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Procedure for providing safety information about medicinal products, for calculating the fees charged for the safety and quality monitoring of medicinal products and for the payment of such fees[1]

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Amended by the following acts

Passed	Published	Entry into force
06.05.2013	RT I, 10.05.2013, 1	13.05.2013

This regulation is enacted in accordance with section 78[5](14) of the Medicinal Products Act.

§ 1. General provisions

This regulation establishes the procedure for providing safety information about medicinal products, for calculating the fees charged for the safety and quality monitoring of medicinal products and for the payment of such fees.

§ 2. Reporting an adverse reaction to a medicinal product

(1) The physician, dentist, veterinarian, nurse, midwife or user of a medicinal product informs the State Agency of Medicines of an adverse reaction to a medicinal product, using the electronic form of the adverse reaction report or a paper report.

(2) The electronic form of the adverse reaction report is available on the webpage of the State Agency of Medicines and the paper form is available at the State Agency of Medicines and pharmacies. If necessary, the assistant pharmacist or pharmacist assists the user of the medicinal product in completing the report on an adverse reaction to a medicinal product and in submitting it to the State Agency of Medicines.

(3) When reporting an adverse reaction, at least the following information must be given:
1) the particulars of the person who gave the information (name, e-mail address, telephone, position and institution); if the information is given by a user of the medicinal product assisted by an assistant pharmacist or pharmacist, the particulars of the user of the medicinal product and of the assistant pharmacist or pharmacist;
2) the particulars of the user of the medicinal product (initials, sex, birth date or age), in the case of a veterinary medicinal product, the identification information of the treated animal(s) or animal group(s), sex and age of the animal(s);
3) the medicinal product associated with the adverse reaction (name, active substance, batch number, strength, pharmaceutical form);
4) a description of the adverse reaction(s).

(4) The State Agency of Medicines or the marketing authorisation holder submits information regarding a serious adverse reaction to the Eudravigilance database within 15 days and regarding a non-serious adverse reaction within 90 days from the date of receiving the information. In the case of a veterinary medicinal product, the marketing authorisation holder submits information regarding a serious adverse reaction to the State Agency of Medicines or the Eudravigilance database within 15 days from receiving the information.

(5) In the case of a medicinal product whose marketing authorisation is issued in Estonia, the holder of the marketing authorisation submits information to the Eudravigilance database in regard to the adverse reactions detected in Estonia, other member states and third countries, reported by a user of the medicinal product or a

person authorised to prescribe the medicinal product, or discovered during a safety survey following the grant of the marketing authorisation, or published in medical research publications, if the indicated source is not included in the list monitored by the European Medicines Agency. In the case of a veterinary medicinal product, the holder of the marketing authorisation submits information to the State Agency of Medicines in regard to adverse reactions detected in Estonia and to the Eudravigilance database in regard to adverse reactions detected in third countries, reported by a user of the medicinal product or a person authorised to prescribe the medicinal product, or discovered during a safety survey following the grant of the marketing authorisation, or published in medical research publications, if the source indicated is not in the list monitored by the European Medicines Agency.

§ 3. Periodic safety update reports

(1) Periodic safety update reports must be prepared according to Directive No. 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67–128) or Directive No. 2001/82/EC of the European Parliament and of the Council on the Community code relating veterinary medicinal products (OJ L 311, 28.11.2001, pp. 1–66) or Commission Implementing Regulation (EU) No. 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ L 159, 19.06.2012, pp. 5–25) and according to good pharmacovigilance practice.
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

(2) The frequency of submitting periodic safety update reports is specified in the terms of the marketing authorisation of the medicinal product. Generally, the marketing authorisation holder submits a safety update report from the date of receiving the marketing authorisation as follows:
1) every six months until the commencement of the marketing of a medicinal product;
2) every six months during the first two years after the commencement of marketing;
3) once a year during the two years following the period provided in point 2;
4) once every three years after the period provided in point 3;
5) without delay, if the State Agency of Medicines demands it.

(3) The terms specified in subsection 2 of this section may be counted from the date determined by the pharmacovigilance risk evaluation committee of the European Medicines Agency, from the time of the granting of the first marketing authorisation for the same active substance or combination of active substances in a member state of the European Economic Area, or from the time of the granting of the marketing authorisation in a third country on the basis of a written authorisation of the European Medicines Agency.

(4) The periodic safety update report must cover the time period starting from the end of the previous reporting period and it must be submitted, taking into consideration the terms specified in subsections 2 and 3 of this section, as follows:
1) within 70 days as of the end of the collection of data if the periodical safety update report covers a period of up to 12 months;
2) within 90 days as of the end of the collection of data if the periodical safety update report covers a period exceeding 12 months;
[RT I, 10.05.2013, 1 – entry into force 13.05.2013]

§ 4. Communication of information to persons authorised to prescribe the medicinal products in the case of risk

(1) When the ratio of benefits and risks connected to the use of the medicinal product has changed in negative direction The information that is to be communicated to persons authorised to prescribe the medicinal product in the case of risk includes information provided to such persons to ensure safe and effective use of the medicinal product.

(2) Persons authorised to prescribe the medicinal product may be informed of a negative change in the ratio of benefits and risks connected to the use of the medicinal product by the marketing authorisation holder or the State Agency of Medicines. If the information concerns a medicinal product of more than one marketing authorisation holder, the relevant marketing authorisation holders must prepare the information together.

(3) Before communicating the information to persons authorised to prescribe the medicinal product, the marketing authorisation holder must obtain the approval of the State Agency of Medicines for the information and for the plan for communicating the information.

(4) The plan for communicating the information must include the following:
1) the schedule of distributing the information;
2) the list of the target group;
3) a description of the method of distributing the information;
4) the contact details of the (Estonian-speaking) representative of the marketing authorisation holder in Estonia;
5) if necessary, additional materials to be distributed to persons authorised to prescribe the medicinal product.

(5) The information must include the following text:

“The State Agency of Medicines or the marketing authorisation holder must be informed of all adverse reactions that have occurred.
State Agency of Medicines: use the form for reporting an adverse reaction to a medicinal product (available at the address: http://www.ravimiamet.ee).
<Name of the holder of the marketing authorisation> :<contact details>.”

(6) The information must not be misleading or include features that are characteristic of material serving to advertise a medicinal product.

(7) Within five working days from the date of receiving the information and the plan for communicating the information, the State Agency of Medicines informs the marketing authorisation holder of granting approval to the information and the plan for communicating the information, of the need to modify the information or the plan, or of refusing to grant its approval.

§ 5. Calculation and payment of the fee for the safety and quality monitoring of the medicinal product

(1) The marketing authorisation holder pays the fee for the safety and quality monitoring of the medicinal product by 1 March of every year according to the invoice issued by the State Agency of Medicines.

(2) The State Agency issues the invoice for the safety and quality monitoring by 1 February of the calendar year following the year for which the fee is calculated.

(3) The State Agency of Medicines is authorised to exempt the marketing authorisation holder from the obligation to pay the safety and quality monitoring fee on the basis of the corresponding reasoned application of the holder, provided:
1) the medicinal product has not been marketed in Estonia in the relevant period, or
2) the wholesale figures for the medicinal product during the relevant period are less than 4,800 euros and 2,000 packages.

(4) The application for exemption from the fee for the safety and quality monitoring of the medicinal product must be submitted to the State Agency of Medicines at the latest by 25 February.

§ 6. Entry into force of this regulation

This regulation enters into force on 21 July 2012.

[1]Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp 1–66), amended by Directives 2004/28/EC (OJ L 136, 30.04.2004, pp. 58–84), 2009/9/EC (OJ L 44, 14.02.2009, pp. 10–61) and 2009/53/EC (OJ L 168, 30.06. 2009, pp. 33–34); Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67–128), amended by Directives 2002/98/EC (OJ L 033, 08.02.2003, pp. 30–40), 2003/63/EC (OJ L 159, 27.06.2003, pp. 46–94), 2004/24/EC (OJ L 136, 27.06.2003, pp. 85–90), 2004/27/EC (OJ L 136, 30.04.2004, pp. 34–57), 2008/29/EC (OJ L 81, 20.03.2008, pp. 51–52), 2009/53/EC (OJ L 168, 30.06.2009, pp. 33–34), 2009/120/EC (OJ L 242, 15.09.2009, pp. 3–12) and 2010/84/EU (OJ L 348, 31.12.2010, pp. 74–99).