KMAG18

PHARMACOVIGILANCE AND PERIODIC SAFETY UPDATE REPORT (PSUR) REQUIREMENTS

1. The marketing authorisation holder shall be required to maintain detailed records of all suspected adverse reactions occurring in Kosovo and other countries where a marketing authorisation for the medicinal product exists. Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report to the competent authority.

2. The marketing authorisation holder shall be required to record and report all suspected serious adverse reactions occurring in Kosovo which are brought to his attention by a health care professional immediately to the competent authority and in no case later than 15 days following the receipt of the information.

3. The marketing authorisation holder shall be required to record and report all other suspected serious adverse reactions occurring in Kosovo which meet the reporting criteria as set out by the European Agency for Evaluation of Medicines (EMEA) of which he can reasonably be expected to have knowledge immediately to the competent authority and in no case later than 15 days following the receipt of the information.

4. The marketing authorisation holder shall ensure that all suspected serious and unexpected adverse reactions occurring on the territory of another country and brought to his attention by a health care professional are reported immediately to the competent authority in accordance with the reporting criteria set out by the EMEA.

5. Marketing authorisation holders shall use internationally agreed medical terminology for the reporting of adverse reactions.

6. Other reporting requirements shall be set out in accordance with guidelines published in Volume IX of the Rules governing medicinal products in the European Community.

7. The marketing authorisation holder shall provide a Periodic Safety Update Report (PSUR) on the authorised medicinal product as follows:

i. for an original medicinal product – either immediately on request or periodically as follows – six monthly for the first two years after authorisation, annually for the subsequent two years, at the time of renewal and thereafter at three yearly intervals;

ii. for a generic or other defined medicinal product – either immediately upon request or periodically as follows – annually for five years and three yearly thereafter.

7. The PSUR is requested to be presented in the following format:

PSUR REPORT

COVER PAGE

- Marketing authorisation number.
- Trade and INN name of the medicinal product
- Period covered by the report
- Date of first authorisation of the medicinal product
- Date of the Report

CONTENTS

1.1 Introduction – brief information about the medicinal product for the period concerned (including references to recent peer reviewed journal articles and media articles where the product was mentioned, including the reference context);
1.2 Cumulative review of worldwide marketing authorisation status of the product: information about regulatory decisions, conditions and limitations of marketing authorisation, lack of approval by regulatory authorities, withdrawal by the company of an authorisation application submission etc;
1.3 Update of regulatory actions taken for safety reasons during the period covered by the report;
1.4 Changes to manufacturer Core Safety Information made during the period covered by the report;
1.5 An estimate of the number of patients exposed and method used to derive this estimate;
1.6 Presentation of individual case histories and analysis;
1.7 Safety data from non-clinical, clinical and epidemiological studies;
1.8 Other information – lack of efficacy (ineffectiveness) reports and important late-breaking information;
1.9 Overall safety evaluation;
1.10 Conclusion including a scientific evaluation of the benefit and risks afforded by the medicinal product and indicating new safety issues and justifying any action recommended or initiated.

1.) The Holder of the Medicinal Product License shall prepare and submit the report regarding the active substance(s) in the product for all pharmaceutical forms and strengths. If necessary the pharmaceutical form, strength, route of administration or indications shall be differentiated.

2.) The report shall contain at least the following informations:

a.) The data about the license status of the medicinal product outside the FRY, including the informations about granting or suspending the license, different name of the product and different indications approved by foreign competent authorities

b.) The review about measures taken abroad for a safety reasons, the date(s) and reasons for safety measures

c.) The data about the product consumption in order to assume the range of product usage

d.) The data about serious and unexpected adverse effects registered during the clinical trials, from spontaneous reporting of the health professionals or published in scientific literature

e.) The new inforamations about the safety of the product from the additional toxicological, pre-clinical or clinical studies and the informations about the new ongoing trials and the aims of those trials

f.) The overall assessment of the safety of the product including critical judgement, assessment of the ratio risk-benefit, evaluation the post-marketing experience if they are in line with Summary of Product Characteristic and if it is necessary for a variations. Especially shall be mentioned:

- not yet registered toxic effects
- increasing of the frequency known adverse effects
- interactions with others medicinal products
- overdose and its treatment
- misuse of the product and possible addiction
- experience with use the product in pregnancy and lactation
- effects during long term use
- safety of the product used by the risk group of the patients

g.) Additional informations available after the date of the report

h.) In the case of the veterinary medicinal products, the overview of the new informations about the residues in organism and products of animal origin and new established protection time – limits.