Njoftim për tërheqjen e serive **G09087, K09548, G10759, H08873, M04154, dhe K09549** të barit Rheumesser 3 ml ampulë

Përmes njoftimit të pranuar nga Bartësi i Autorizimit për Marketing (BAM) "GL Pharma - Austria", Agjencia e Kosovës për Produkte dhe Pajisje Medicinale (AKPPM) është njoftuar për tërheqjen nga tregu të serive **G09087, K09548, G10759, H08873, M04154, dhe K09549,** të produktit medicinal **Rheumesser ampula**.

Tërheqja nga tregu është iniciuar për arsye parandaluese për shkak të dyshimit për një defekt në cilësinë e produktit medicinal, i cili lidhet me praninë e mundshme të grimcave të huaja në tretësirë.

Në Republikën e Kosovës janë importuar seritë **G09087 dhe K09548** të produktit medicinal **Rheumesser ampula**.

Pacientët të cilët tash më veq e kanë blerë ampulën nga ndonjë seri e lertëcekur i rekomandojmë ta kthejn në barnatoren në të cilën e kanë blerë ose të kontaktojn përfaqësuesin e prodhuesit përmes e-mailit: E-mail: regulatory@provitpharmaceuticals-al.com

Këshillë për pacientët

Pacientët që janë duke përdorur ose kanë përdorur produktin **Rheumesser 3 ml ampulë**, me ndonjë numër serie **të lartëpërmedur**, dhe që kanë vërejtur ndonjë efekt të padëshiruar ose shqetësim pas përdorimit të produktit, duhet të kontaktojnë mjekun, farmacistin ose profesionistin tjetër shëndetësor.

Këshillë për profesionistët shëndetësorë

Të gjithë profesionistët shëndetësorë që kanë pranuar ndonjë raportim lidhur me shfaqjen e ndonjë efekti të dyshuar anësor pas përdorimit të **Rheumesser 3 ml ampulë**, me ndonjë nga numër serie **të lartëpërmedur**, inkurajohen që rastet t'i raportojnë te personi lokal përgjegjës për Farmakovigjilencë, i autorizuar nga Bartësi i Autorizimit për Marketing "GL Pharma - Austria", në adresën:
E-mail: miniverehajdarifoniqi@gmail.com ose minapha@hotmail.com

Rastet e dyshuara për reaksione/efekte anësore mund të raportohen gjithashtu drejtpërdrejt në AKPPM, përmes formularit standard **CIOMS** për raportimin e reaksioneve të dyshuara anësore, i publikuar në uebfaqen e AKPPM-së, ose në adresën:
E-mail: info.akppm@rks-gov.net

AKPPM i këshillon profesionistët shëndetësorë që, gjatë raportimit, të përfshijnë sa më shumë informacione relevante lidhur me pacientin, produktin medicinal, numrin e serisë dhe reaksionin/efektin e dyshuar anësor.

Agjencia e Kosovës për Produkte dhe Pajisje Medicinale (AKPPM)

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Institute Surveillance
Enforcement, Medicine Shortages & Quality Defects
(EVEQ)

Defective Product Report Template for Marketing

For marketing authorisation holders to report a quality defect relating to a medicinal product
Pursuant to Section 75q of the Austrian Medicinal Products Act (*AMG*), as amended, and/or Section 42 of the Austrian Veterinary Medicinal Products Act (*TAMG*), as amended.

Contact:	Institute Surveillance Tel.: +43 (0)50555-36411, -36466, -36476, -36418

1 Origin of the Report

Information required	**Information provided**
1.1 Name of the reporting individual	Gerlinde Muster
1.2 Organisation	G.L. Pharma GmbH
1.3 Address	Schlossplatz 1 8502 Lannach
1.4 Telephone	00 43 1 / 485 35 05 – 139 00 43 664 42 83 011
1.5 Fax.	---
1.6 Email address	gerlinde.muster@gl-pharma.at
1.7 Date and time of the report	30.07.2026

Defective Product Report Template for Marketing

2 Product Details / Scope of the Defect

Remark: A separate form is to be completed for each medicinal product

Information required	Information provided
2.1 Name of the medicinal product affected	Rheumesser 3ml ampoules
2.2 Marketing authorisation number	17.397
2.3 Name and address of the MAH or importer[1]	G.L. Pharma GmbH Schlossplatz 1, 8502 Lannach, Austria
2.4 Galenic form	Parenteral ampoule
2.5 API(s) (INN)	Ketophenylbutazone Salicylamide-O-acetic acid Lidocaine Dexamethasone Cyanocobalamin
2.6 Name and address of the manufacturer (end product and finished product)	G.L. Pharma GmbH, Vienna site (1160) Arnethgasse 3, 1160 Vienna, Austria Gansterergasse 9-13, 1160 Vienna, Austria
2.7 Foreign manufacturer (end and finished product)	Which foreign regulatory authority is competent for the foreign manufacturer? Not applicable When was this body informed about the defect? Not applicable What evaluation of the defect is available from the competent regulatory authority? Not applicable

[1] In the case of parallel imports

Defective Product Report Template for Marketing

2.8 Batches affected (batch number / date of manufacture / dosage strength / expiry date / batch size / number of packs)	Set up a separate list if required Refer to separate list
2.9 Bulk goods	Are the relevant batches listed under Section 2.7 from a bulk batch from which other end and/or finished products have been manufactured? ☐ Yes, ☒ No If yes, which and intended for which country?
2.10 Distribution of the batches affected (domestic and/or international / customers supplied / distribution period / inventory level)	Set up a separate list if required To be submitted at a later date
2.11 Impact on medicine shortages (domestic and/or foreign)	Are medicine shortages possible? ☒ Yes ☐ No If Yes, which markets/territories are affected? Austria, Albania, Kosovo
2.12 Marketing data (what is the market share of the relevant medicinal product in Austria?)	Under 40% market share: ☐ 40% market share and higher: ☒
2.13 Other medicinal products affected (name / marketing authorisation number)[2]	None

[2] If other medicinal products are affected, please complete a defective product report for each.

Defective Product Report Template for Marketing

3 Nature of the Defect

Information required	Information provided
3.1 Who identified the defect:	☐ Patient ☐ User ☐ Hospital ☐ Pharmacy ☒ Manufacturer ☐
3.2 Detailed description of the quality defect / problem	Particles in the ampoule solution Batch G09087 (distributed in Albania and Kosovo): Particles detected during visible inspection as per Ph. Eur.; Batches G10759, K09548, K09549, H08873, M04154 (distributed in Austria and Albania): Particles not detected during visible inspection as per Ph. Eur. but visible during APC background lighting inspection;
3.3 Is the defect related to an adverse reaction? If yes, please describe and add the in-house identification number of the PV incident	☐ Yes ☒ No
3.4 Are there indications or suspicions of a risk to public health (adverse reaction or lack of efficacy)?	A risk to patients on the grounds of parenteral use cannot be excluded
3.5 Has a risk assessment been performed?	☒ Yes (please provide details in the annex) ☐ No If No, when will this be provided? To be included in the investigation report
3.6 Has an investigation report, including corrective and preventative action, already been prepared?	☒ Yes (please provide details in the annex) ☐ No If No, when will this be provided? Deadline cannot yet be defined
3.7 Provision of the defective sample or a photo as a basis for processing and illustrating the defect identified. Provided by means of: Photo Send sample of defect by post to **BASG** **Institut Begutachtung & Analytik /** **Abteilung CPAA**	☒ ☐

Defective Product Report Template for Marketing

Spargelfeldstraße 191, 1220 Wien A sample of the defect cannot be provided: Explanation:	☐

Defective Product Report Template for Marketing

4 Action Undertaken and Planned

Information required	Information provided
4.1 Name and address of public authorities already informed	
4.2 Action already undertaken	Root cause analysis and deviation report including a risk assessment as a draft Status of affected batches changed to rejected
4.3 Is it planned to initiate a batch recall or withdraw the product? If Yes, please enclose/attach a draft of the recall notification. What is planned with the packs received back as a result of the recall?	☒ Yes ☐ No These will be destroyed once the root cause analysis has been completed
4.4 In the case of a recall: Classification of the defect (I, II or III)[3] with explanation	I: A risk to patients on the grounds of parenteral use cannot be excluded
4.5 Other planned or proposed action	Further root cause analysis at G.L. Pharma and ampoule supplier
4.6 Other relevant details	Answers missing on the form cannot currently be provided and will be made available as soon as possible.

5 List of attachments to this report

Annex 1: Batches affected; Annex 2: Photos Particles

Venue, date Vienna, 30.07.2026

Signature and name in block capitals: Dr. Gerlinde Muster

6 Submission of the signed report by means of

Email to: am-qualitaetsmangel@basg.gv.at

Fax: International: +43 50555-36408
From Austria: 050555-36408

[3] *cf.* Compilation of Union Procedures on Inspections and Exchange of Information, www.ema.europa.eu