Unofficial translation
from Romanian Language

Parliament of the Republic of Moldova

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Amending and Supplementing Certain Legislative Acts

No. 24 of 23.02.2018

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For the purpose of transposing the provisions of Articles 10, 10a, 10b and 10c 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, published in the Official Journal of the European Union L 311 of 28 November 2001,
The Parliament hereby adopts this organic Law.

Article I. - Law No.1456/1993 on Pharmaceutical Activity (republished in the Official Monitor of the Republic of Moldova, 2005, No. 59-61, Article 200), as subsequently amended and supplemented, shall be supplemented as follows:

1. In Article 1, after the term "unauthorized medicinal product" the following terms shall be introduced:
   "data protection period - the period during which the holder of the preclinical and clinical trials data has the right to prohibit the use of such data;
   marketing protection period - the period during which a generic medicinal product cannot be placed on the market;
   first authorization - authorization obtained for the first time anywhere in the world for an original medicinal product;".
2. The Law shall be supplemented with Article 11^5, worded as follows:
   "**Article 11^5.** Data protection and protection of the placing on the market of pharmaceuticals
   (1) By way of derogation from the legislation on trade secrecy and access to information and without prejudice to the legislation on industrial property protection, holders of an original medicinal product for which marketing authorization is requested shall benefit from a 5-year period of data protection for preclinical and clinical trials from the date of authorization and an additional 2-year period of marketing protection for the medicinal product concerned.
   (2) The 2-year period of market protection referred to in paragraph (1) may be extended to a maximum of 3 years if, during the data protection period for tests and trials, the marketing authorization holder obtains an authorization for one or more new therapeutic indications thereof which, following a scientific evaluation prior to the authorization of the medicinal product, are considered to bring significant clinical benefits in comparison with existing therapies provided that significant preclinical tests and clinical trials are carried out and presented with regard to the new indication/new indications.

(3) During the data protection period of the original medicine test data, any other manufacturer may refer to preclinical and clinical documentation contained in the registration file of the medicinal product for the purpose of submitting an application for a marketing authorization of a generic medicinal product, unless the holder of the original medicine test data provides consent. Upon expiry of the data protection period for the original medicine test, reference may be made to the preclinical and clinical documentation contained in the registration file of the medicinal product concerned without the consent of the holder of these data. If a registration certificate for a generic medicinal product has been obtained on the territory of the Republic of Moldova prior to requesting such authorization from the holder of the original medicinal product, the rights granted under this Article shall not be invoked with respect to the generic medicinal product.

(4) Only the information that the applicant is required to submit for obtaining the registration certificate for the medicinal product and which relates to:
- pharmaceutical (physico-chemical, biological or microbiological) tests;
- preclinical (toxicological and pharmacological) tests;
- clinical studies.

fall under the provisions relating to medicine test data.

(5) Presentation of the results of preclinical and clinical trials shall not be mandatory if the applicant proves that the medicinal product is a generic product of a reference medicinal product manufactured under the Good Manufacturing Practices (GMP) and registered by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for at least 8 years.

(6) The applicant for the registration certificate of a generic medicinal product shall present appropriate bioavailability studies to demonstrate bioequivalence with the reference medicinal product. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the salts, esters or derivatives of an authorized active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms are considered to be the same pharmaceutical form. The applicant is not required to carry out bioavailability studies if he can demonstrate that the generic medicine meets the relevant criteria as defined by the applicable detailed guidelines. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need to be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

(7) In cases where the medicinal product does not fall under the definition of a generic medicinal product according to paragraph (6) or where bioequivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, dosage, pharmaceutical form or route of administration in relation to the reference medicinal product, the results of the appropriate preclinical tests or clinical trials shall be provided by the applicant for the registration certificate of a generic medicinal product.

(8) Where a biological medicinal product which is similar to a reference medicinal product does not meet the conditions in the definition of a generic medicinal product, owing to, in particular, differences relating to raw materials or in manufacturing

processes of the similar biological medicinal product and the reference biological medicinal product, the results of appropriate preclinical tests or clinical trials relating to these conditions must be provided by the applicant for the registration certificate of a generic medicinal product. The type and quantity of supplementary data to be provided must comply with the relevant criteria provided for by the legislation. The results of other tests and trials from the reference medicinal product`s dossier shall not be provided.

(9) The applicant for the registration certificate of a generic medicinal product shall not be required to provide the results of the preclinical tests and clinical trials if he can demonstrate that the medicinal product or the active substances of the medicinal product are in well-established medicinal use for at least 10 years, with recognized efficacy and a an acceptable level of safety under the conditions provided for in this Law. In this case, the applicant may only refer to the results of the tests and trials provided for the first time anywhere in the world within the authorization procedures or may replace these data with the appropriate scientific documentation.

(10) In the case of medicinal products containing active substances used in the composition of authorized medicinal products but not hitherto used in combination for therapeutic purposes, the results of new pre-clinical tests or new clinical trials relating to that combination shall be provided, but it shall not be necessary to provide scientific references relating to each individual active substance.

(11) Pursuant to this Article, protection will be granted exclusively to those data related to medicinal products the provision of which is mandatory in the marketing authorization procedure for the medicinal product.

(12) Exceptions to the provisions on the data protection and the protection of the placing on the market of medicinal products are made in exceptional situations in accordance with Article 11 paragraph (7) of this Law or in other cases that might endanger the public health according to Article 28 paragraph (3) of Law No.50/2008 on the Protection of Inventions."

Article II. - Law No.1409/1997 on Medicinal Products (Official Monitor of the Republic of Moldova, 1998, No. 52-53, Article 368), as subsequently amended and supplemented, is hereby amended and supplemented as follows:

1. In Article 3, the term "original medicinal product (novelty or new chemical entity)" shall be replaced by "reference (original) medicinal product " , worded as follows:
   "reference (original) medicinal product shall mean a medicinal product authorized for the first time anywhere in the world based on its own preclinical tests and clinical trials;".
2. Article 6^1:
   in paragraph (3), the word "original" shall be replaced by the words "reference (original)";
   in paragraph (4), the word "original" shall be replaced by the words "reference (original)".
3. Article 14 shall be supplemented by paragraph (2) as follows:
   "(2) Authorization of a generic medicinal product shall be made separately from that of the (original) reference medicinal product."

Article III. – (1) This Law shall enter into force on the day of its publication in the Official Monitor of the Republic of Moldova, except for the provisions of Article I paragraph 2, which shall apply from 1 January 2020.

(2) The Government shall, within 6 months from the date of publication of this Law, align its normative acts with this Law.

CHAIRMAN OF THE PARLIAMENT **Andrian CANDU**

No.24. Chisinau, 23 February 2018