MINISTRY OF HEALTH

2350

Pursuant to Article 187, paragraph 3 of the Medicinal Products Act (Official Gazette 76/13 and 90/14), the Minister of Health hereby issues the

ORDINANCE

ON THE TYPE OF DATA AND MANNER OF DRAFTING THE REPORT ON MEDICINAL PRODUCT CONSUMPTION

Article 1

(1) This Article establishes the type of data and manner of drafting the report on medicinal product consumption for all legal and natural persons performing wholesale or retail trade of medicinal products.

(2) The data and reports from paragraph 1 of this Article are submitted to the Agency for Medicinal Products and Medical Devices (hereinafter: the Agency).

Article 2

Legal and natural persons performing wholesale and retail trade of medicinal products are obliged to submit annual reports on consumption, classifying the medicinal products according to the Anatomic-Therapeutic-Chemical (hereinafter: ATC) classification of medicinal products of the World Health Organisation (hereinafter: WHO), which is valid for the year to which the report pertains.

Article 3

(1) The report from Article 2 of this Ordinance should contain the following data:

1. name of the medicinal product, form, strength and size of the packaging,

2. International Non-proprietary Name (INN) of the medicinal product,

3. ATC classification code of medicinal products of the WHO,

4. number of packages of the medicinal product (total number and number of packages delivered to wholesalers, hospitals, pharmacies and specialised retail sales outlets for medicinal products),

5. total amount in Croatian kuna (HRK) based on the wholesale prices for each medicinal product,

6. wholesale price (WP) of issuance of the medicinal product,

7. manner of issuing the medicinal product: subscription or over-the-counter,

8. whether or not the medicinal product is issued at the expense of the Croatian Health Insurance Fund (hereinafter: the Fund),

9. place of delivery of the medicinal product in wholesale,

10. place of issuance of the medicinal product.

(2) The report is submitted to the Agency by 1 March of the current year for the preceding year.

(3) The report is submitted in electronic form, via the web application created by the Agency.

(4) Legal and natural persons from Article 2 of this Ordinance are obliged in the report to list their address, registration number of the natural or legal person, and name and surname of the responsible person submitting the data.

(5) The format of the report in electronic form is determined by the Agency.

Article 4

(1) The report of the Agency consists of an overview that includes:

1. an overview of total consumption for each main anatomical group at the first, second, third, fourth and fifth level of the ATC classification of medicinal products, expressed as the number of defined daily doses per 1000 residents per day (DDD/1000/day), with the total amount in Croatian kuna according to the wholesale prices for each medicinal product,

2. the 50 most used medicinal products expressed as the number of defined daily doses per 1000 residents per day (DDD/1000/day), with the total amount in Croatian kuna according to the wholesale prices for each medicinal product,

3. the 30 most used medicinal products expressed as the number of defined daily doses per 1000 residents per day (DDD/1000/day), with the total amount in Croatian kuna according to the wholesale prices for each medicinal product, out of hospital consumption,

4. the 30 most used medicinal products expressed as the number of defined daily doses per 1000 residents per day (DDD/1000/day), with the total amount in Croatian kuna according to the wholesale prices for each medicinal product, hospital consumption,

5. the 30 most used medicinal products expressed as the number of defined daily doses per 1000 residents per day (DDD/1000/day), with the total amount in Croatian kuna according to the wholesale prices for each medicinal product, at the expense of the Fund,

6. the 30 most used medicinal products expressed as the number of defined daily doses per 1000 residents per day (DDD/1000/day), with the total amount in Croatian kuna according to the wholesale prices for each medicinal product, not at the expense of the Fund,

7. the consumption of medicinal products expressed by the number of defined daily doses per 1000 residents per day (DDD/1000/day) with the total amount in Croatian kuna according to the wholesale prices for each medicinal product, by county, out of hospital consumption,

8. overview of the consumption of 30 most consumed medicinal products that are issued by a prescription in a pharmacy,

9. overview of the consumption of 30 most consumed medicinal products that are issued without a prescription (over-the-counter) in a pharmacy,

10. overview of the consumption of medicinal products that are issued without a prescription (over-the-counter) in specialised retail sales outlets for medicinal products,

(2) For the calculation of the number DDD/1000/day, the DDD determined by the WHO for the year to which the report pertains is used. Where there are no WHO data for the DDD for any medicinal product or group of ATC classifications of medicinal products, only the consumption in Croatian kuna is listed.

(3) The Agency submits the written report on the consumption of medicinal products to the ministry responsible for health, based on the data from paragraph 1 of this Article.

(4) In addition to the overview of consumption from paragraph 1 of this Article, the minister responsible for health (hereinafter: the minister) may request additional data on medicinal product consumption.

Article 5

The Agency is obliged to draft the written report from Article 4, paragraph 3 of this Ordinance no later than 31 August for the previous calendar year.

Article 6

Once a year, the Agency shall publish a brochure on medicinal product consumption following the publication of data on medicinal product consumption on the Agency website.

Article 7

With the entry of this Ordinance into effect, the Ordinance on the type of data and manner of drafting reports on the trade of finished medicinal products (Official Gazette 29/05) shall cease to have effect.

Article 8

This Ordinance shall enter into force as of the eighth day from the date of its publication in the Official Gazette.

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Reg no: 534-10-1-2-2/4-14-1

In Zagreb, 1 October 2014

Minister

Primarius Siniša Varga, DDM, m. p.