

KINGDOM OF BELGIUM

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FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Royal Decree amending the Royal Decree of 21 January 2009 laying down instructions for pharmacists, the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use and the Royal Decree of 15 November 2017 on the materiovigilance contact point and the registration of medical device distributors

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC;

Having regard to Article 108 of the Constitution;

Having regard to the Law of 25 March 1964 on medicinal products for human use, Article 3(2), (3) and (4), Article 6*quater*, (1), first subparagraph, 4), *in fine*, Article 7*ter* and Article 12*bis*, third subparagraph;

Having regard to the opinion of the Inspector of Finance, given on 6 June 2023.

WE HAVE DECREED AND HEREBY DECREE:

**CHAPTER 1. Amendment of the Royal Decree of 21 January 2009 laying down instructions for pharmacists**

**Article 1.** In the Royal Decree of 21 January 2009 laying down instructions for pharmacists, an Article 19/1 is inserted, worded as follows:

‘Article 19/1. The pharmacist shall not dispense more antibiotics for human use prescribed in solid oral form in ATC class J01 than the quantity necessary for the intended duration and dosage of treatment, as prescribed by the doctor. If there is no authorised packaging containing only the required number of doses, the pharmacist shall split the packaging and dispense only the portion corresponding to the quantity prescribed.

The first subparagraph shall only apply insofar as the doctor’s prescription mentions the name of the substance (international non-proprietary name), the dosage, route of administration, daily dosage and duration of treatment.

The first subparagraph shall not apply to medicinal products containing the following active substances with the following ATC codes:

- 1° cefalexin (J01DB01);
- 2° lincomycin (J01FF02);
- 3° ofloxacin (J01MA01);
- 4° norfloxacin (J01MA06);
- 5° roxithromycin (J01FA06).’

**Article 2.** The Minister for Public Health shall be responsible for the implementation of this Decree.

Issued in \_\_\_\_\_, on \_\_\_\_\_

By the King:

The Minister for Public Health,

Frank VANDENBROUCKE