Pursuant to item 39 of Article 6, Article 137, paragraph four of Article 138 and paragraph two of Article 140 of the Medicinal Products Act (Official Gazette of RS, no. 17/14), the Minister of Health hereby issues the following

# RULES
# on the pharmacovigilance of medicinal products for human use

## I. GENERAL PROVISIONS

### Article 1

(Scope of application)

(1) Pursuant to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code related to medicinal products for human use (OJ L 311, 28. 11. 2001, p. 67), last amended by 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1), (hereinafter: Directive 2001/83/EC) and Implementing Regulation (EU) no. 520/2012 of 19 June 2012 on the performance of activities in the field of pharmacovigilance, set out by Directive (EC) no. 726/2004 of the European Parliament and Council and Directive 2001/83/EC of the European Parliament (OJ L no. 159 of 20 June 2012, p. 5; hereinafter: Directive 520/2012/EC) regulating the pharmacovigilance system in the field of medicinal products for human use (hereinafter: medicinal products), as follows:

– method of reporting on adverse reactions to medicinal products;

– method of collecting and evaluating of adverse reactions to medicinal products and other data regarding pharmacovigilance of the medicinal product;

– measures to be taken with the aim of managing and reducing the risks associated with medicinal products;

– obligations of the marketing authorization holder and the temporary marketing authorisation holder (hereinafter: marketing authorization holder), wholesale marketing authorization holder, manufacturer with authorization for importing medicinal products, holder of authorization for marketing parallel imported medicinal products, holder of parallel distribution certificate and holder of authorization for compassionate use;

– tasks of the national pharmacovigilance center;

– tasks of the Public Agency for Medicinal Products and Medicinal Devices (hereinafter: Agency) in pharmacovigilance;

– detailed conditions for obtaining consent to the draft protocol for non-interventional clinical trials of a medicinal product according to Article 138 of the Medicinal Products Act (Official Gazette of RS, no. 17/14; hereinafter: non-interventional trial of safety of a medicinal product).

(2) Pharmacovigilance of advanced therapy medicinal product prepared on a non-routine basis shall be governed by Article 82 of the Act.

Article 2

(More detailed instructions)

More detailed instructions for the marketing authorization holder and the Agency on the management of the pharmacovigilance system are set out in guidelines on good practices in the field of pharmacovigilance, published on the website of the European Medicines Agency

http://www.ema.europa.eu/ ema/index.jsp?curl= pages/ regulation/ document_listing/ document_listing_000345.jsp &mid= WC0b01ac058058f32c.

Article 3

(Definition of terms)

In addition to the terms delineated in Articles 5 and 6 of the Act, the following expressions shall also be used in these Rules and shall have the following meaning:

1. Assessment of the report on adverse effect of a medicinal product means a review of the report in terms of its compliance with the requirements pursuant to paragraph one of Article 5 hereof, establishment of severity, expectedness and causal relation of the suspect adverse effect with the medicinal product in question. It also includes an initial assessment of the report, acquisition of data required for the assessment, if the report does not contain sufficient data, further monitoring of information on suspect adverse effects of the medicinal product and keeping of detailed documentation.

2. Pharmacovigilance Risk Assessment Committee (PRAC) is the expert body with the European Medicines Agency (hereinafter: EMA), competent for assessment and monitoring of the risk of medicinal products for human use and consists of representatives of EU member states (hereinafter: EU), individually appointed experts, representatives of associations of healthcare workers and patient organisations.

3. Committee for Medicinal Products for Human Use (CHMP) is the EMA expert body competent of assessing medicinal products for human use and consists of representatives of EU member and individually appointed experts.

4. Reporting party is the persons that reports on supposed adverse reactions to a medicinal product.

5. A regularly updated report on the safety of a medicinal product is an intermittent report submitted at predetermined times or at the request of the Agency by the marketing authorisation holder. The report contains predetermined information on medicinal product safety and a risk-benefit assessment.

6. Severe supposed adverse reactions of medicinal products shall include adverse reactions that cause another medically relevant clinical state.

7. The List of European Union Reference Dates and frequency of submission of Periodic safety update reports (hereinafter: List of reference dates of the EU is the list prepared pursuant to paragraph seven of Article 107c of Directive 2001/83/EC by the EMA at the European medicinal products portal, established pursuant to Article 26 of Directive (EC) no. 726/2004/EC 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 (OJ L 136, 30. 4. 2004, p. 1), last amended by Regulation No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending the Regulation No 726/2004/EC regarding pharmacovigilance (Official Journal L 316 of 14.11.2012, p. 38), (hereinafter: Regulation 726/2004/EC).

8. Coordination Group is a group that works on behalf of bodies responsible for medicinal products within the Member States of the EU. It studies matters related to acquisition and maintenance of marketing authorizations by the mutual recognition or decentralised procedure and pharmacovigilance of medicinal products.

9. Safety signal is information gathered from one or more sources, including monitoring and experimentation, that shows a possible new causal relationship or another aspect of a known causal relationship between exposure to a medicinal product or series of interconnected events, adverse or beneficial, that is deemed probable enough to warrant examination.

10. Scientific assessment of a report on supposed adverse reaction to a medicinal product is the consideration of the report following assessment for possible influence on the risk benefit ratio, taking into account other pharmacovigilance data and clinical benefits of the medicinal product.

## II. TASKS OF HEALTHCARE PROFESSIONALS

### Article 4

(Reporting on supposed adverse reactions to medicinal products)

(1) A healthcare professional shall report to the national pharmacovigilance centre about the following adverse reactions to medicinal products in accordance with the first and second paragraph of Article 129 of the Act.

(2) Healthcare professionals shall also report:

– when the use of a medicinal product caused or is suspected to have caused a harmful interaction with another medicinal product;

– any suspicion of an increase of frequency of the occurrence of supposed adverse reaction of a medicinal product;

– any suspicion of inefficiency of a medicinal product, the consequences of which are assessed as clinically relevant.

(3) A healthcare professional shall report supposed adverse reactions to the national pharmacovigilance centre under paragraphs one and two hereof immediately and no later than within 15 days of the day of establishment.

(4) If the healthcare professional reports supposed adverse reactions, pertaining to the use of a vaccine, to the institution which is in accordance with the rules on databases in the field of healthcare responsible for keeping a register of adverse reactions to vaccination, the institution shall submit such a report to the national pharmacovigilance centre. Supposed severe adverse reactions shall be reported immediately and not later than within seven days, while less severe supposed adverse reactions shall be reported immediately or no later than within 15 days of receiving notification of alleged adverse reaction.

(5) The Agency shall submit reports on supposed adverse reactions of vaccinations it received directly to the institution which is in accordance with the rules on databases in the field of healthcare responsible for keeping a register of adverse reactions to vaccination.

(6) Reports on supposed adverse reactions to medicinal products shall be submitted in the manner published on the Agency's website: http://www.jazmp.si.

Article 5

(Form and content of a report on adverse reactions)

(1) Reports suspected adverse reaction to a medicinal product shall contain at least the following information:

- data on the relevant medicinal product (name, pharmaceutical form, strength, indications for which it was prescribed, application method, duration of therapy);

– description of the adverse reaction to the medicinal product;

– data on the reporter;

– encoded data on the patient (initials and/or age and/or date of birth, gender);

– medicinal product batch number, of the report relates to a biological medicinal product.

(2) The reporting party shall assure any eventual additional data required to assess the supposed adverse reaction to the medicinal product, if so requested by the Agency or the national pharmacovigilance center.

Article 6

(Data confidentiality)

(1) Personal data from the Article above shall be deemed confidential and may only be used for the performance of the Act, these Rules and measures necessary for assuring safety and effectiveness of medicinal products.

(2) Reports on supposed adverse reactions to the medicinal product in accordance with paragraphs one and two of Article 4 hereof shall be treated as a confidential document, which shall not serve as basis for any assessment of liability of the healthcare professional who prescribed or dispensed the medicinal product.

III. TASKS OF THE WHOLESALE MARKETING AUTHORIZATION HOLDER, MANUFACTURER WITH AUTHORIZATION FOR IMPORTING MEDICINAL PRODUCTS, HOLDER OF AUTHORIZATION FOR MARKETING PARALLEL IMPORTED MEDICINAL PRODUCTS, HOLDER OF PARALLEL DISTRIBUTION CERTIFICATE AND HOLDER OF AUTHORIZATION FOR COMPASSIONATE USE

Article 7

(Reporting on supposed adverse reactions to medicinal products)

(1) A wholesale marketing authorisation holder, a manufacturer with import authorization, holder of marketing authorisation for parallel imported medicinal product, holder of parallel distribution certificate and holder of authorization for compassionate use shall report any supposed adverse reactions to medicinal products referenced in paragraphs one and two of Article 4 hereof to the national pharmacovigilance center fortwith, and no later than in 15 days of receiving the report on supposed adverse reaction to the medicinal product.

(2) Reports on supposed adverse reactions to medicinal products shall be submitted in one of the possible methods published on the Agency's website: http://www.jazmp.si.

(3) The business subject referenced in paragraph one of this Article shall inform the national pharmacovigilance center and the Agency within 24 hours of receiving information that warrants emergency measures due to a direct threat to public health.

Article 8

(Publishing of information on pharmacovigilance related issues)

The business subject in the first paragraph of the previous Article shall reasonably observe the provisions of Article 17 hereof when notifying the public of pharmacovigilance related issues.

Article 9

(Risk reduction measures)

(1) The business subject referenced in the first paragraph of Article 7 hereof shall carry out measures prescribed by the Agency for the purposes of reducing or preventing risks in relation to pharmacovigilance.

(2) The business subject referenced in the first paragraph of Article 7 hereof shall reasonably observe the provisions of paragraphs four, five and six of Article 16 hereof when notifying the expert public.

IV. OBLIGATIONS OF THE MARKETING AUTHORISATION HOLDER

Article 10

(Person responsible for pharmacovigilance)

(1) The person responsible for the pharmacovigilance system shall:

– be responsible for the establishment and maintenance of the pharmacovigilance system in a manner that assures collection and comparison of data on all supposed adverse reactions of medicinal products;

– have access to the main pharmacovigilance file and sufficient competences for assuring that the content of the main pharmacovigilance file presents an accurate and updated image of the pharmacovigilance system;

– have sufficient competences to influence the implementation of a system of quality and activity of pharmacovigilance;

– have an overview of the safety profiles of medicinal products and safety issues and shall observe and monitor the conditions of marketing authorizations and other obligations pertaining to the safety of medicinal products, and measures for reducing risk;

– have sufficient competences regarding the content of risk management plans;

– participate in the review and approval of post-authorisation clinical studies of medicinal products;

– assure appropriate quality, correctness and completeness of pharmacovigilance data for each medicinal product that is submitted to the Agency and immediatelly respond to any requests from the Agency for additional information required for the evaluation of the benefits and risks afforded by a medicinal product are answered fully and promptly, including the information on the volume of sales;

– submit to the Agency any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post-authorization clinical tests;

– assure 24-hour availability.

(2) The marketing authorisation holder shall promptly inform the Agency of any changes in relation to the responsible person for the pharmacovigilance system and changes in contact data thereof in accordance with implementing regulations governing marketing authorization for medicinal products for human use.

(3) A marketing authorisation holder that does not have its registered office in the Republic of Slovenia and has an appointed an appropriately qualified contact person in charge of pharmacovigilance in the Republic of Slovenia shall inform the Agency of said contact person and duly notify any relevant changes.

(4) The Agency may request the appointment of a contact person for pharmacovigilance in the Republic of Slovenia when the Agency within the course of inspection establishes that the marketing authorization holder referenced in the above paragraph is not performing its pharmacovigilance related tasks in accordance with the law and these Rules.

Article 11

(Keeping of documentation on supposed adverse reactions to medicinal products)

(1) The marketing authorisation holder shall keep detailed documentation on all supposed adverse reactions to medicinal products in the EU or third countries, as reported by healthcare workers, patients or other business subjects or arising within a post-registration non-interventional clinical trial.

(2) The marketing authorisation holder shall assure accessibility of data referenced in the above paragraph at a single location within the EU.

Article 12

(Reporting on supposed adverse reactions to medicinal products)

(1) The marketing authorisation holder shall:

– electronically submit reports on supposed severe adverse reactions to medicinal products occurring in the EU and third countries into the EudraVigilance database within 15 days of receiving notification of supposed adverse reactions;

– electronically submit reports on supposed non severe adverse reactions to medicinal products occurring in the EU into the EudraVigilance database within 90 days of receiving notification of supposed adverse reactions;

– establish procedures for acquiring accurate and verifiable data for scientific evaluation of reports on supposed adverse reactions to medicinal products, collect further information regarding such reports and submit updated information into the EudraVigilance database;

– cooperate with the Agency and EMA in discovering duplicate reports on adverse reactions to medicinal products;

– monitor any medical and scientific literature in the Republic of Slovenia that is not on the list of publications monitored by the EMA, and report on supposed adverse reactions to medicinal products to the EudraVigilance database within 15 days of receiving notification of supposed adverse reactions;

– immediately, or no later than within 24 hours of receiving notification of supposed severe adverse reaction, notify the Agency of supposed severe adverse reactions that warrant emergency measures due to a direct threat to public health.

(2) Beside the tasks listed in the above paragraph, the marketing authorisation holder shall fulfill additional requests regarding reporting on supposed adverse reactions to medicinal products as directed by the Agency based on substantiated reasons pertaining to the pharmacovigilance system.

Article 13

(Regularly updated report on the safety of medicinal products)

(1) The marketing authorisation holder shall submit a regularly updated report on the safety of a medicinal product in accordance with the frequency and submission dates set out in the marketing authorization. The frequency and submission date shall apply until the relevant marketing authorization states otherwise.

(2) The marketing authorisation holder shall electronically submit a regularly updated report on the safety of a medicinal product to the EMA in accordance with item eight of paragraph one of Article 133.

(3) Notwithstanding the first paragraph of the present Article, the marketing authorization holder referenced under Articles 45, 47, paragraph two of Article 52 and paragraph two of Article 53 of the Act shall submit a regularly updated report on the safety of a medicinal product only in the following cases:

– when the obligation of reporting is set out as a condition in the marketing authorization;

– when so required by the Agency for reasons of pharmacovigilance or because not enough regular updated reports on the safety of the relevant active substance is available after marketing authorization has been issued;

– if the active substance is included in the list of reference dates of the EU.

(4) The marketing authorisation holder shall submit an updated medicinal product safety report for medicinal products that gained marketing authorization prior to 21 July 2012 and for which the frequency and dates of submission of reports are not set out by the marketing authorization:

– immediately, if so requested by the Agency;

– at least every six months following the issue of marketing authorization in the period prior to putting the medicinal product on the market;

– after putting the medicinal product on the market:

– at least every six months during the first two years;

– after two years have elapsed since putting the medicinal product on the market once annually in the following two years;

– After four years of post-marketing period – in three-year intervals.

(5) The frequency and dates of submission of regular updated medicinal product safety reports as set out under paragraphs one, three and four of the present Article may change, if the active substance or combination of substances is subject to a coordinated frequency of submission and EU reference date in order to enable a unified assessment in relation to the process of division of labour, as published on the EMA website. The marketing authorisation holder shall in such a case submit to the Agency an application for a change in the marketing authorisation in accordance with the implementing regulation governing marketing authorization for medicinal products for human use.

(6) The marketing authorisation holder may, for reasons of pharmacovigilance or to prevent duplication of assessment, or to achieve international coordination, submit to the Committee for Medicinal Products for Human Use or the Coordination Group with a request for determination of an EU reference date or amendment of the frequency of

submission of regular updated medicinal product safety reports. Applications shall be submitted in writing and appropriately substantiated.

(7) The marketing authorisation holder shall monitor the list of EU reference dates regarding amendments of dates or submission frequency at the European medicinal products portal and shall, if required, submit to the Agency an application for a change in the marketing authorisation in accordance with the implementing regulation governing marketing authorization for medicinal products for human use.

(8) Any amendment of the dates or frequency of submission of regular updated medicinal product safety reports for reasons listed under paragraphs five, six and seven of the present Article, shall enter into force six months from the date of publication of the List of EU reference dates at the European medicinal products portal.

(9) Regular updated reports on the safety of medicinal products shall include:

– summaries of data relevant for the benefits and risks of a medicinal product, including results of clinical testing after acquisition of marketing authorization, taking into account any eventual influence on the marketing authorization;

– scientific evaluation of the risk benefit ratio of the medicinal product, based on all available data, including data from clinical trials for unregistered indications and populations;

– all data pertaining to the scope of medicinal product sales and all data available to the marketing authorization holder regarding the number of prescriptions, including an assessment of the share of the general population exposed to the medicinal product.

Article 14

(Detection of safety signals)

(1) The marketing authorization holder shall monitor all available pharmacovigilance data with the aim of determining whether any new risk has arisen, whether the risks have changed and whether the risks of a medicinal product have affected the risk-benefit balance.

(2) The marketing authorization holder shall monitor data referenced in the above paragraph with a frequency proportionate to defined risks, possible risks and need for additional information pursuant to guidelines set out under Article 2 hereof.

(3) The marketing authorization holder shall inform the Agency of any newly established or changed risks, and influences of such risks on the risk-benefit balance.

Article 15

(Risk management system)

(1) The marketing authorization holder shall manage and update the risk management system for each medicinal product, with the exception of medicinal products listed under paragraph 2 of Article 203 of the Act.

(2) The marketing authorisation holder shall monitor the results of risk reduction measures contained in the risk management plan and measures set out in the relevant marketing authorization pursuant to Article 58 of the Act.

(3) The marketing authorization holder referenced in the second paragraph of Article 203 of the Act shall at the substantiated request of the Agency submit a risk management plan to be introduced for a specific medicinal product.

(4) The marketing authorisation holder may within 30 days of receiving notification of the obligation imposed by the Agency, request from the Agency the option of submitting written explanations as a response to said imposed obligation.

(5) The marketing authorisation holder shall provide an answer to the imposed obligation within the deadline set out by the Agency.

(6) Based on the submitted written explanations, the Agency shall cancel or confirm the obligation to submit a risk management plan for the relevant medicinal product.

Article 16

(Additional risk reduction measures)

(1) The marketing authorization holder shall implement additional measures for reducing risks within the risk management system in accordance with the guidelines under Article 2 hereof.

(2) The marketing authorization holder shall prior to the commencement of implementation of any additional risk reduction measures referenced in the above paragraph acquire the consent of the Agency, regardless of the type of procedure of marketing authorization acquisition.

(3) The marketing authorization holder shall submit to the Agency the educational materials for healthcare workers or patients, which are in accordance with the guidelines under Article 2 hereof a part of the additional risk reduction measures, and shall list target groups, method and timeframe for the submission of educational materials. If the Agency does not request supplementation or amendments within 30 days, it shall be deemed that the educational materials are appropriate.

(4) The marketing authorisation holder shall inform the expert public on pharmacovigilance issues with direct notification for healthcare workers in accordance with the guidelines under Article 2 hereof, or shall inform it of so directed by the Agency.

(5) The marketing authorization holder shall submit direct notifications for healthcare workers, as referenced in the above paragraph, shall be submitted in coordination with the Agency with regard to content, target groups, method and timeframe of notification.

(6) Envelopes containing notification sent in accordance with paragraphs four and five of the present Article must be clearly marked with the following text in red color: "Important notification regarding medicinal product safety".

(7) Educational materials from the third paragraph of this Article and direct notification from the fourth paragraph of this Article shall not contain any elements of advertising.

(8) The marketing authorization holder shall carry out any other measures directed by the Agency towards reduction or prevention of risks.

(9) At the request of the Agency, the marketing authorisation holder shall submit an assessment of efficiency of additional risk reduction measures.

(10) If educational materials from the third paragraph of this Article and direct notification from the fourth paragraph of this Article relate to a medicinal product on the list of medicinal product that require additional monitoring of safety, as published by EMA in accordance with Article 23 of Directive 726/2004/EC, the materials shall be marked by a downturned filled out triangle in black. The symbol shall be followed by the notation "This medicinal product is subject to additional safety monitoring" and a short standard explanation in accordance with the guidelines set out by Article 2 hereof.

Article 17

(Publishing of information on pharmacovigilance related issues)

The marketing authorization holder shall assure that all published information regarding pharmacovigilance of a medicinal product are presented objectively, are not misleading and do not contain advertising elements.

Article 18

(Pharmacovigilance system master file)

(1) The marketing authorization holder shall keep a master file on the pharmacovigilance system in the content and form determined by Directive 520/2012/EU and guidelines under Article 2 hereof.

(2) The marketing authorization holder shall assure that the content of the master pharmacovigilance file shall represent an accurately and regularly updated image of the pharmacovigilance system and shall contain all available data on the safety of medicinal products which the holder is authorised to market in the EU.

(3) The master pharmacovigilance system file be kept in the EU member state in which the marketing authorization holder is performing the main pharmacovigilance tasks or in the EU member state in which the person responsible for pharmacovigilance is operating.

(4) The marketing authorization holder shall assure that the master pharmacovigilance file shall be permanently and immediately accessible at the location of its keeping.

(5) The marketing authorization holder shall regularly assess its pharmacovigilance system and shall enter any remarks on the main findings of its assessment into the master pharmacovigilance system file and prepare and implement and appropriate plan of measures for correcting the established shortcomings.

(6) A remark referenced above may be withdrawn from the master pharmacovigilance system file once measures for correcting the established shortcomings have been implemented in full.

V. TASKS OF THE NATIONAL PHARMACOVIGILANCE CENTER

Article 19

(Responsibilities)

The national pharmacovigilance center:

– collects and evaluates reports on supposed adverse reactions to medicinal products, including any data on inappropriate use, abuse or inefficacy of medicinal products, falsification of medicinal products and all other data relevant to safe use of medicinal products in accordance with guidelines in Article 2 hereof;

– submits assessments of reports on supposed adverse reactions to the Agency within seven days of receiving notification of supposed adverse reactions;

– provides the A with other relevant information concerning medicinal product safety;

– informs the Agency in case of a need for immediate action, within 24 hours of receiving notification that warrants emergency action.

VI. (TASKS OF THE AGENCY)

Article 20

(Assessment of reports on supposed adverse reactions to medicinal products)

Within the scope of the performance of tasks set out under Article 134 of the Act pertaining to assessment of reports on supposed adverse reactions, the Agency shall perform the following tasks:

– managing the pharmacovigilance system for collecting information on risks to health of patients or public health due to medicinal products. This information shall particularly concern supposed adverse reactions of medicinal products arising from the use of medicinal products within the conditions and/or use outside of the scope of the marketing authorization, including supposed adverse reactions of medicinal products arising from errors in medicinal product use, abuse, incorrect use, excessive dosage, unauthorised use and professional exposure;

– scientific evaluation of reports on supposed adverse reactions of medicinal products and adoption of measures for acquiring accurate and verifiable data for scientific evaluation of reports. Further monitoring of reports on supposed adverse reactions to medicinal products may include healthcare workers and patients, as is appropriate, and the marketing authorization holder for reports it submits to the Agency;

– electronic submission of reports on supposed severe adverse reactions to medicinal products within 15 days of receiving notification of supposed severe adverse reactions to a medicinal product into the EudraVigilance database in accordance with guidelines detailed in Article 2 hereof;

– electronic submission of reports on supposed severe adverse reactions to medicinal products into the EudraVigilance database in accordance with guidelines detailed in Article 2 hereof within 90 days of notification of supposed severe adverse reactions to a medicinal product;

– cooperation with marketing authorization holders and EMA in discovering duplicate reports on supposed adverse reactions to medicinal products;

– stimulate healthcare workers and patients to report on supposed adverse reactions to medicinal products, including into such activities also the national pharmacovigilance center and healthcare workers' associations, associations of patients and consumers.

Article 21

(Measures taken in emergency pharmacovigilance cases)

(1) The Agency shall implement measures in emergency pharmacovigilance cases (hereinafter: emergency procedure of the EU) when it decides that action is required based on an assessment of data from the pharmacovigilance system.

(2) The Agency shall commence the procedure referenced in the above paragraph by notifying the European Commission, the EMA and authorities competent for medicinal products in other EU Member States when:

– it shall be revoking or temporarily suspending a marketing authorization;

– it shall be prohibiting the use of a medicinal product;

– it shall reject the extension of a marketing authorization;

– it shall receive notification from the marketing authorization holder that it has due to safety reasons ceased marketing the medicinal product in question, requested the Agency to terminate the marketing authorization or intended to do so or has not applied for an extension of marketing authorization.

(3) The Agency shall notify EMA in writing of the intended measures set out in the above paragraph and shall submit all relevant technical data, including results of its assessment.

(4) Until adoption of a final decision in the procedure referenced in paragraph one of this Article, the Agency may in the interest of protecting public health enforce measures set out under paragraph five of Article 64 of the Act.

(5) If the Agency on the basis of an assessment of data from the pharmacovigilance system finds that new contraindications, reduction of the suggested dose or a limitation of indications are required, the Agency shall inform the European Commission, the EMA and bodies competent for medicinal products in other EU member states. The Agency shall list reasons for such measures and shall commence an emergency procedure of the EU if it believes that emergency measures are required. If the Agency does not commence the procedure determined in paragraph one of the present Article and the medicinal product in question has acquired a marketing authorisation by the mutual recognition or decentralised procedure, the matter shall be submitted to the Coordination Group.

(6) Notwithstanding paragraphs one, two and five of this Article, a medicinal product that has been granted marketing authorisation solely for the Republic of Slovenia, the Agency shall process the pharmacovigilance case it it assesses that emergency measures are required, and shall notify the relevant marketing authorization holder of the commencement.

(7) The marketing authorisation holder may submit its written remarks on the assessment of the pharmacovigilance case referenced in the above paragraph.

(8) The Agency shall within 60 days of commencement of the procedure set out under paragraph 6 of the present Article:

– establish that further assessment of data and measures are not required;

– direct the marketing authorization holder to perform further assessments of data and monitor its results;

– direct the marketing authorization holder to perform a non-intervention clinical study on the safety of the medicinal product and assess its results;

– direct the marketing authorization holder to perform risk reduction measures, including conditions and limitations stipulated by the authorisation, as directed by the Agency;

– temporarily revoke the marketing authorization;

– revoke the marketing authorization, or

– amend the marketing authorisation.

Article 22

(Informing)

(1) The Agency shall via its website inform the public of at least:

– methods of reporting on supposed adverse reactions to medicinal products for healthcare workers and patients;

– pharmacovigilance related issues;

– list of medicinal products that require additional safety monitoring as published by EMA pursuant to Article 23 of the Regulation (EC) No. 726/2004;

– summaries of legally approved risk management plans for medicinal products;

– list of national medical and scientific literature monitored by the marketing authorization holder for the purpose of reporting on supposed adverse reactions to medicinal products.

(2) In publishing notifications on pharmacovigilance related issues, the Agency shall observe provisions of the Act, act governing companies and act governing protection of personal data.

VII. NON-INTERVENTIONAL STUDY ON POST-AUTHORIZATION MEDICINAL PRODUCT SAFETY

Article 23

(detailed conditions for acquisition of consent to the draft protocol of the non-interventional study of medicinal product safety)

(1) The marketing authorization holder shall submit to the Agency a draft protocol of a non-interventional study of medicinal product safety, that shall take place only in the Republic of Slovenia and that requires consent referred to in Article 138 of the Act.

(2) The content and form of the protocol stated in the above paragraph shall correspond to Appendix III to Directive 520/2012/EU and guidelines from Article 2 hereof.

(3) The Agency shall issue a resolution of consent to the draft protocol within 60 days of receiving said draft protocol, provided the following conditions are met:

– the content and form of the protocol fulfill the requirements set out in the previous paragraph;

– the plan of the non-interventional medicinal product safety study shall correspond to the definition of non-interventional clinical testing in accordance with the law and guidelines from Article 2 hereof;

– the study plan referenced in the above indent assures the achievement of the purpose and goals of the study;

– sufficient evidence is submitted that the person responsible for the pharmacovigilance system in included in the review and approval of the protocol;

– implementation of the non-interventional medicinal product safety study does not accelerate prescription and consumption of the medicinal product.

(4) When non-interventional medicinal product safety studies are performed also in another EU member state that requires consent set out under Article 138 of the Act, the marketing authorization holder shall submit to the Pharmacovigilance Risk Assessment Committee a draft protocol in accordance with the procedure set out under Articles 107n to 107q of Directive 2001/83/EC.

Article 24

(content related amendments to protocol of the non-interventional study of medicinal product safety)

(1) Following commencement of the medicinal product safety study referenced in the first paragraph of Article 23 hereof, the marketing authorisation holder shall submit any content related amendment of the protocol to the Agency prior to its implementation.

(2) Content related amendments shall mean substantial amendments to the protocol, as defined in the guidelines in Article 2 hereof.

(3) The Agency shall decide on the adequacy of the proposed amendment within 30 days.

(4) Following commencement of the study referenced in the fourth paragraph of Article 23 hereof, the marketing authorisation holder shall submit any content related amendment of the protocol to the Pharmacovigilance Risk Assessment Committee in accordance with Article 107o of Directive 2001/83/EC.

Article 25

(Post EU authorization submission of data into the electronic clinical trials register)

Prior to commencement of data collection, the sponsor shall submit data on all post-registration non-intervention studies on medicinal product safety into the electronic post-registration clinical trials register, the EU PAS Register, in accordance with the guidelines of Article 2 hereof, which is accessible vie the European medicines portal http://www.encepp.eu/encepp_studies/indexRegister.shtml.

VIII. FINAL PROVISIONS

Article 26

(Termination of validity)

Rules on the pharmacovigilance of medicinal products for human use (Official Gazette of the Republic of Slovenia, Nos 53/06 and 16/11) shall cease to apply on the date the present Rules enter into force.

Article 27

(Effective date)

These Rules shall enter into force on the fifteenth day after their publication in the Official Gazette of the Republic of Slovenia.

No. 0070-31/2014

Ljubljana, 16 June 2014

EVA 2014-2711-0041

in her capacity as Minister of Health
mag. Alenka Bratušek
President of the Government