tropes and Precursors No. 02/L-128** **Article 5** Precursor mean any substance, natural or synthetic which can be used to obtain thenarcotic medicament or psychotrope substance, presented in Table IV, based on Lists Iand II of Convention of the United Nations of year 1988, Against Illegal Trafficking of Narcotic Medicaments and Psychotrope Substances and in the Regulation of (EC) No.273/2004 of European Council and Parliament on 11.02.244 regarding Precursors. Any other substance presented in Table	Fully compliant	

	IV of this Law will be interpreted as precursors		
10. *Medicinal products derived from humanblood or human plasma:* Medicinal products based on blood constituentswhich are prepared industrially by public orprivate establishments, such medicinal productsincluding, in particular, albumin, coagulatingfactors and immunoglobulins of human origin.		Not compliant	**National legislation** does not determine the term Amendment of the Law in a period 3-4 years
11. *Adverse reaction:* A response to a medicinal product which is noxious and unintended	**Law on Medicinal and Medical Devices no.04/L-190** **Article 3 paragraph 1.21** Adverse Reaction - a response to a medicinal product used in a therapeutic dosage which is noxious and unintended.	FullyCompliant	
12. *Serious adverse reaction:* An adverse reaction which results in death, islife-threatening, requires inpatient hospitalization or prolongation of existing hospitalisation,; results in persistent or significant disability orincapacity, or is a congenital anomaly/birthdefect.	**Law on Medicinal and Medical Devices no.04/L-190** **Article 3 paragraph 1.22** **Serious Adverse Reaction** - an adverse reaction which results in death; is life threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; or is a congenital anomaly/birth defect.	Fully Compliant	
13. *Unexpected adverse reaction:* An adverse reaction, the nature, severity oroutcome of which is not consistent with thesummary of product characteristics.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
15. *Post-authorisation safety study;* Any study relating to an authorised		Not compliant	National legislation does not determine the term

medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.			Amendment of the Law in a period 3-4 years
16. *Abuse of medicinal products:* Persistent or sporadic, intentional excessive useof medicinal products which is accompanied byharmful physical or psychological effects.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
17. *Wholesale distribution of medicinalproducts:* All activities consisting of procuring, holding,supplying or exporting medicinal products, apart from supplying medicinal products to the public.Such activities are carried out withmanufacturers or their depositories, importers,other wholesale distributors or with pharmacistsand persons authorized or entitled to supplymedicinal products to the public in the MemberState concerned.	**Law on Medicinal and Medical Devices no.04/L-190** **Article 3 paragraph 1.34** **Pharmaceutical wholesale distribution** - all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public.	Fully Compliant	
17a. *Brokering of medicinal products:* All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
18. *Public service obligation:* The obligation placed on		Not compliant	National legislation does not determine the term

wholesalerstoguarantee permanently an adequate range ofmedicinal products to meet the requirements of aspecific geographical area and to deliver thesuppliesrequested within a very short time overthe whole of the area in question.			Amendment of the Law in a period 3-4 years
18a. *Representative of the marketingauthorization holder:* The person, commonly known as localrepresentative, designated by the marketingauthorization holder to represent him in theMember State concerned.	**Law on Medicinal and Medical Devices no.04/L-190** **Article 3 paragraph 1.45** **Representative of the marketing authorization holder** - a legal entity, commonly known as local representative, designated by the marketing authorization holder to represent him in the Republic of Kosovo.	Fully Compliant	
19. *Medicinal Prescription:* Any medicinal prescription issued by a professional person qualified to do so.	**Law on Medicinal and Medical Devices no.04/L-190** **Article 3 paragraph 1.51** **Prescription** – any medical prescription issued by professional person qualified to do so.	Fully Compliant	
20. *Name of the medicinal product:* The name, which may be either an inventedname not liable to confusion with the commonname, or a common or scientific nameaccompanied by a trade mark or the name of themarketingauthorization holder.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.2.** **Name of the medicinal productis** the name that may be either an invented name which does not cause confusion with the common name, or a common or scientific name accompanied by a trade mark or by the name of marketing authorization holder.	Fully Compliant	

21. *Common name:* The international non-proprietary name recommended by the World HealthOrganization, or, if one does not exist, the usual common name.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.3.** **Common name**is the international non-proprietary name (INN) recommended by the World Health Organization or, if one does not exist, the usual common name.	Fully Compliant	
22. *Strength of the medicinal product:* The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.4.** **Strength of the medicinal product** is the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.	Fully Compliant	
23. *Immediate packaging:* The container or other form of packagingimmediately in contact with the medicinal product.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.9** **Immediate packing** is the container or other form of packaging immediately in contact with the medicinal product	Fully Compliant	
24. *Outer packaging:* The packaging into which is placed theimmediate packaging.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.10**	Fully Compliant	

	Outer packaging is the packaging into which is placed the immediate packaging.		
25. *Labelling:* Information on the immediate or outer packaging.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.49** **Labeling** - all texts and symbols on the inside and outer packaging of a medicinal product or medical device.	Fully Compliant	
26. *Package leaflet:* A leaflet containing information for the user which accompanies the medicinal product.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.11** **Package Information Leaflet** is the leaflet containing information for user, which accompanies the medicinal product.	Fully Compliant	
27. *Agency:* The European Medicines Agency established by Regulation (EC) No 726/2004.		Not applicable	
28. *Risks related to use of the medicinal product:* - any risk relating to the quality, safety orefficacy of the medicinal product as regards patients' health or public health; - any risk of undesirable effects on the environment.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.12** **Risks related to the use of medicinal products** are: Any risk related to the quality, safety or efficacy of a medicinal product related to the patient's health or public health; Any risk of undesirable effects on	Fully Compliant	

	the environment.		
28a. *Risk-benefit balance:* An evaluation of the positive therapeutic effectsof the medicinal product in relation to the risksas defined in point 28, first indent.	**Administrative Instruction (Health) No. 01/2015Marketing Authorization for Medicinal Products** **Article 3 paragraph 1.13** **Risk-benefit balance** is the assessment of positive therapeutic effects of the medicinal product in relation to the risks as defined in this administrative instruction.	Fully Compliant	
28b. *Risk management system:* a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
28c. *Risk management plan:* a detailed description of the risk management system.		Not compliant	National legislation does not determine the term Amendment of the Law in a period 3-4 years
28d. *Pharmacovigilance system:* a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3paragraph 1.20** **Pharmacovigilance System** - a system used by the marketing authorization holder and by the Kosovo Medical Agency (KMA) to fulfill the tasks andresponsibilities of pharmacovigilance and designed to monitor the safety ofauthorized medicinal products and detect any change to the risk benefit balance.	Fully compliant	
28e. *Pharmacovigilance system master file:*		Not compliant	National legislation does not determine the term

A detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products.			Amendment of the Law in a period 3-4 years
29. *Traditional herbal medicinal product:* A herbal medicinal product that fulfils theconditions laid down in Article 16a(1).	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.12** **Traditional herbal medicinal product** - a herbal medicinal product that fulfils the followingconditions: -have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner or for diagnostic purposes or for prescription or monitoring of treatment; - are exclusively for administration in accordance with a specified strength and posology; - are preparation for an oral, external and/or inhalation use; - have the period of traditional use at least thirty (30) years preceding of the date ofapplication including at least fifteen (15) years in Europe; - the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of longstanding use and experience.	Fully Compliant	

30. *Herbal medicinal product:* Any medicinal product, exclusively containing as active ingredients one or more herbalsubstances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.9.** **Herbal medicinal products** - any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.	Fully Compliant	
31. *Herbal substances:* All mainly whole, fragmented or cut plants, plantparts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to aspecific treatment are also considered to beherbal substances. Herbal substances areprecisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.11** **Herbal Substance** - all mainly whole, fragmented or cut plants, plant parts,algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh.Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system, such as:genus, species, variety and author.	Fully Compliant	
32. *Herbal preparations:* Preparations obtained by subjecting herbal substances to treatments such as extraction,distillation, expression, fractionation,purification,concentration or fermentation.These include comminuted or powdered herbalsubstances, tinctures, extracts, essential oils,expressed juices and processed exudates.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.10** **Herbal preparations** - preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification,	Fully Compliant	

	concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.		
33. *Falsified medicinal product:* Any medicinal product with a false representation of: (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients andthe strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization holder; or (c) its history, including the records and documents relating to the distribution channels used. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.14** **Falsified products** - any medicinal product or medical device with a false representation of: - its juridical identity, including its packaging and labeling, its name as regards any of theincluding excipients and the strength of those ingredients; - its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization polder; - its history, including the records and document related to the distribution channels. - this definition does not include unintentional quality defects and does not prejudice other law violations or issues related to the right on intellectual property.	Fully Compliant	
TITLE II **SCOPE** ***Article 2*** 1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 2** **Scope** This Law applies to all public authorities, public and private enterprises as well as legal and natural entities engaged in the manufacturing, trading and other	Fully Compliant	

industrially or manufactured by a method involving an industrial process.	activities that involve medicinal products and medical devices, products containing radioactive substances or dealing with the safety of using radioactive radiation, immunologic preparations and blood products, medicinal gas, vitaminose, herbal and mineral preparations, diet and cosmetic preparations with therapeutic action, raw material for manufacturing medicinal products, semi products of medicinal products.		
2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.		Not applicable	
3. Notwithstanding paragraph 1 of this Article and Article 3(4), Title IV of this Directive shall apply to the manufacture of medicinal products intended only for export and to intermediate products, active substances and excipients.	**Article 2** **Scope** This Law applies to all public authorities, public and private enterprises as well as legal and natural entities engaged in the manufacturing, trading and other activities that involve medicinal products and medical devices, products containing radioactive substances or dealing with the safety of using radioactive radiation, immunologic preparations and blood products, medicinal gas, vitaminose, herbal and mineral preparations, diet and cosmetic preparations with therapeutic action, raw material for manufacturing medicinal products, semi products of medicinal products.	Fully compliant	

4. Paragraph 1 shall be without prejudice to Articles 52b and 85a.		Not applicable	
Article 3 This Directive shall not apply to: 1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula).		Not applicable	
2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula).		Not applicable	
3. Medicinal products intended for research and development trials, but without prejudice to the provisions of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (1).		Not applicable	
4.Intermediate products intended for further processing by an authorized manufacturer.		Not applicable	
5. Any radionuclides in the form of sealed sources.		Not applicable	
6. Whole blood, plasma or blood cells of human origin, except for plasma		Not applicable	

which is prepared by a method involving an industrial process.			
7. Any advanced therapy medicinal product, as defined in Regulation (EC) No 1394/2007, which is prepared on a non- routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient. Manufacturing of these products shall be authorised by the competent authority of the Member State. Member States shall ensure that national traceability and pharmacovigilance requirements as well as the specific quality standards referred to in this paragraph are equivalent to those provided for at Community level in respect of advanced therapy medicinal products for which authorisation is required pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (1).		Not applicable	
Article 4 1. Nothing in this Directive shall in any way derogate from the Community rules for the radiation protection of persons undergoing		Not applicable	

Republika e Kosovës
RepublikaKosova - Republic of Kosovo
Qeveria - Vlada - Government

Ministria e Sh[ndetësisë
MinistarstvoZdravstva- Ministry of Health

1. Title of the normative act: DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation o good clinical practice in the conduct of clinical trials on medicinal products for human use
2. Proposing body: European Commission
3. Table: 22/06/2015
4. List of relevant national legislation (full title of the act and number) with which the normative act of the Republic of Kosovo is compliant: - Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products. - Law on Medicinal Products and Medical Devices no.04/L-190 - Administrative Instuction (Health) no.01/2015 Marketing Authorization for Medicinal Products
5. The level of compliance (fully compliant, partially compliant, not compliant or not applicable) of the normative act with EU legislation: Partially compliant

European Union – Republic of Kosovo

a)	b)	c)	d)
EU normative act (Article, paragraph, sub-paragraph, etc.)	Provisions of normative act of Kosovo (Article, paragraph, sub-paragraph, etc.)	Compliance of EU legislation with Kosovo legislation (fully compliant, partially compliant, non-compliant or not applicable)	Comments on reasons for partial compliance or non-compliance and the period foreseen for achieving full compliance

Article 1 ***Scope*** 1. This Directive establishes specific provisions regarding the conduct of clinical trials, including multi-centre trials, on human subjects involving medicinal products as defined in Article 1 of Directive 65/65/EEC, in particular relating to the implementation of good clinical practice. This Directive does not apply to non-interventional trials.		Not compliant	Clinical trials will be regulated by law under article 84 paragraph 2 of the Health Law. end of 2015
2. Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.24** Good clinical practice-a set of internationally recognized ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.	Fully compliant	
3. The Commission shall adopt the principles relating to good clinical practice and detailed rules in line with those principles and shall, if necessary, revise those principles and detailed rules to take account of technical and scientific progress.		Not applicable	

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3). The principles and detailed rules shall be published by the Commission.			
4. All clinical trials, including bioavailability and bioequivalence studies, shall be designed, conducted and reported in accordance with the principles of good clinical practice.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
Article 2 ***Definitions*** For the purposes of this Directive the following definitions shall apply: (a) 'clinical trial': any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy; 2001L0020 — EN — 07.08.2009 — 002.001 — 5	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph1.25.** Clinical trial - any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medicinal product(s), or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. This includes clinical trials carried out in either one site or multiple sites.	Fully compliant	

(1) OJ L 184, 17.7.1999, p. 23. This includes clinical trials carried out in either one site or multiple sites, whether in one or more than one Member State;			
(b) 'multi-centre clinical trial': a clinical trial conducted according to a single protocol but at more than one site, and therefore by more than one investigator, in which the trial sites may be located in a single Member State, in a number of Member States and/or in Member States and third countries;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(c) 'non-interventional trial': a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(d) 'investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing**	Fully compliant	

authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form	**Practice for Medicinal Products. Article 2 pparagraph 1subparagraph 1.10** Investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form.		
(e) 'sponsor': an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial;	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.26.** Sponsor - an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.	Fully compliant	
(f) 'investigator': a doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

(g) 'investigator's brochure': a compilation of the clinical and nonclinical data on the investigational medicinal product or products which are relevant to the study of the product or products in human subjects;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(h) 'protocol': a document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(i) 'subject': an individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(j) 'informed consent': decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(k) 'ethics committee': an independent body in a Member State, consisting of healthcare	**Law on Medicinal Products and Medical Devices no.04/L-190**	Fully compliant	

professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent; 2001L0020 — EN — 07.08.2009 — 002.001 — 6	**Article 3 paragraph 1.27** Ethics Committee - an independent body, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of the facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.		
(l) 'inspection': the act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(m) 'adverse event': any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
(n) 'adverse reaction': all untoward and unintended responses to an	**Law on Medicinal Products and Medical Devices no.04/L-190**	Partiallycompliant	Will be fully compliant by the

investigational medicinal product related to any dose administered;	**Article 3 paragraph 1.21.** Adverse Reaction - a response to a medicinal product used in a therapeutical dosage which is noxious and unintended.		amendment of the law
(o) 'serious adverse event or serious adverse reaction': any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.22.** Serious Adverse Reaction - an adverse reaction which results in death; is life threatening; requires inpatient hospitalization or prolongation of existing 6 hospitalization; results in persistent or significant disability or incapacity; or is a congenital anomaly/birth defect.	Fully compliant	
(p) 'unexpected adverse reaction': an adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. investigator's brochure for an unauthorised investigational product or summary of product characteristics for an authorised product).		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
Article 3 ***Protection of clinical trial subjects*** 1. This Directive shall apply without prejudice to the national provisions on the protection of clinical trial subjects if they are		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

more comprehensive than the provisions of this Directive and consistent with the procedures and time-scales specified therein. Member States shall, insofar as they have not already done so, adopt detailed rules to protect from abuse individuals who are incapable of giving their informed consent.			
2. A clinical trial may be undertaken only if, in particular: (a) the foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A clinical trial may be initiated only if the Ethics Committee and/or the competent authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored; (b) the trial subject or, when the person is not able to give informed consent, his legal representative has had the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and has also been informed of his right to withdraw from the trial at any time;		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

(c) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with Directive 95/46/EC are safeguarded; (d) the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial; if the individual is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation; 2001L0020 — EN — 07.08.2009 — 002.001 — 7 (e) the subject may without any resulting detriment withdraw from the clinical trial at any time by revoking his informed consent; (f) provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor.			
3. The medical care given to, and medical decisions made on behalf of, subjects shall be the responsibility of an appropriately qualified doctor or, where appropriate, of a qualified dentist.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
4. The subject shall be provided with a contact point where he may obtain further information.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law.

			End of 2015
Article 4 ***Clinical trials on minors*** In addition to any other relevant restriction, a clinical trial on minors may be undertaken only if: (a) the informed consent of the parents or legal representative has been obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor; (b) the minor has received information according to its capacity of understanding, from staff with experience with minors, regarding the trial, the risks and the benefits; (c) the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to be withdrawn from the clinical trial at any time is considered by the investigator or where appropriate the principal investigator; (d) no incentives or financial inducements are given except compensation; (e) some direct benefit for the group of patients is obtained from the clinical trial and only where such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods; additionally, such research should either relate		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

directly to a clinical condition from which the minor concerned suffers or be of such a nature that it can only be carried out on minors; (f) the corresponding scientific guidelines of the Agency have been followed; (g) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress have to be specially defined and constantly monitored; (h) the Ethics Committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol; and (i) the interests of the patient always prevail over those of science and society.			
Article 5 ***Clinical trials on incapacitated adults not able to give informed legal consent*** In the case of other persons incapable of giving informed legal consent, all relevant requirements listed for persons capable of giving such consent shall apply. In addition to these requirements, inclusion in clinical trials of incapacitated adults who have not given or not refused informed consent before the onset of their		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

incapacity shall be allowed only if: 2001L0020 — EN — 07.08.2009 — 002.001 — 8 (a) the informed consent of the legal representative has been obtained; consent must represent the subject's presumed will and may be revoked at any time, without detriment to the subject; (b) the person not able to give informed legal consent has received information according to his/her capacity of understanding regarding the trial, the risks and the benefits; (c) the explicit wish of a subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator or where appropriate the principal investigator; (d) no incentives or financial inducements are given except compensation; (e) such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods and relates directly to a life-threatening or debilitating clinical condition from which the incapacitated adult concerned suffers; (f) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress shall be specially defined and constantly monitored;			

(g) the Ethics Committee, with expertise in the relevant disease and the patient population concerned or after taking advice in clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol; (h) the interests of the patient always prevail over those of science and society; and (i) there are grounds for expecting that administering the medicinal product to be tested will produce a benefit to the patient outweighing the risks or produce no risk at all.			
Article 6 ***Ethics Committee*** 1. For the purposes of implementation of the clinical trials, Member States shall take the measures necessary for establishment and operation of Ethics Committees. 2. The Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested.	**Law on Medicinal Products and Medical Devices no.04/L-190** **Article 3 paragraph 1.27** Ethics Committee - an independent body, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of the facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent.	Fully Compliant	
3. In preparing its opinion, the Ethics Committee shall consider,		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health

in particular: (a) the relevance of the clinical trial and the trial design; (b) whether the evaluation of the anticipated benefits and risks as required under Article 3(2)(a) is satisfactory and whether the conclusions are justified; (c) the protocol; (d) the suitability of the investigator and supporting staff; (e) the investigator's brochure; (f) the quality of the facilities; (g) the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent and the justification for the research on persons incapable of giving informed consent as regards the specific restrictions laid down in Article 3; 2001L0020 — EN — 07.08.2009 — 002.001 — 9 (h) provision for indemnity or compensation in the event of injury or death attributable to a clinical trial; (i) any insurance or indemnity to cover the liability of the investigator and sponsor; (j) the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects and the relevant aspects of any agreement between the sponsor and the site; (k) the arrangements for the recruitment of subjects.			Law. End of 2015
4. Notwithstanding the provisions of this Article, a Member State may decide that the competent		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health

authority it has designated for the purpose of Article 9 shall be responsible for the consideration of, and the giving of an opinion on, the matters referred to in paragraph 3(h), (i) and (j) of this Article. When a Member State avails itself of this provision, it shall notify the Commission, the other Member States and the Agency.			Law. End of 2015
5. The Ethics Committee shall have a maximum of 60 days from the date of receipt of a valid application to give its reasoned opinion to the applicant and the competent authority in the Member State concerned.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
6. Within the period of examination of the application for an opinion, the Ethics Committee may send a single request for information supplementary to that already supplied by the applicant. The period laid down in paragraph 5 shall be suspended until receipt of the supplementary information.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
7. No extension to the 60-day period referred to in paragraph 5 shall be permissible except in the case of trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms. In this case, an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy, there shall be no time limit to the authorisation period.			
Article 7 ***Single opinion*** For multi-centre clinical trials limited to the territory of a single Member State, Member States shall establish a procedure providing, notwithstanding the number of Ethics Committees, for the adoption of a single opinion for that Member State. In the case of multi-centre clinical trials carried out in more than one Member State simultaneously, a single opinion shall be given for each Member State concerned by the clinical trial.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
Article 8 ***Detailed guidance*** The Commission, in consultation with Member States and interested parties, shall draw up and publish detailed guidance on the application format and documentation to be submitted in an application for an ethics committee opinion, in particular regarding the information that is given to subjects, and on the		Not applicable	

appropriate safeguards for the protection of personal data.			
Article 9 ***Commencement of a clinical trial*** 1. Member States shall take the measures necessary to ensure that the procedure described in this Article is followed for commencement of a clinical trial. The sponsor may not start a clinical trial until the Ethics Committee has issued a favourable opinion and inasmuch as the competent authority of the Member State concerned has not informed the sponsor of any grounds for non-acceptance. The procedures to reach these decisions can be run in parallel or not, depending on the sponsor.		Not compliant	This issue will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
2. Before commencing any clinical trial, the sponsor shall be required to submit a valid request for authorisation to the competent authority of the Member State in which the sponsor plans to conduct the clinical trial.		Not compliant	This issue will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
3. If the competent authority of the Member State notifies the sponsor of grounds for non-acceptance, the sponsor may, on one occasion only, amend the content of the request referred to in paragraph 2 in order to take due account of the grounds given. If the sponsor fails to amend the request accordingly, the request shall be considered rejected and the clinical trial may		Not compliant	This issue will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

not commence.			
4. Consideration of a valid request for authorisation by the competent authority as stated in paragraph 2 shall be carried out as rapidly as possible and may not exceed 60 days. The Member States may lay down a shorter period than 60 days within their area of responsibility if that is in compliance with current practice. The competent authority can nevertheless notify the sponsor before the end of this period that it has no grounds for non-acceptance. No further extensions to the period referred to in the first subparagraph shall be permissible except in the case of trials involving the medicinal products listed in paragraph 6, for which an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy there shall be no time limit to the authorisation period		Not compliant	This issue will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
5. Without prejudice to paragraph 6, written authorisation may be required before the commencement of clinical trials for such trials on medicinal products which do not have a marketing authorisation		Not compliant	This issue will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

within the meaning of Directive 65/65/EEC and are referred to in Part A of the Annex to Regulation (EEC) No 2309/93, and other medicinal products with special characteristics, such as medicinal products the active ingredient or active ingredients of which is or are a biological product or biological products of human or animal origin, or contains biological components of human or animal origin, or the manufacturing of which requires such components.			
6. Written authorisation shall be required before commencing clinical trials involving medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing genetically modified organisms. No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity.		Not compliant	This issue will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
7. This authorisation shall be issued without prejudice to the application of Council Directives 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (1) and 2001L0020 — EN — 07.08.2009 — 002.001 — 11 (1) OJ L 117, 8.5.1990, p. 1. Directive as last amended by Directive 98/81/EC (OJ L 330, 5.12.1998, p. 13). 90/220/EEC of 23 April 1990 on		Not compliant	

the deliberate release into the environment of genetically modified organisms (1).			
8. In consultation with Member States, the Commission shall draw up and publish detailed guidance on: (a) the format and contents of the request referred to in paragraph 2 as well as the documentation to be submitted to support that request, on the quality and manufacture of the investigational medicinal product, any toxicological and pharmacological tests, the protocol and clinical information on the investigational medicinal product including the investigator's brochure; (b) the presentation and content of the proposed amendment referred to in point (a) of Article 10 on substantial amendments made to the protocol; (c) the declaration of the end of the clinical trial		Not applicable	
Article 10 ***Conduct of a clinical trial*** Amendments may be made to the conduct of a clinical trial following the procedure described hereinafter: (a) after the commencement of the clinical trial, the sponsor may make amendments to the protocol. If those amendments are substantial and are likely to have an impact on the safety of the trial subjects or to change the interpretation of the		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

scientific documents in support of the conduct of the trial, or if they are otherwise significant, the sponsor shall notify the competent authorities of the Member State or Member States concerned of the reasons for, and content of, these amendments and shall inform the ethics committee or committees concerned in accordance with Articles 6 and 9. On the basis of the details referred to in Article 6(3) and in accordance with Article 7, the Ethics Committee shall give an opinion within a maximum of 35 days of the date of receipt of the proposed amendment in good and due form. If this opinion is unfavourable, the sponsor may not implement the amendment to the protocol. If the opinion of the Ethics Committee is favourable and the competent authorities of the Member States have raised no grounds for non-acceptance of the abovementioned substantial amendments, the sponsor shall proceed to conduct the clinical trial following the amended protocol. Should this not be the case, the sponsor shall either take account of the grounds for nonacceptance and adapt the proposed amendment to the protocol accordingly or withdraw the proposed amendment; (b) without prejudice to point (a), in the light of the circumstances, notably the occurrence of any new event relating to the conduct of the trial			

or the development of the investigational medicinal product where that new event is likely to affect the safety of the subjects, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against any immediate hazard. The sponsor shall forthwith inform the competent authorities of those new events and the measures taken and shall ensure that the Ethics Committee is notified at the same time; (c) within 90 days of the end of a clinical trial the sponsor shall notify the competent authorities of the Member State or Member States concerned and the Ethics Committee that the clinical trial has 2001L0020 — EN — 07.08.2009 — 002.001 — 12 (1) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72). ended. If the trial has to be terminated early, this period shall be reduced to 15 days and the reasons clearly explained.			
Article 11 ***Exchange of information*** 1. Member States in whose territory the clinical trial takes place shall enter in a European database, accessible only to the competent authorities of the Member States, the Agency and the Commission: (a) extracts from the request for authorisation		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. This article will be transposed after becoming member state.

referred to in Article 9(2); (b) any amendments made to the request, as provided for in Article 9(3); (c) any amendments made to the protocol, as provided for in point a of Article 10; (d) the favourable opinion of the Ethics Committee; (e) the declaration of the end of the clinical trial; and (f) a reference to the inspections carried out on conformity with good clinical practice.			
2. At the substantiated request of any Member State, the Agency or the Commission, the competent authority to which the request for authorisation was submitted shall supply all further information concerning the clinical trial in question other than the data already in the European database.		Not applicable	
3. In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in this European database, which it operates with the assistance of the Agency, as well as the methods for electronic communication of the data. The detailed guidance thus drawn up shall ensure that the confidentiality of the data is strictly observed. 4. By way of derogation from paragraph 1, the Agency shall make public part of the information on paediatric clinical trials entered in the European		Not applicable	

database in accordance with the provisions of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (1).			
Article 12 ***Suspension of the trial or infringements*** 1. Where a Member State has objective grounds for considering that the conditions in the request for authorisation referred to in Article 9(2) are no longer met or has information raising doubts about the safety or scientific validity of the clinical trial, it may suspend or prohibit the clinical trial and shall notify the sponsor thereof. Before the Member State reaches its decision it shall, except where there is imminent risk, ask the sponsor and/or the investigator for their opinion, to be delivered within one week. In this case, the competent authority concerned shall forthwith inform the other competent authorities, the Ethics Committee concerned, the Agency and the Commission of its decision to suspend or prohibit the trial and of the reasons for the decision. 20011.0020 — EN — 07.08.2009 — 002.001 — 13 (1) OJ L 378, 27.12.2006, p. 1.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
2. Where a competent authority has objective grounds for considering that the sponsor or the investigator or any other person		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health

involved in the conduct of the trial no longer meets the obligations laid down, it shall forthwith inform him thereof, indicating the course of action which he must take to remedy this state of affairs. The competent authority concerned shall forthwith inform the Ethics Committee, the other competent authorities and the Commission of this course of action.			Law. End of 2015
Article 13 **Manufacture and import of investigational medicinal products** 1. Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products is subject to the holding of authorisation. The Commission shall lay down the minimum requirements which the applicant and, subsequently, the holder of the authorisation must meet in order to obtain the authorisation. Those measures, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3).	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 7** **Compliance with manufacturing authorization** 1.The manufacturer of medicinal products shall manufacture only products or investigational medicinal products for which they hold valid manufacturing authorization.	Partially compliant	Manufacture is fully compliant while import is going to be regulated with another administrative instruction End of 2015Second part of this paragraph is not applicable.

2. Member States shall take all appropriate measures to ensure that the holder of the authorisation referred to in paragraph 1 has permanently and continuously at his disposal the services of at least one qualified person who, in accordance with the conditions laid down in Article 23 of the second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (1), is responsible in particular for carrying out the duties specified in paragraph 3 of this Article.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 9** **Personel** 1. Key personnel of the manufacturer consists of a person responsible for manufacture, a person responsible for quality control and a person responsible for batch release of medicinal products. **Article 10 paragraph 1** The person responsible for the batch release as per article 3 paragraph 1.39 and article 10 paragraph 5 and 6 of the Law must have proficient knowledge, obtained through the course of studies, of following subjects : Experimental physics , General and inorganic chemistry , Organic chemistry, Analytical chemistry, Pharmaceutical chemistry, including analysis of medicinal products, General and applied biochemistry (medical), Physiology, Microbiology, Pharmacology, Pharmaceutical technology , Toxicology, Pharmacognosy (study of the composition and effects of the natural active substances of plant and	Partially compliant	For import is going to be regulated with another administrative instruction End of 2015

	animal origin). **Law on Medicinal Products and Medical Devices no. 04/L-190** **Article 3 paragraph (1.39)** **Qualified Person of manufacturer or importer** - employed personresponsible for quality assurance. He possess diploma, certificate or other evidence of official qualification, gained after the completion of university studies in duration of at least four (4) year, of theoretical studies and practical studies in one of the following scientific fields: pharmacy, human medicine, chemistry, biology, chemical-pharmaceutical technology.		
3. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 21 of Directive 75/319/EEC, without prejudice to his relationship with the manufacturer or importer, is responsible, in the context of the procedures referred to in Article 25 of the said Directive, for ensuring: (a) in the case of investigational medicinal products manufactured in the Member State concerned, that each batch of medicinal products has been manufactured	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 10 paragraph 5 subparagraph 5.1** 5.KMA shall take all appropriate measures to ensure that the qualified person referred to in Article 10, without prejudice to his relationship with the holder of the manufacturing	Partially compliant	This is a requirement which can be transposed also before the accession. How and when this will be regulated?

and checked in compliance with the requirements of Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (2), the product specification file and the information notified pursuant to Article 9(2) of this Directive;	authorization, is responsible, in the context of the procedures referred to in Article 10 paragraph 5 and 6, for securing: 5.1.That each batch of medicinal products has been manufactured and checked in compliance with the laws in force in and in accordance with the requirements of the marketing authorization,		
(b) in the case of investigational medicinal products manufactured in a third country, that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/356/EEC, in accordance with the product specification file, and that each production batch has been checked in accordance with the information notified pursuant to Article 9(2) of this Directive;	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 10 paragraph 5 subparagraph 5.2** 5.2. In the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in Kosovo, that each production batch has undergone in Republic of Kosovo full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.	Partially compliant	End of 2015

(c) in the case of an investigational medicinal product which is a comparator product from a third country, and which has a marketing authorisation, where the documentation certifying that 20011.0020 — EN — 07.08.2009 — 002.001 — 14 (1) OJ L 147, 9.6.1975, p. 13. Directive as last amended by Council Directive 93/39/EC (OJ L 214, 24.8.1993, p. 22). (2) OJ L 193, 17.7.1991, p. 30. each production batch has been manufactured in conditions at least equivalent to the standards of good manufacturing practice referred to above cannot be obtained, that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the information notified pursuant to Article 9(2) of this Directive. Detailed guidance on the elements to be taken into account when evaluating products with the object of releasing batches within the Community shall be drawn up pursuant to the good manufacturing practice guidelines, and in particular Annex 13 to the said guidelines. Such guidelines will be adopted in accordance with the procedure referred to in Article 21(2) of this Directive and published in accordance with Article 19a of Directive 75/319/EEC. Insofar as the provisions laid down in (a), (b) or (c) are complied with,	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products. Article 10 paragraph 5 subparagraph 5.2** 5.2. In the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in Kosovo, that each production batch has undergone in Republic of Kosovo full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.	Partially compliant	End of 2015

investigational medicinal products shall not have to undergo any further checks if they are imported into another Member State together with batch release certification signed by the qualified person.			
4. In all cases, the qualified person must certify in a register or equivalent document that each production batch satisfies the provisions of this Article. The said register or equivalent document shall be kept up to date as operations are carried out and shall remain at the disposal of the agents of the competent authority for the period specified in the provisions of the Member States concerned. This period shall in any event be not less than five years.	**Draft Administrative Instruction (Health) NO. XX/2015 On laying down the requirements of Good Manufacturing Practice, Issuing Manufacturing Authorization and Certificate of Good Manufacturing Practice for Medicinal Products.** **Article 10 paragraph 7** 7.In all cases and particularly where the medicinal products are released for sale, the qualified person must certify in a register or equivalent document provided for that purpose, that each production batch satisfies the provisions of this Article; the said register or equivalent document must be kept up to date as operations are carried out and must remain at the disposal of gmp auditors KMA for the period specified by competent authority and in any event for at least five years.	Fully compliant	
5. Any person engaging in activities as the qualified person referred to in Article 21 of Directive 75/319/EEC as regards investigational medicinal products at the time when this Directive is applied in the Member State where that person is, but without complying with the conditions laid		Not applicable	

down in Articles 23 and 24 of that Directive, shall be authorised to continue those activities in the Member State concerned.			
Article 14 ***Labelling*** The particulars to appear in at least the official language(s) of the Member State on the outer packaging of investigational medicinal products or, where there is no outer packaging, on the immediate packaging, shall be published by the Commission in the good manufacturing practice guidelines on investigational medicinal products adopted in accordance with Article 19a of Directive 75/319/EEC. In addition, these guidelines shall lay down adapted provisions relating to labelling for investigational medicinal products intended for clinical trials with the following characteristics: — the planning of the trial does not require particular manufacturing or packaging processes; — the trial is conducted with medicinal products with, in the Member States concerned by the study, a marketing authorisation within the meaning of Directive 65/65/EEC, manufactured or		Not applicable	

imported in accordance with the provisions of Directive 75/319/EEC; — the patients participating in the trial have the same characteristics as those covered by the indication specified in the abovementioned authorisation.			
Article 15 ***Verification of compliance of investigational medicinal products with good clinical and manufacturing practice*** 1. To verify compliance with the provisions on good clinical and manufacturing practice, Member States shall appoint inspectors to inspect the sites concerned by any clinical trial conducted, particularly the trial site or sites, the manufacturing site of the investigational medicinal product, any laboratory used for analyses in the clinical trial and/or the sponsor's premises. The inspections shall be conducted by the competent authority of the Member State concerned, which shall inform the Agency; they shall be carried out on behalf of the Community and the results shall be recognised by all the other Member States. These inspections shall be coordinated by the Agency, within the framework of its powers as provided for in Regulation (EEC) No 2309/93. A Member State may request		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

assistance from another Member State in this matter.			
2. Following inspection, an inspection report shall be prepared. It must be made available to the sponsor while safeguarding confidential aspects. It may be made available to the other Member States, to the Ethics Committee and to the Agency, at their reasoned request.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
3. At the request of the Agency, within the framework of its powers as provided for in Regulation (EEC) No 2309/93, or of one of the Member States concerned, and following consultation with the Member States concerned, the Commission may request a new inspection should verification of compliance with this Directive reveal differences between Member States.		Not applicable	
4. Subject to any arrangements which may have been concluded between the Community and third countries, the Commission, upon receipt of a reasoned request from a Member State or on its own initiative, or a Member State may propose that the trial site and/or the sponsor's premises and/or the manufacturer established in a third country undergo an inspection. The inspection shall be carried out by duly qualified Community inspectors.		Not applicable	

5. The detailed guidelines on the documentation relating to the clinical trial, which shall constitute the master file on the trial, archiving, qualifications of inspectors and inspection procedures to verify compliance of the clinical trial in question with this Directive shall be adopted and revised in accordance with the procedure referred to in Article 21(2).		Not applicable	
Article 16 ***Notification of adverse events*** 1. The investigator shall report all serious adverse events immediately to the sponsor except for those that the protocol or investigator's brochure identifies as not requiring immediate reporting. The immediate report shall be followed by detailed, written reports. The immediate and follow-up reports shall identify subjects by unique code numbers assigned to the latter.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
2. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations shall be reported to the sponsor according to the reporting requirements and within the time periods specified in the protocol. 3. For reported deaths of a subject, the investigator shall supply the sponsor and the Ethics Committee with any additional information requested. 4. The sponsor shall		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

keep detailed records of all adverse events which are reported to him by the investigator or investigators. These 2001L0020 — EN — 07.08.2009 — 002.001 — 16 records shall be submitted to the Member States in whose territory the clinical trial is being conducted, if they so request.			
Article 17 **Notification of serious adverse reactions** 1. (a) The sponsor shall ensure that all relevant information about suspected serious unexpected adverse reactions that are fatal or life-threatening is recorded and reported as soon as possible to the competent authorities in all the Member States concerned, and to the Ethics Committee, and in any case no later than seven days after knowledge by the sponsor of such a case, and that relevant follow-up information is subsequently communicated within an additional eight days. (b) All other suspected serious unexpected adverse reactions shall be reported to the competent authorities concerned and to the Ethics Committee concerned as soon as possible but within a maximum of fifteen days of first knowledge by the sponsor. (c) Each Member State shall ensure that all suspected unexpected serious adverse reactions to an investigational medicinal product which are		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015

brought to its attention are recorded. (d) The sponsor shall also inform all investigators.			
2. Once a year throughout the clinical trial, the sponsor shall provide the Member States in whose territory the clinical trial is being conducted and the Ethics Committee with a listing of all suspected serious adverse reactions which have occurred over this period and a report of the subjects' safety.		Not compliant	It will be regulated by law under article 84 paragraph 2 of the Health Law. End of 2015
3. (a) Each Member State shall see to it that all suspected unexpected serious adverse reactions to an investigational medicinal product which are brought to its attention are immediately entered in a European database to which, in accordance with Article 11(1), only the competent authorities of the Member States, the Agency and the Commission shall have access. (b) The Agency shall make the information notified by the sponsor available to the competent authorities of the Member States.		Not applicable	
Article 18 ***Guidance concerning reports*** The Commission, in consultation with the Agency, Member States and interested parties, shall draw up and publish detailed guidance on the collection, verification and presentation of adverse		Not applicable	

event/reaction reports, together with decoding procedures for unexpected serious adverse reactions			
Article 19 ***General provisions*** This Directive is without prejudice to the civil and criminal liability of the sponsor or the investigator. To this end, the sponsor or a legal representative of the sponsor must be established in the Community. Unless Member States have established precise conditions for exceptional circumstances, investigational medicinal products and, as the case may be, the devices used for their administration shall be made available free of charge by the sponsor. 2001L0020 — EN — 07.08.2009 — 002.001 — 17 The Member States shall inform the Commission of such conditions.		Not applicable	
Article 20 The Commission shall adapt this Directive to take account of scientific and technical progress. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3)		Not applicable	
Article 21		Not applicable	

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, referred to in Article 121(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (1).			
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.		Not applicable	
3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.		Not applicable	
Article 22 *Application* 1. Member States shall adopt and publish before 1 May 2003 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. They shall apply these provisions at the latest with effect from 1 May 2004. When Member States adopt these provisions, they shall contain		Not applicable	

a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.			
2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive.		Not applicable	
Article 23 Entry into force This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.		Not applicable	
Article 24 Addressees This Directive is addressed to the Member States.		Not applicable	

Republika e Kosovës
RepublikaKosova - Republic of Kosovo
Qeveria - Vlada - Government

Ministria e Shëndetësisë
Ministarstvo Zdravstva – Ministry of Health

1. Title of the normative act: Draft Administrative Instruction (Health) NO. XX/2015ON LAYING DOWN THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICE, ISSUING MANUFACTURING AUTHORIZATION AND CERTIFICATE OF GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS.
2. Proposing body: Ministry of Health
3. Table: 22.06.2015
4. List of relevant EU legislation (full title of the act and number) with which the normative act of the Republic of Kosovo is compliant - COMMISSION DIRECTIVE 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use,(consolidated version) - DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (consolidated version) - DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version)
5. The level of compliance (fully compliant, partially compliant, not compliant or not applicable) of the normative act with EU legislation: Partially compliant

a)	b)	c)	d)
Provisions of the normative act of Kosovo (Article, paragraph, sub-paragraph, etc.)	The EU normative act (Article, paragraph, sub-paragraph, etc.)	Compliance of Kosovo legislation with EU legislation (fully compliant, partially compliant, non-compliant or not applicable)	Comments on reasons for partial compliance or non-compliance and the period foreseen for achieving full compliance
Article 1 This Administrative Instructions lays down the principles and requirements of good manufacturing practice for medicinal products and investigational medicinalproducts, whose manufacture requires authorization, in Republic of Kosovo, and the requirements for issuing manufacturing authorizations and certificates of good manufacturing practice.	2003/94/EC *Article 1* Scope This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use whose manufacture requires the authorization referred to in Article 40 of Directive 2001/83/EC and in respect of investigational medicinal products for human use whose manufacture requires the authorisation referred to in Article 13 of Directive 2001/20/EC.	Fully compliant	
Article 2 ***Definitions*** 1.For the purposes of this administrative instruction shall be applieddefinitions as in Law on Medical Products and Devices 04 / L-190 including the following definitions:	**Directive 2003/94/EC** ***Article 2*** ***Definitions*** For the purposes of this Directive, the following definitions shall apply: 1. 'medicinal product' means any product as defined in Article 1(2) of Directive 2001/83/EC; 2. 'investigational medicinal product' means any product as defined in Article 2(d) of Directive	**Partially compliant**	Some definitions are already laid down in Kosovo law Nr. 04/L -190 on Medicinal products

1.1.Pharnaceutical quality assurance means the total sum of organized activities and procedures with the objective of ensuring that medicinal products and investigational medicinal products are of the quality required for their intended use. 1.2.Blinding means the deliberate disguising of the identity of an investigational medicinal product in accordance with the instructions of the sponsor. 1.3.Unblinding of the identity of investigational medicinal product means the disclosure of the identity of a blinded product.	2001/20/EC; 3. 'manufacturer' means any person engaged in activities for which the authorisation referred to in Article 40(1) and (3) of Directive 2001/83/EC or the authorisation referred to in Article 13(1) of Directive 2001/20/EC is required; 4. 'qualified person' means the person referred to in Article 48 of Directive 2001/83/EC or in Article 13(2) of Directive 2001/20/EC; 5. 'pharmaceutical quality assurance' means the total sum of the organised arrangements made with the object of ensuring that medicinal products or investigational medicinal products are of the quality required for their intended use; 6. 'good manufacturing practice' means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use; 7. 'blinding' means the deliberate disguising of the identity of an investigational medicinal product in accordance with the instructions of the sponsor;		

1.4.Individual parts of manufacturing of medicinal products include all operations from the supply of materials and products, the manufacture of medicinal products in the narrow sense, immediate packaging, outer packaging, quality control, batch release, import, storage and delivery to wholesale distributors. The manufacturing of medicinal products in the narrow sense is divided according to manufacturing procedures and pharmaceutical forms and includes all manufacturing procedures from receiving starting materials, pharmaceutical and technological forming to packaging of medicinal products. Quality control is divided according to types of conducted tests and includes physical and chemical, biological and microbiological tests that may include microbiological testing of non- sterile and sterile products. 1.5. Certificate of good manufacturing practice is a certificate with limited validity term which represents final evaluation of compliance of a manufacturing process or its parts with the requirements of good manufacturing practice. 1.6. Manufacturing site means a defined area on the address where an integral manufacturing process or its individual parts are carried out. 1.7. Documentation on the manufacturing	8. 'unblinding' means the disclosure of the identity of a blinded product.		

site means a document developed by the manufacturer of the medicinal product which includes information on the quality management policy and all activities carried out on that manufacturing site. 1.8.Cross-contamination means contamination of starting materials or products with other materials or products. 1.9. Batch release means inspection of all relevant documentation with the objective of establishing the compliance of a batch with the marketing authorisation for a medicinal product and requirements of good manufacturing practice, and providing a final assessment of the batch compliance. 1.10.Investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form. 1.11.KMA- Kosovo Medicines Agency for Medicinale Products and Medical Devices.			

1.12.QCL-Official Laboratory for the Control of the Quality of Medicinal Products and Medical Devices. 1.13.GMP-Good Manufacturing Practice			
Manufacture of medicinal products *Article 3* Medicinal products and / or investigational medicinal products in Republic of Kosovo, may be manufactured by legal or natural person established in Republic of Kosovo on the basis and in accordance with manufacturing authorization and must fulfill requirements form article 3 paragraph 1.29 and article 10 of Law Nr. 04/L -190 on Medicinal Products and Medical Devices (hereinafter the Law).		Not applicable	
Article 4 The manufacturer of the medicinal products is required to use active substances manufactured in compliance with requirements of good manufacturing practice which are conform to the European Pharmacopoeia		Not applicable	
Article 5 ***Conformity with Good Manufacturing Practice*** The manufacturer of medicinal products shall ensure that all manufacturing operations for medicinal products and / or investigational medicinal products are carried out in	**Directive 2003/94/EC** *Article 4* **Conformity with good manufacturing practice** 1. The manufacturer shall ensure that manufacturing operations are carried out in accordance with good	Fully compliant	

compliance with good manufacturing practice and the manufacturing authorization; this applies also to medicinal products intended for export only.	manufacturing practice and with the manufacturing authorisation. This provision shall also apply to medicinal products intended only for export.2. For medicinal products and investigational medicinal products imported from third countries, the importer shall ensure that the products have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down by the Community. In addition, an importer of medicinal products shall ensure that such products have been manufactured by manufacturers duly authorised to do so. An importer of investigational medicinal products shall ensure that such products have been manufacturedby a manufacturer notified to the competent authorities and accepted by them for that purpose.		
Article 6 ***Conformity with marketing authorization*** 1.The manufacturer shall ensure that all manufacturing operations for medicinal products subject to a marketing authorization are carried out in accordance with the information provided in the application for marketing authorization as accepted by the competent authorities. In the case of	**Directive 2003/94/EC** ***Article 5*** **Compliance with marketing authorization** 1. The manufacturer shall ensure that all manufacturing operations for medicinal products subject to a marketing authorisation are carried out in accordance with	Fully compliant	

investigational medicinal products, the manufacturer shall ensure that all manufacturing operations are carried out in accordance with the information provided by the sponsor to the competent authority in Republic of Kosovo. 2.The manufacturer shall regularly review his manufacturing methods and quality control procedures in the light of their adjustment to scientific and technical progress. 3.In case there is a necessity for modification of the dossier of the medicinal product, based on which marketing authorization or clinical trials authorization has been granted, the authorization holder shall submit the application for modification to the competent authority.	the information provided in the application for marketing authorisation as accepted by the competent authorities. In the case of investigational medicinal products, the manufacturer shall ensure that all manufacturing operations are carried out in accordance with the information provided by the sponsor pursuant to Article 9(2) of Directive 2001/20/EC as accepted by the competent authorities. 2. The manufacturer shall regularly review his manufacturing methods in the light of scientific and technical progress and the development of the investigational medicinal product. If a variation to the marketing authorisation dossier or an amendment to the request referred to in Article 9(2) of Directive 2001/20/EC is necessary, the application for modification shall be submitted to the competent authorities.		
Article 7 ***Compliance with manufacturing authorization*** 1.The manufacturer of medicinal products shall manufacture only medicinal products or investigational medicinal products for which they hold valid manufacturing authorization. 2.During issuance or modification of	**Directive 2001/20/EC** **Article 13** Manufacture and import of investigational medicinal products ▼M2 1. Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products	Partially compliant	Manufacture is fully compliant while import is going to be regulated with another administrative instruction

manufacturing authorization, manufacturer of medicinal products and/or investigational medicinal products must ensure conformity of all manufacturing operations with the information submitted to the KMA in Republic of Kosovo or competent authority of other countries.	is subject to the holding of authorisation. The Commission shall lay down the minimum requirements which the applicant and, subsequently, the holder of the authorisation must meet in order to obtain the authorisation. Those measures, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(3). **Directive 2001/83/EC** **Article 40** **MANUFACTURE AND IMPORTATION** 1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to the holding of an authorization. This manufacturing authorization shall be required nothwithstanding that the medicinal products manufactured are intended for export. 2. The authorization referred to in paragraph 1 shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation. However, such authorization shall not be required for preparation,		

	dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorized in the Member States to carry out such processes. ▼B 3. Authorization referred to in paragraph 1 shall also be required for imports coming from third countries into a Member State; this Title and Article 118 shall have corresponding application to such imports as they have to manufacture.		
Article 8 ***Pharmaceutical quality assurance system*** The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different departments.	**Directive 2003/94/EC** ***Article 6*** **Quality assurance system** The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different departments	Fully compliant	
Article 9 ***Personnel*** 1.At each manufacturing site, the manufacturer shall have a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance objective. 2.Key personnel of the manufacturer consists of a person responsible for manufacture, a	**Directive 2003/94/EC** ***Article 7*** **Personnel** 1. At each manufacturing site, the manufacturer shall have a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance	Fully compliant	

person responsible for quality control and a person responsible for batch release of medicinal products. 3.The person responsible for manufacturing and the person responsible for quality control shall act independently of each other. 4.The duties of the managerial and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures. 5.The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice, and, where appropriate, the particular requirements for the manufacture of investigational medicinal products. 6.Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.	objective. 2. The duties of the managerial and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures. 3. The staff referred to in paragraph 2 shall be given sufficient authority to discharge their responsibility correctly. 4. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice, and, where appropriate, the particular requirements for the manufacture of investigational medicinal products. 5. Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel. Article 13 paragraph 1 B		

	▼B 2. Member States shall take all appropriate measures to ensure that the holder of the authorisation referred to in paragraph 1 has permanently and continuously at his disposal the services of at least one qualified person who, in accordance with the conditions laid down in Article 23 of the second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (1), is responsible in particular for carrying out the duties specified in paragraph 3 of this Article.		
Article 10 1. The person responsible for the batch release as per article 3 paragraph 1.39 and article 10 paragraph 5 and 6 of the Law must have proficient knowledge, obtained through the course of studies, of following subjects: 1.1. Experimental physics, 1.2. General and inorganic chemistry , 1.3. Organic chemistry, 1.4. Analytical chemistry, 1.5. Pharmaceutical chemistry, including analysis of medicinal products, 1.6. General and applied biochemistry (medical), 1.7. Physiology,	**Directive 2001/83/EC** ***Article 49*** 1. Member States shall ensure that the qualified person referred to in Article 48 fulfils the conditions of qualification set out in paragraphs 2 and 3. 2. A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the	Fully compliant	

1.8. Microbiology, 1.9. Pharmacology, 1.10. Pharmaceutical technology, 1.11. Toxicology, 1.12. Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin). 2. If the study programme does not include proficiency in some of the subjects referred in paragraph 1 of this article, the qualified person shall provide evidence of adequate proficiency in subjects involved. 3. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products. The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years. 4. The person responsible for batch release of medicinal products may also be the person responsible for quality control or for manufacturing of medicinal products.	following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology. However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level. Where two university courses or two courses recognized by the State as equivalent co-exist in a Member State and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognized equivalent shall be considered to fulfil the condition of duration referred to in the second subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognized as equivalent by the State in question. The course shall include theoretical and practical study bearing upon at least the following basic subjects:		

	— Experimental physics — General and inorganic chemistry — Organic chemistry — Analytical chemistry — Pharmaceutical chemistry, including analysis of medicinal products — General and applied biochemistry (medical) — Physiology — Microbiology — Pharmacology — Pharmaceutical technology — Toxicology — Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin). Studies in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 51. In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first subparagraph do not fulfil the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved. 3. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized to manufacture medicinal products,		

	in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products. The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.		
5.KMA shall take all appropriate measures to ensure that the qualified person referred to in Article 10, without prejudice to his	**Directive 2001/83/EC** ***Article 51*** 1. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 48, without prejudice to his relationship with the holder of the manufacturing authorization, is responsible, in the context of the	Partially compliant	Part c of directive 2001/20/EC Article 13 has to be defined with another Anotheradministrative and the rest is included in paragraph 5 a and b of our Administrative instruction .

relationship with the holder of the manufacturing authorization, is responsible, in the context of the procedures referred to in Article 10 paragraph 8 for securing: a. that each batch of medicinal products and/or investigational medicinal product has been manufactured and checked in compliance with the laws in force in and in accordance with the requirements of the marketing authorization; b. in the case of medicinal products and/or investigational medicinal products coming from third countries, irrespective of whether the product has been manufactured in Kosovo, that each production batch has undergone in Republic of Kosovo full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation. 6.The qualified person referred to in Article 10 shall in the case of medicinal products intended to be placed on the market , ensure that the safety features have been affixed on the packaging.	procedures referred to in Article 52, for securing: (a) in the case of medicinal products manufactured within the Member States concerned, that each batch of medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorization; (b) in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Community, that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation. The qualified person referred to in Article 48 shall in the case of medicinal products intended to be placed on the market in the Union, ensure that the safety features referred to in point (o) of Article 54 have been affixed on the packaging. 3. In all cases and particularly		

7.In all cases and particularly where the medicinal products are released for sale, the qualified person must certify in a register or equivalent document provided for that purpose, that each production batch satisfies the provisions of this Article; the said register or equivalent document must be kept up to date as operations are carried out and must remain at the disposal of the agents of the competent authority for the period specified by competent authority and in any event for at least five years.	where the medicinal products are released for sale, the qualified person must certify in a register or equivalent document provided for that purpose, that each production batch satisfies the provisions of this Article; the said register or equivalent document must be kept up to date as operations are carried out and must remain at the disposal of the agents of the competent authority for the period specified in the provisions of the Member State concerned and in any event for at least five years. **Directive 2001/20/EC** **Article 13** 3. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 21 of Directive 75/319/EEC, without prejudice to his relationship with the manufacturer or importer, is responsible, in the context of the procedures referred to in Article 25 of the said Directive, for ensuring: (a) in the case of investigational medicinal products manufactured in the Member State concerned, that each batch of medicinal products has been manufactured and checked in compliance with the requirements of Commission Directive 91/356/EEC of 13 June		

	1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (2), the product specification file and the information notified pursuant to Article 9(2) of this Directive; (b) in the case of investigational medicinal products manufactured in a third country, that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/356/EEC, in accordance with the product specification file, and that each production batch has been checked in accordance with the information notified pursuant to Article 9(2) of this Directive; (c) in the case of an investigational medicinal product which is a comparator product from a third country, and which has a marketing authorisation, where the documentation certifying that ▼B 2001L0020 — EN — 07.08.2009 — 002.001 — 14 (1) OJ L 147, 9.6.1975, p. 13. Directive as last amended by Council Directive 93/39/EC (OJ L 214, 24.8.1993, p. 22). (2) OJ L 193, 17.7.1991, p. 30. each production batch has been manufactured in conditions at least equivalent to the standards of good		

	manufacturing practice referred to above cannot be obtained, that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the information notified pursuant to Article 9(2) of this Directive. Detailed guidance on the elements to be taken into account when evaluating products with the object of releasing batches within the Community shall be drawn up pursuant to the good manufacturing practice guidelines, and in particular Annex 13 to the said guidelines. Such guidelines will be adopted in accordance with the procedure referred to in Article 21(2) of this Directive and published in accordance with Article 19a of Directive 75/319/EEC. Insofar as the provisions laid down in (a), (b) or (c) are complied with, investigational medicinal products shall not have to undergo any further checks if they are imported into another Member State together with batch release certification signed by the qualified person. 4. In all cases, the qualified person must certify in a register or equivalent document that each production batch satisfies the provisions of this Article. The said register or equivalent document shall be kept up to date as		

8.Competent authority shall ensure that the duties of qualified persons referred to in Article 10 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct. 9.Competent authority may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against him for failure to fulfill his obligations.	operations are carried out and shall remain at the disposal of the agents of the competent authority for the period specified in the provisions of the Member States concerned. This period shall in any event be not less than five years. **Directive 2001/83/EC** ***Article 52*** Member States shall ensure that the duties of qualified persons referred to in Article 48 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct. Member States may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against him for failure to fulfil his obligations.		
Article 11 ***Premises and Equipment*** **1.**Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations.	**Directivew 2003/94/EC** ***Article 8*** **Premises and equipment** 1. Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended	Fully compliant	

2. Premises and manufacturing equipment shall be laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product. 3. Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.	operations. 2. Premises and manufacturing equipment shall be laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product. 3. Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.		
Article 12 ***Documentation*** 1.The manufacturer shall establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of each batch and the changes introduced during the	**Directive 2003/94/EC** ***Article 9*** **Documentation** 1. The manufacturer shall establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the	Fully compliant	

development of an investigational medicinal product to be traced. 2.For a medicinal product, the batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates or at least five years after the certification referred to in Article 10 paragraph 7, whichever is the longer period. 3.When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the competent authorities at their request. The electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.	manufacture of each batch and the changes introduced during the development of an investigational medicinal product to be traced. For a medicinal product, the batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates or at least five years after the certification referred to in Article 51(3) of Directive 2001/83/EC, whichever is the longer period. For an investigational medicinal product, the batch documentation shall be retained for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used. The sponsor or marketing authorization holder, if different, shall be responsible for ensuring that records are retained as required for marketing authorisation in accordance with the Annex I to Directive 2001/83/EC, if required for a subsequent marketing authorisation. 2. When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be		

	made readily available in legible form and shall be provided to the competent authorities at their request. The electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.		
Article 13 ***Production*** 1.The different production operations shall be carried out in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the inprocess controls. All process deviations and product defects shall be documented and thoroughly investigated. 2.Appropriate technical or organizational measures shall be taken to avoid cross contamination and mix-ups. In the case of investigational medicinal products, particular attention shall be paid to the handling of products during and after any blinding operation. 3.For medicinal products, any new manufacture or important modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly re-	**Directive 2003/94/EC** ***Article 10*** **Production** 1. The different production operations shall be carried out in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the in process controls. All process deviations and product defects shall be documented and thoroughly investigated. 2. Appropriate technical or organisational measures shall be taken to avoid cross contamination and mix-ups. In the case of investigational medicinal products, particular attention shall be paid to the handling of products during and after any blinding operation. 3. For medicinal products, any new manufacture or important	Fully compliant	

validated. 4.For investigational medicinal products, the manufacturing process shall be validated in its entirety in so far as is appropriate, taking into account the stage of product development. At least the critical process steps, such as sterilization, shall be validated. All steps in the design and development of the manufacturing process shall be fully documented. 5.The manufacturing processes used in the manufacture of immunological products should be properly validated in order to attain batch-to-batch consistency.	modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly re-validated. 4. For investigational medicinal products, the manufacturing process shall be validated in its entirety in so far as is appropriate, taking into account the stage of product development. At least the critical process steps, such as sterilisation, shall be validated. All steps in the design and development of the manufacturing process shall be fully documented. **Directive 2001/83/EC** **Article 111** 2. Member States shall take all appropriate steps to ensure that the manufacturing processes used in the manufacture of immunological products are properly validated and attain batch-to-batch consistency.		
Article 14 ***Quality control*** 1.The manufacturer shall establish and	**Directive 2003/94/EC** ***Article 11*** **Quality control** 1. The manufacturer shall establish	**Fully compliant**	

maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production. That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and packaging materials and the testing of intermediate and finished products 2.Contract laboratories may be used if authorized in accordance with Article 15 of this administrative instruction and if approved in manufacturing authorization procedure. 3.For investigational medicinal products, the sponsor shall ensure that the contract laboratory complies with the requirements of the KMA 4.During the final control of the finished product before its release for sale or distribution or for use in clinical trials, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack. 5.Samples of each batch of finished medicinal product shall be retained for at least one year after the expiry date.	and maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production.That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and packaging materials and the testing of intermediate and finished products. 2. For medicinal products, including those imported from third countries, contract laboratories may be used if authorized in accordance with Article 12 of this Directive and point (b) of Article 20 of Directive 2001/83/EC.For investigational medicinal products, the sponsor shall ensure that the contract laboratory complies with the content of the request referred to in Article 9(2) of Directive 2001/20/EC, asaccepted by the competent authority. When the products are imported from third countries, analytical control shall not be mandatory. 3. During the final control of the finished product before its release for sale or distribution or for use in clinical trials, thequality control system shall take into account, in addition to analytical results,		

6.For an investigational medicinal product, sufficient samples of each batch of bulk formulated product and of key packaging components used for each finished product batch shall be retained for at least two years after completion or formal discontinuation of the last clinical trial in which the batch was used, whichever period is the longer. 7.Samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained for at least two years after the release of product. That period may be shortened if the period of stability of the material, as indicated in the relevant specification, is shorter. All those samples shall be maintained at the disposal of the gmp auditor KMA. Other conditions may be defined, by agreement with the KMA, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities, or when their storage could raise special problems.	essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of theproduct to its specifications, including the final finished pack. 4. Samples of each batch of finished medicinal product shall be retained for at least one year after the expiry date. For an investigational medicinal product, sufficient samples of each batch of bulk formulated product and of key packaging components used for each finished product batch shall be retained for at least two years after completion or formaldiscontinuation of the last clinical trial in which the batch was used, whichever period is the longer.Unless a longer period is required under the law of the Member State of manufacture, samples of starting materials, other thansolvents, gases or water, used in the manufacturing processshall be retained for at least two years after the release ofproduct. That period may be shortened if the period of stability of the material, as indicated in the relevant specification, is shorter. All those samples shall be maintained at the disposal of the competent authorities.Other conditions may be defined, by		

	agreement with thecompetent authority, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities, or when their storage could raise specialproblems.		
Article 15 ***Work contracted out*** 1.Any manufacturing operation or operation linked thereto which is carried out under contract shall be the subject of a written contract. 2.The contract shall clearly define the responsibilities of each party and shall define, in particular, the observance of good manufacturing practice to be followed by the contract acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities. 3.The contract-acceptor shall not subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver. 4.The contract-acceptor shall comply with the principles and guidelines of good manufacturing practice and shall submit to audits carried out by gmp auditors KMA.	**Directive 2003/94/EC** ***Article 12*** **Work contracted out** 1. Any manufacturing operation or operation linked thereto which is carried out under contract shall be the subject of a written contract. 2. The contract shall clearly define the responsibilities ofeach party and shall define, in particular, the observance ofgood manufacturing practice to be followed by the contract acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities. 3. The contract-acceptor shall not subcontract any of thework entrusted to him under the contract without writtenauthorisation from the contract-giver. 4. The contract-acceptor shall comply with the principlesand guidelines of good manufacturing practice and shall submit to inspections carried out by the competent authorities pursuant to	Fully compliant	

	Article 111 of Directive 2001/83/EC and Article 15 of Directive 2001/20/EC.		
Article 16 ***Complaints, product recall and emergency unblinding*** 1.Manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and at any time, medicinal products in the distribution network. Any complaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall inform the KMA of any defect that could result in a recall or abnormal restriction on supply and, in so far as is possible, indicate the countries of destination.Any recall shall be made in accordance with the KMA regulations. 2.In the case of investigational medicinal products, the manufacturer shall, in cooperation with the sponsor, implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time investigational medicinal products which have already entered the distribution network. The manufacturer shall record and investigate any complaint concerning a defect and shall inform the competent authority of any defect that could result in a recall or abnormal restriction on supply. In the case of investigational medicinal products, all trial sites shall be identified and, in so far as is possible, the countries of destination shall be	**Directive 2003/94/EC** ***Article 13*** **Complaints, product recall and emergency unblinding** 1. In the case of medicinal products, the manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and atany time, medicinal products in the distribution network. Anycomplaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall inform thecompetent authority of any defect that could result in a recall or abnormal restriction on supply and, in so far as is possible, indicate the countries of destination. Any recall shall be made in accordance with the requirements referred to in Article 123 of Directive 2001/83/EC. 2. In the case of investigational medicinal products, the manufacturer shall, in cooperation with the sponsor, implementa system for recording and reviewing complaints together with an effective system for recalling	Fully compliant	

indicated. In the case of an investigational medicinal product for which a marketing authorization has been issued, the manufacturer of the investigational medicinal product shall, in cooperation with the sponsor, inform the marketing authorization holder of any defect that could be related to the authorized medicinal product. 3.The sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 2. The sponsor shall ensure that the procedure discloses the identity	promptly and at any time investigational medicinal products which have already entered the distribution network. The manufacturer shall record and investigate any complaint concerning a defect and shall inform the competent authority of any defect that could result in a recall or abnormal restriction on supply. In the case of investigational medicinal products, all trial sites shall be identified and, in so far as is possible, the countries of destination shall be indicated. In the case of an investigational medicinal product for which amarketing authorisation has been issued, the manufacturer of the investigational medicinal product shall, in cooperation with the sponsor, inform the marketing authorisation holder of any defect that could be related to the authorised medicinalproduct. 3. The sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 2. The sponsor shall ensure that the procedure discloses the identity of the blinded product only in so far as is necessary.		

Self-inspection ***Article 17*** The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures. Records shall be maintained of such self-inspections and any corrective action subsequently taken.	**Directive 2003/94/EC** ***Article 14*** **Self-inspection** The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor theimplementation and respect of good manufacturing practice and to propose any necessary corrective measures. Recordsshall be maintained of such self-inspections and any corrective action subsequently taken.	Fully compliant	
Labelling ***Article 18*** In the case of an investigational medicinal product, labelling shall be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the investigational medicinal product.	**Directive 2003/94/EC** ***Article 15*** **Labelling** In the case of an investigational medicinal product, labelling shall be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the investigational medicinal product.	Fully compliant	
Requirements and guidelines of good manufacturing practice ***Article 19*** In addition to provisions laid down in the		Not applicable	

Law and this administrative instruction, manufacture of medicinal products is governed by the requirements and guidelines of good manufacturing practice for medicinal products and by specifics concerning individual procedures and forms of medicinal products " Good Manufacturing Practices, medicinal products for human and veterinary use", including all amendments, and they are available on the Eudralex websit			
Article 20 **Issuing of manufacturing authorization** 1. For the purpose of issuing manufacturing authorization, natural or legal person established in Republic of Kosovo shall submit: 1.1. application to KMA 1.2. Specification of the medicinal products and pharmaceutical forms which are to be manufactured 1.3. Manufacturing site particulars documenting suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements. 1.4. A written statement by the applicant declaring that he shall enable the person responsible for batch release to carry out his activities independently and ensure all requisite resources. 1.5. A written statement by the applicant that he shall carry out the manufacturing activities in	**Directive 2001/83/EC** ***Article 41*** In order to obtain the manufacturing authorization, the applicant shall meet at least the following requirements: (a) specify the medicinal products and pharmaceutical forms which are to be manufactured or imported and also the place where they are to be manufactured and/or controlled; (b) have at his disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements which the Member State concerned lays down as regards both manufacture and control and the storage of medicinal products, in accordance with Article 20; (c) have at his disposal the services	Fully compliant	

compliance with good manufacturing practice. 1.6. A written statement by the applicant that for manufacture of medicinal products , only active substances which are produced in line with good manufacturing practice, will be used. 1.7. A written statement by the applicant declaring that he shall manufacture only medicinal products for which he holds a valid manufacturing authorization. 1.8. Proof of payment as per administrative instruction nr. 01/2014 KMA.	of at least one qualified person within the meaning of Article 48. The applicant shall provide particulars in support of the above in his application.		
Article 21 ***Kma Gmp Audits*** 1.KMA shall ensure that that the legal requirement governing medicinal products are complied with, by means of audits by KMA gmp auditors. 2.Audits can be unannounced and where appropriate, by asking QCL or a designated laboratory to carry out tests on samples. 3.Manufacturers located in Republic of Kosova and in other countries shall be subject to repeated audits.	**Directive 2001/83/EC** **Article 3** Inspections 1. By means of the repeated inspections referred to in Article 111(1) of Directive 2001/83/EC and by means of the inspections referred to in Article 15(1) of Directive 2001/20/ EC, the Member States shall ensure that manufacturers respect the principles and guidelines of good manufacturing practice laid down by this Directive. Member States shall also take into account the compilation, published by the Commission, of Community	Fully compliant	

4.By specific request of the manufacturers KMA may carry out audits of starting material manufacturers. 5.For interpretation of the principles and guidelines of good manufacturing practice , KMA shall take into account the detailed guidelines refferred to in article 19 of this administrative instruction.	procedures on inspections and exchange of information. 2. For the interpretation of the principles and guidelines of good manufacturing practice, the manufacturers and the competent authorities shall take into account the detailed guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC, published by the Commission in the 'Guide to good manufacturing practice for medicinal products and for investigational medicinal products'.		
Article 22 1.For issuing manufacturing authorization KMA will conduct audits of the regularity of the application and KMA gmp auditor shall give his opinion on compliance with good manufacturing practice. 2.For the purpose of determining the compliance with good manufacturing practice requirements, KMA gmp auditor can be joined by commission appointed by KMA, which may include experts from individual fields 3.When determining the compliance with good manufacturing practice requirements , a record shall be compiled presenting factual state and signed by KMA gmp auditor, members of the commission and representative of the applicant.	**Directive 2001/83/EC** *Article 42* 1. The competent authority of the Member State shall issue the manufacturing authorization only after having made sure of the accuracy of the particulars supplied pursuant to Article 41, by means of an inquiry carried out by its agents.	Fully compliant	

Article 23 1.Within 30 days of the date of the audit of good manufacturing practice, the KMA gmp auditor shall compile a report on the fulfilment of requirements of good manufacturing practice and submit it to the applicant. 2.In the event shortcomings are identified during audit referred to in paragraph 1 of this Article, the applicant is obliged to submit a written explanation on the established shortcomings to the KMA gmp auditor within 30 days of the audit. 3.The KMA gmp auditor shall give his written opinion on the fulfilment of the requirements of good manufacturing practice for the activity of manufacturing medicinal products on the basis of the audit report, and in the event shortcomings are identified, on the basis of the written statement of the applicant. 4.Manufacturing authorization will be granted, if requirements are met, not later than 90 days from request submission. 5.If additional data is required by KMA gmp auditors application of the time-limits referred to in Article 23 paragraph 4 and 24 paragraph 2, shall be suspended until the additional data required have been supplied.	**Directive 2001/83/EC** ***Article 43*** The Member States shall take all appropriate measures to ensure that the time taken for the procedure for granting the manufacturing authorization does not exceed 90 days from the day on which the competent authority receives the application. *Article 44* If the holder of the manufacturing authorization requests a change in any of the particulars referred to in points (a) and (b) of the first paragraph of Article 41, the time taken for the procedure relating to this request shall not exceed 30 days. In exceptional cases this period of time may be extended to	Not aplicable Fully compliant	

	90 days. *Article 45* **▼B** The competent authority of the Member State may require from the applicant further information concerning the particulars supplied pursuant to Article 41 and concerning the qualified person referred to in Article 48; where the competent authority concerned exercises this right, application of the time-limits referred to in Article 43 and 44 shall be suspended until the additional data required have been supplied.		
Article 24 **Temporary manufacturing authorization** 1.If during the procedure for the issuance of manufacturing authorisation it is ascertained that the applicant does not fully meet all the prescribed requirements of good manufacturing practice, KMA may issue a temporary manufacturing authorisation and set the deadlines for the elimination of identified shortcomings. 2 The authorisation referred to in paragraph 1 of this article shall cease to be valid upon the expiry of the deadline set for the elimination of identified shortcomings, if such shortcomings have not been eliminated within	**Directive 2001/83/EC** **Article 42** 2. In order to ensure that the requirements referred to in Article 41 are complied with, authorization may be made conditional on the carrying out of certain obligations imposed either when authorization is granted or at a later date.	Fully compliant	

the specified deadline.			
Article 25 ***Change approval*** 1.The manufacturer of medicinal products shall submit to the KMA a request for the approval of any change in documentation, or in the data and documents based on which the manufacturing authorisation was granted. 2.In the procedure of the change approval referred to in paragraph 1 of this Article, the KMA gmp auditors shall give they opinion on the compliance with the requirements of good manufacturing practice if the change affects the fulfilment of the requirements of good manufacturing practice. The Auditors shall give they opinion in 30 days from submission of the request, in exceptional cases not more than 90 days. 3.The applicant shall enclose the documentation on the change to the written application for change approval referred to in paragraph 1 of this Article, confirmation of the payment of administrative fee and of the costs of procedure. 4.The provisions of Articles 22 and 23 of this administrative instruction shall adequately apply to the procedure for change approval, where the audit of good manufacturing practice is conducted. 5.If an approved change does not require any data amendment in the manufacturing authorisation, the KMA shall approve the		Not applicable	

change by means of a written notification.			
Article 26 **Certificate of good manufacturing practice** 1.The KMA audit by gmp auditors shall issue a certificate of good manufacturing practice (hereinafter: the certificate) within 90 days after the audit of good manufacturing practice and at the request of the manufacturer. 2.The application for the issuance of the certificate may also be submitted by the manufacturer from the third country through his representative in the Republic of Kosovo. 3.The certificate shall be issued if requirements of good manufacturing practice have been observed as established during the manufacturing authorisation procedure or audit conducted by the KMA gmp auditors.	**Directive 2001/83/EC** **Article 111** 5. Within 90 days of an inspection as referred to in paragraph 1, a certificate of good manufacturing practice or good distribution practices shall, when applicable, be issued to the inspected entity if the outcome of the inspection shows that it complies with the principles and guidelines of good manufacturing practice or good distribution practices as provided for by Union legislation. If inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a certificate shall be drawn up.	Partially compliant	Distribution is to be regulated by another another administrative instruction
Article 27 The certificate shall be issued for the manufacturing site, manufacturing parts, manufacturing processes carried out and pharmaceutical forms manufactured at the production site concerned, with mention of the date of audit.		Not applicable	
Article 28 1.The certificate testifies to the fulfilment of		Not applicable	

the requirements of good manufacturing practice for the manufacturing site at the time of audit ,and to the conformity with good manufacturing practice for the period of three years following the day of audit. 2.The period of validity may be extended or reduced on the basis of the risk management applied by the Agency audit			
Article 29 If during audit supervision it is established that the holder of manufacturing authorisation has failed to carry out his activities in conformity with good manufacturing practice, the audit from gmp KMA auditors may revoke the certificate.		Not applicable	
Article 30 **Application forms and guidelines** 1. Applications and guidelines which are part of this Administrative instruction will be updated from KMA and can be accessed through web page of KMA. 2. List of MA Guidelines are: 2.1. Part I - Basic Requirements for Medicinal Products 2.1.1. Chapter 1 Pharmaceutical Quality System 2.1.2. Chapter 2 Personnel 2.1.3. Chapter 3 Premise and Equipment	Article 46 (f) (f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use as starting materials only active substances, which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials. This point shall also be applicable to certain excipients, the list of which as well as the specific conditions of application shall be established by a Directive adopted by the Commission in accordance with the procedure referred to in Article 121(2).	Fully compliant	

2.1.3.1. transitional arrangement for toxicological evaluation on page 1 of Chapter 3 2.1.3.2. Previous 2.1.4. Chapter 4 Documentation (January 2011) 2.1.5. Chapter 5 Production 2.1.5.1. See transitional arrangement for toxicological evaluation on pages 1-2 of Chapter 5 2.1.5.2. Previous 2.1.6. Chapter 6 Quality Control 2.1.7. Chapter 7 on Outsourced activities 2.1.8. Chapter 8 Complaints and Product Recall 2.1.9. Chapter 9 Self Inspection 2.2. Part II - Basic Requirements for Active Substances used as Starting Materials 2.2.1. Basic requirements for active substances used as starting materials 2.3. Part III - GMP related documents 2.3.1. Site Master File			

2.3.2. Q9 Quality Risk Management 2.3.3. Q10 Note for Guidance on Pharmaceutical Quality System 2.3.4. MRA Batch Certificate 2.3.5. Template for the 'written confirmation' for active substances exported to the European Union for medicinal products for human use 2.3.6. Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities. 2.3.7. Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use. A risk assessment as set out in these guidelines should be carried out for excipients for authorised medicinal products for human use by 21 March 2016.			

2.4. Annexes 2.4.1. Annex 1 - Manufacture of Sterile Medicinal Products 2.4.2. Annex 2 - Manufacture of Biological active substances and Medicinal Products for Human Use 2.4.3. Annex 3 - Manufacture of Radiopharmaceuticals 2.4.4. Annex 4 - Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products 2.4.5. Annex 5 - Manufacture of Immunological Veterinary Medicinal Products 2.4.6. Annex 6 - Manufacture of Medicinal Gases 2.4.7. Annex 7 - Manufacture of Herbal Medicinal Products 2.4.8. Annex 8 - Sampling of Starting and Packaging Materials 2.4.9. Annex 9 - Manufacture of Liquids, Creams and Ointments 2.4.10. Annex 10 - Manufacture of Pressurised Metered Dose Aerosol Preparations for Inhalation 2.4.11. Annex 11 -			

ComputerisedSystems 2.4.12. Annex 12 - Use of Ionising Radiation in the Manufacture of Medicinal Products 2.4.13. Annex 13 - Manufacture of Investigational Medicinal Products 2.4.14. Annex 14 - Manufacture of Products derived from Human Blood or Human Plasma 2.4.15. Annex 15 - Qualification and validation 2.4.16. Annex 16 - Certification by a Qualified person and Batch Release 2.4.17. Annex 17 - Parametric Release 2.4.18. X 2.4.19. Annex 19 - Reference and Retention Samples 2.5. Glossary 2.5.1. Glossary 2.6. Other documents related to GMP 2.6.1. Compilation of Community Procedures on Inspections and Exchange of Information updated to include new EU formats and procedures 2.6.2. A revised version of the "Guidelines on Good			

Distribution Practice of Medicinal Products for Human Use Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use.			
Article 30 ***Entry in force*** This Administrative Instuction enteries into force seven days after it\s signing by Minister of Health. This Administrative Instruction abrogates previous administrative instruction (M H) no.16/2013			