KINGDOM OF BELGIUM

FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Royal Decree implementing Article 12 *nonies* of the Act of 25 March 1964 on medicinal products for human use with a view to creating a Stock Monitoring Tool.

PHILIPPE, King of the Belgians,

To all, present and to come,

Greetings.

Having regard to the Act of 25 March 1964 on medicinal products for human use, Articles 6, §1 *sexies*, as last amended by the Act of 5 May 2022, and 12 *nonies* inserted by the Act of 11 July 2023.

Having regard to Royal Decree of 14 December 2006 on medicinal products for human use;

Having regard to the opinion of the Finance Inspectorate issued on [date];

Having regard to the deliberation of the Council of Ministers held on dd.mm.yyyy ;

Having regard to the communication to the European Commission of dd.mm.yyyy pursuant to Article 5(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the opinion xxxx/x of the Council of State, given on [date], pursuant to Article 84, §1, subparagraph 1(2), of the acts on the Council of State, consolidated on 12 January 1973;

On the proposal of our Minister for Public Health and the opinion of our Ministers who deliberated on the Council,

WE HAVE DECREED AND HEREBY DECREE:

CHAPTER I – Scope of application
Art. 1. This Decree shall apply to: 1° prescription-only medicinal products for human use; 2° reimbursable medicinal products for human use; 3° non-prescription medicinal products with the same ATC code as the medicinal products referred to in points 1° and 2°. which are authorised in accordance with Article 6, §1, or imported in parallel in accordance with Article 12 *ter*, §1, of the Act of 25 March 1964 on medicinal products for human use, and which are placed on the market in Belgium.
By way of derogation from paragraph 1, this decree also applies to medicines that are no longer marketed in Belgium for a period of two years from the date of cessation of their placement on the market.
Art. 2. The obligation to provide information as referred to in Article 3 shall apply to:
1° marketing authorisation holders for medicinal products for human use (MAHs) or, where applicable, manufacturers or wholesale distributors responsible for distribution on behalf of the MAH;
2° wholesale distributors referred to in Article 12 *ter*, §1, paragraph 3, of the Act on Medicinal Products for Human Use of 25 March 1964, who place on the market in Belgium the medicinal products referred to in Article 1, whether or not they are established in Belgium;
3° wholesalers-distributors;
4° hospital pharmacies;
5° pharmacies open to the public.
CHAPTER II. – Communication of data on stocks of medicinal products.
Art. 3. The persons referred to in Article 2 shall communicate the following information to the AFMPS every day, for the day preceding the communication:
1° the exact date to which the stock information relates;
2° an overview of the end-of-day stock, classified by CTI-ext code;
3° the volume sold the previous day.

Art. 4. The persons referred to in Article 2, points 1° to 3° shall communicate to the AFMPS, at the time of entry into force of this Royal Decree, the average monthly sales volume calculated on the basis of the last twelve months preceding the entry into force of this Decree and during which there was no temporary cessation of placing on the market.
Art. 5. The persons referred to in Article 2, points 1° and 2° shall provide the AFMPS with the following information, where known. For the purposes of this article, the word 'delivery' must be understood as referring to new stocks placed on the market in Belgium:
1° the date of the next delivery;
2° the volume of the next delivery;
3° the date of delivery following the delivery referred to in point 1;
4° the volume of the delivery referred to in point 3.
Art. 6. By way of exception, the Minister or his delegate may exempt the person referred to in article 2 from the obligations set out in articles 3 to 5 where, due to circumstances beyond their control, the communication of the required data cannot reasonably be ensured.
The exemption is granted for a maximum period of six months.
Art. 7. The data referred to in Articles 3 to 5 shall be communicated by means of the application made available by the AFMPS.
Art. 8. The AFMPS shall retain the data referred to in Articles 3 to 5 for ten years. Without prejudice to Article 14 of the Act of 25 March 1964 and without prejudice to the powers of judicial police officers, the AFMPS uses these data for the following purposes.
1° to assess, predict, prevent, offset and remedy shortages of medicinal products;
2° to assess and evaluate the needs of patients in Belgium;
3° to develop a strategy for the unavailability and continuous supply of medicinal products in order to meet the needs of patients in Belgium;
CHAPTER III: Final provisions
Art. 9. Article 100/1 of the Royal Decree of 14 December 2006 on medicinal products for

human use is repealed.
Art. 10. This decree shall enter into force on 1 July 2026.
Art. 11. The Minister for Public Health shall be responsible for the implementation of this Decree.
Done in
By the King:
The Minister for Public Health,
Frank VANDENBROUCKE