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| **KINGDOM OF BELGIUM** |
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| **FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS** |
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| **Royal Decree implementing Article 12f, paragraph 2, of the Law of 25 March 1964 on medicinal products** |
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| **PHILIPPE, King of the Belgians,** |
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| To all present and those to come, Greetings. |
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| Having regard to the Law of 25 March 1964 on medicinal products, Article 12f, subparagraph 2, introduced by the Law of 20 December 2019; |
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| Having regard to the communication to the European Commission of ...(date), 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; |
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| Having regard to the opinion of the Inspector of Finance, given on XX XX XXXX; |
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| Having regard to the agreement of the Secretary of State for the Budget, given on XX XX XXXX; |
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| Having regard to Notice No. XX.XXX/XX of the Council of State, given on XX XX XXXX, pursuant to Article 84(1), subparagraph 1, 2, of the Laws on the Council of State, coordinated on 12 January 1973; |
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| On the proposal of the Minister for Public Health, |
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| We have decreed and hereby decree: |
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| **Chapter 1. Scope, definitions and administrative provision** |
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| **Article 1.** This Order regulates the temporary export prohibitions applicable to wholesale distributors of medicinal products intended for the Belgian market, including wholesale distributors, where they do not hold the marketing authorisation for the medicinal products concerned, following a judgement notified or established in accordance with Article 6(1f) of the Law of 25 March 1964 on medicinal products, pursuant to Article 12f, paragraph 2, of the Law of 25 March 1964 on medicinal products. |
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| **Article 2.** For the application of the present Decree, the following definitions shall apply: |
| 1. " Law on Medicinal Products: the Medicines Act of 25 March 1964; |
| 1. ‘export’: parallel export or parallel distribution to another Member State of the European Economic Area (‘EEA’) of medicinal products intended for Belgium; |
| 1. ‘parallel export’: the export to another Member State of the European Economic Area (‘EEA’) for the placing on the market in that State of a medicinal product for which a marketing authorisation is granted in Belgium by a distributor independent of the holder of the marketing authorisation for the medicinal product and who has for that purpose a parallel import authorisation in that Member State of the European Economic Area (‘EEA’); |
| 1. ‘parallel distribution’:  the placing on the market in another Member State or in a State which is party to the Agreement on the European Economic Area (‘EEA’) and which has for that purpose a notification from the European Agency for the Evaluation of Medicinal Products for the parallel distribution of a medicinal product from Belgium for which a marketing authorisation is granted in accordance with Article 3 of Regulation (EC) No 726/2004 of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use, and establishing a European Medicines Agency, by a distributor independent of the holder of that authorisation, and who has for that purpose a notification issued by the European Agency for the Evaluation of Medicinal Products for Parallel Distribution; |
| 1. ‘unavailability’: unavailability within the meaning of Article 2(29) of the Royal Decree of 14 December 2006 on   medicinal products for human and veterinary use or interruption of placing on the market within the meaning of Article 2(30) of the same Royal Decree; |
| 1. ‘medicine intended for the Belgian market’: a medicine sold to a wholesale distributor who has a wholesale distribution authorisation pursuant to section 12b of the Drugs Act. |
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| **Article 3.** For the application of this Decree, the General Administrator of the FAMHP is designated as the Minister's delegate. |
| The Minister may also designate other members of the FAMHP staff as delegates, while indicating the limitation of powers delegated to them. |
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| **Chapter 2. Submission of the export of medicinal products for authorisation** |
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| **Art. 4, §1.** The Minister or his delegate may subject the export of medicinal products to the Belgian market for authorisation if all of the following conditions are met: |
| 1. the unavailability of the medicinal product has been notified to the FAMHP or has been identified by the FAMHP; |
| 1. the unavailability of the medicinal product concerned is likely or certain for a minimum of one month; |
| 1. the administration of the medicinal product is urgent and necessary, either immediately or within a few days, as the absence of an urgent diagnosis or treatment with the medicinal product may lead to acute or chronic physical or mental deterioration of health, which may consist of contracting of a disease, the progression of a disease, hospitalisation or more intensive treatment, or which may lead to other forms of damage such as physical or mental impairment or death; |
| 1. unavailability cannot or cannot be sufficiently addressed by other authorised medicinal products which have the same therapeutic effect, irrespective of the active substance. |
| §2. The Minister or his delegate shall define the period for which the authorisation referred to in paragraph 1 is required. This period may not exceed the expected period of unavailability. |
| If the Minister or his delegate finds that the unavailability ceases or has ended on a date prior to the anticipated period of unavailability referred to in paragraph 1, the end of the unavailability shall be published without delay on the FAMHP website. This publication on the FAMHP website shall automatically repeal the decision taken in accordance with paragraph 1. The Minister or his delegate shall publish the repeal of that decision to the Belgian Official Journal as soon as possible. |
| If the anticipated period of unavailability is subsequently extended, the Minister or his delegate may extend the period for which the authorisation referred to in paragraph 1 is required. This period may not exceed the expected period of unavailability. |
| §3. The decision of the Minister or his delegate under paragraph 1 shall be published in the Belgian Official Journal. |
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| **Chapter 3. Authorisation for the export of medicinal products** |
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| **Article 4.** If a medicinal product is subject to the authorisation referred to in Article 3, the wholesale distributor referred to in Article 1 shall, in advance, apply for authorisation to export the medicinal product to the FAMHP via the form published on the FAMHP website. |
| The application shall include at least the following elements: |
| 1. the name of the medicinal product; |
| 1. the number(s) of the MA(s) of the medicinal product; |
| 1. the size of the package(s) and the national code number(s) (CNK); |
| 1. the number of packages or doses to be exported, per MA number. |
| The data referred to in paragraph 2 shall be presumed to be business information which, by its nature, is confidential, as referred to in Article 6(1)(7) of the Law of 11 April 1994 on publicity of the administration. |
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| **Article 5(1).** The Minister or his delegate shall decide, on the basis of the request referred to in Article 4, to authorise or prohibit the export of the medicinal product, which has been the subject of the notification referred to in Article 4, within five working days from the day after receipt of the notification. |
| **§2.** The Minister or his or her delegate may request the person responsible for the notification to complete it if it does not include at least all the elements referred to in Article 4, paragraph 2. It may also request additional information which it deems necessary to take a decision. |
| In that case, the period of five working days referred to in paragraph 1 shall be suspended until receipt of the complete notification or additional information. The suspension shall start on the day following that of the request for additional information. |
| If the notification is not filled in correctly or if the questions do not receive an adequate answer, the notification shall be rejected. |
| **§3.** The export of the medicine is prohibited until the decision of the Minister or his delegate. |
| If the decision is not notified to the applicant within the period referred to in paragraph 1, export shall be authorised. |
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| **Article 6.** The Minister for Public Health shall be responsible for the implementation of this Decree. |
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| By the King: |
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| The Minister for Public Health, |
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| FRANK VANDENBROUCKE |