Ministerie van Volksgezondheid,
Welzijn en Sport

Regulation of the Minister for Health, Welfare and Sport, of date TBC, No TBC, amending the Medicines Act Regulation in connection with delivery on doctor's certificate and shortage decisions (Chain ID 27698)

The Minister for Health, Welfare and Sport,

Having regard to Article 40(3)(c) of the Medicines Act (Geneesmiddelenwet);

Hereby decrees the following:

Article I

The Medicines Act Regulation is amended as follows:

A

Article 3.17 is amended as follows:

1. The introductory wording of paragraph 1 now reads as follows:

1. The Health and Youth Care Inspectorate may grant an exemption as referred to in Article 40(3)(c) of the Act to a manufacturer, a wholesaler or a pharmacist regarding a medicinal product for which a marketing authorisation as referred to in Article 40(1) of the Act has not been granted, if:.

B

Article 3.17a now reads as follows:

Article 3.17a
1. The Health and Youth Care Inspectorate may grant a general waiver as referred to in Article 40(3)(c) of the Act to manufacturers, wholesalers and pharmacists regarding a medicinal product for which a marketing authorisation as referred to in Article 40(1) of the Act has not been granted if:
a. no adequate medicinal alternative to the medicinal product is available on the market or otherwise in the Netherlands;
b. the medicinal product is an adequate medicinal alternative to the medicinal product that is temporarily not available on the market or otherwise in the Netherlands; and
c. the medicinal product has a marketing authorisation in another Member State of the European Union, in the United Kingdom or in a country with a mutual recognition agreement.
2. The Health and Youth Care Inspectorate attaches to the general waiver a restriction regarding the period during which the medicinal product may be dispensed.
3. The Health and Youth Care Inspectorate may limit the general waiver with regard to the indications for which the medicinal product may be placed on the market.
4. The manufacturer, wholesaler or pharmacist concerned shall keep records recording the quantity of the medicinal product dispensed, the number of patients for whom the medicinal product is intended and the adverse reactions observed.

Article II

This Regulation shall enter into force on the date of entry into force of Article II(A) and (C) of the Health, Welfare and Sport (Miscellaneous Provisions) Act 2024.

This Regulation and the explanatory notes shall be published in the Government Gazette.

The Minister for Health, Welfare and Sport,

Explanation

I. General section

1. Introduction

The purpose of this amendment is to enable groups of patients to be effectively treated with similar medicinal products from abroad when necessary during medicinal product shortages. This amending regulation amends Articles 3.17 and 3.17a of the Medicines Act Regulation (hereinafter: the Regulation).

It is important that patients can be treated with the medicinal products that they need. Shortages of medicinal products can hinder effective and timely treatment. On 20 November 2024, the Administrative Jurisdiction Division of the Council of State (hereinafter: the Division) ruled on Article 3.17a of the Regulation, referred to as the article on the decree regarding shortages.[1] The Division declared said article to be non-binding because Article 40(3)(c) of the Medicines Act (hereinafter: the Act) did not provide a sufficient legal basis for the Regulation on the decree regarding shortages as set out in Article 3.17a of the Regulation. That ruling eliminated an important instrument for mitigating medicinal product shortages. This led to concerns among healthcare providers and patients, among others, about whether patients could still be treated in a timely and adequate manner during shortages. In addition, there were concerns about a sharp increase in the administrative burden, both for healthcare providers and for the Health and Youth Care Inspectorate (hereinafter: the Inspectorate).[2] As a response to this ruling, Article 40(3)(c) of the Act has now been amended.[3]

2. Main features of the amending order

A holder of a marketing authorisation is required to report an anticipated supply interruption of a medicinal product for which a marketing authorisation is valid in the Netherlands to the Reporting Centre for Medicinal Product Shortages and Defects (hereinafter: the Reporting Centre). The Reporting Centre is coordinated by the Medicines Evaluation Board (hereinafter: MEB) and the Inspectorate. For the handling of reports of anticipated medicinal product shortages, a roadmap has been drawn up indicating which solutions the Reporting Centre may investigate to prevent or mitigate medicinal product shortages.[4] The Reporting Centre assesses the anticipated interruptions in supply and checks, for each report, whether there are sufficient alternatives in the Netherlands or whether there are alternatives that can become available if a medicinal product is temporarily unavailable. This includes the same medicinal product from another manufacturer, one in another pharmaceutical form or strength, or another active substance for the same use.

If there are insufficient alternatives for patients to deal with a supply problem and there is a life-threatening or very serious condition, or if the shortage has a major impact on patients, the Reporting Centre refers to it as a critical shortage. The Reporting Centre will then investigate whether measures can be taken to limit the adverse consequences of shortages for patients.

The solutions explored may involve medicinal products authorised to be placed on the market in the Netherlands, or solutions in the form of a new authorisation for a medicinal product. However, a new application for authorisation, including through

[1] Ruling 202201407/1/A3 of 20 November 2024, ECLI:NL:RVS:2024:4766.

[2] Parliamentary Papers II, 2024/25, 28477, No. 914.

[3] Parliamentary Papers II, 2024/25, 36682, No 2. **Replace TBC with reference to the Bulletin of Acts and Decrees (Stb).**

[4] Parliamentary Papers II, 2016/17, 29477, No 426.

a shortened procedure, takes time. This means that new authorisations are not suitable for acute and/or short-term shortages. In addition, the initiative as regards various authorisation applications lies with the (foreign) authorisation holder. The possibility of an authorisation being granted for public health reasons also does not provide a sufficient remedy in practice.[5] This instrument is primarily intended for situations where the medicinal product in question is not yet on the market in the Netherlands, but in another Member State and only in situations where public health is at stake. However, in the event of a shortage, there is usually a medicinal product that has already been authorised in the Netherlands, but is temporarily not sufficiently available. In addition, there must be a proposed authorisation holder, and said holder must also be able to take sufficient responsibility for the quality of the product after registration and for pharmacovigilance.

In addition, the MEB may grant permission for a Temporary Deviating Packaging (TDP): a foreign packaging of the same medicinal product instead of a Dutch packaging. However, the TDP may be issued only for the exact same medicinal product for which a shortage has arisen. If the holder of the marketing authorisation does not have a marketing authorisation for the medicinal product in question in another country, the medicinal product may not be made available to patients in the Netherlands via a TDP.

Finally, the Reporting Centre also investigates solutions in the form of medicinal products that are not registered in the Netherlands, such as pharmacy preparations[6] or parallel imports.[7] There are statutory restrictions as regards pharmacy preparations. For example, a pharmacy may prepare solely for its own patients and on a small scale. In the event of several shortages, this capacity is insufficient to meet the full demand, either quickly enough or in the required quantities. Finally, parallel imports on the basis of a parallel marketing authorisation also do not always offer a solution. In addition to the fact that the application and assessment process of the parallel marketing authorisation takes time and the initiative for this lies with the holder of the marketing authorisation, there are few guarantees that this holder of the marketing authorisation can actually import sufficient quantities to cover the shortfall fully.

The above solutions should be explored in order to determine the extent to which those solutions constitute an appropriate medicinal alternative marketed in the Netherlands or otherwise available as referred to in the Regulation. For the sake of completeness, it is noted that the statutory solutions as described above take precedence over solutions based on a policy of tolerance, such as collegially supplied preparations.[8]

Due to the restrictions as regards the solutions mentioned above, it is necessary in certain cases to be able to switch to similar medicinal products from abroad in order to be able to treat patients adequately. Having regard to the Division's ruling, it has no longer been possible to use the 'decree regarding shortages' for that purpose since 20 November 2024. As a result, it was necessary to fall back on 'delivery on doctor's certificate'.[9,10] However, this leads to risks for patients. In the case of 'delivery on doctor's certificate', the Inspectorate's consent is required for

[5] Article 52 of the Act.

[6] As referred to in Article 40(3)(a) of the Act.

[7] As referred to in Article 48 of the Act.

[8] Decree of the Minister for Health, Welfare and Sport of 28 November 2024, ref. 4013782-1075740-GMT, on non-enforcement action against the collegial supply and provision of pharmacy preparations (Policy Rule on collegial supply and provision of pharmacy preparations), Government Gazette 2024, 39917.

[9] The introductory wording and paragraph 3(c) of Article 40 of the Act in conjunction with Article 3.17 of the Regulation.

each patient. Each application must be assessed separately by the Inspectorate and it is only after the authorisation has been granted that various actions, such as the import of the medicinal product from abroad, may take place. All these steps take time, which means that this solution arrives too late for some patients. In addition, the administrative burden associated with this route, for both healthcare providers and the Inspectorate, is very high, especially with shortages that affect many, sometimes (hundreds of) thousands of patients. An example of this is the shortage of salbutamol, a medicinal product that is used by 850 000 asthma patients in the Netherlands every year for breathlessness. If the event of a shortage of salbutamol where other solutions do not prove sufficient, it may be necessary to decide that these patients must be able to switch to a similar medicinal product from abroad. A report by the Stichting Farmaceutische Kengetallen (Dutch Foundation for Pharmaceutical Statistics - SFK) shows that between April 2024 and November 2024 some 180 000 patients were eventually helped by imports of salbutamol aerosols from abroad.[11] If this is not possible with a general waiver, individual permission should be requested (by the healthcare provider) and granted (by the Inspectorate) for each of these patients. The associated administrative burden is considerable.

It is, therefore, in the interest of patients, healthcare providers and the Inspectorate, among others, that an additional solution is available for situations where other instruments to mitigate medicinal product shortages are inadequate. Article 3.17a of the Regulation offers this solution, by making it possible to grant a general waiver from the prohibition on carrying out various actions with unregistered medicinal products. As a result, similar medicinal products from abroad may be used.

The amendment of Article 3.17a of the Regulation takes into account the experience gained from the previous order as regards the Regulation on the decree regarding shortages. The conditions now laid down in Article 3.17a of the Regulation are, therefore, based on the method used at the time, which has proved to be effective in practice.

In addition, Article 3.17 of the Regulation is amended (concerning the ‘delivery on doctor’s certificate’). With the aforementioned adjustment in Article 40(3)(c) of the Act, a distinction is made in Article 40 between granting an exemption in individual cases and granting of a general waiver. The wording of the introduction to Article 3.17 of the Regulation has been amended accordingly. The conditions under which such an exemption may be granted are unchanged.

3. Relationship to higher law

The basis for Article 3.17a of the Regulation is the introductory wording and paragraph 3(c) of Article 40 of the Act. This paragraph constitutes an implementation of Article 5(1) of the Medicinal Products Directive.[12]

Article 5(1) of the Medicinal Products Directive allows Member States not to apply provisions of the Directive to fulfil special needs. An important starting point of the Medicinal Products Directive is (in short) that use is made only of medicinal products for which a marketing authorisation has been granted in the Member State concerned. Article 5(1) of the Medicinal Products Directive sets out the

[10] The Minister for Health, Welfare and Sport has given the Inspectorate an instruction not to take enforcement action. Government Gazette 2024, 39386.
[11] *300 000 people assisted by temporary authorisation* (2024, 12 December). Stichting Farmaceutische Kengetallen. See also:
[12] 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.

conditions under which Member States may derogate from it. A core aspect of this is the presence of ‘special needs’. Therefore, it fits within this system that other alternatives have first been considered before invoking an exception such as the present one.

Making medicinal products available under this general waiver does not affect the professional consideration made by doctors when prescribing them. The doctor remains responsible for prescribing a medicinal product and, even when applying this general waiver, shall continue to do so at their own initiative and for each individual patient.

4. Regulatory burden

One of the objectives of the amendment to the Regulation is to keep the regulatory burden manageable. If this amendment is not implemented, it will be necessary to fall back on the ‘delivery on doctor’s certificate’ for shortages that require switching to similar medicinal products from abroad. However, some shortages affect (hundreds of) thousands of patients. Under the ‘delivery on doctor’s certificate’, individual consent must then be requested (by the healthcare provider) and given (by the Inspectorate) for each patient prior to dispensing. This amendment, therefore, does not increase the regulatory burden, but rather keeps it as manageable as possible for both healthcare providers and the Inspectorate.

The Advisory Board on Regulatory Burden has been asked for advice. The Advisory Board has decided not to select the file for a formal opinion.

5. Implementation, supervision and enforcement

Supervision of compliance with Article 18 and Article 40 of the Act is assigned to the Inspectorate.[13] In the context of its supervisory duties, the Inspectorate has the general supervisory powers laid down in Title 5.2 of the Dutch General Administrative Law Act (Algemene wet bestuursrecht). The Inspectorate already has the power to impose administrative measures by virtue of a mandate from the Minister.[14]

It is the role of the Inspectorate to examine the extent to which the conditions have been met and to grant the general waiver. The Inspectorate already has experience in carrying out the necessary investigations, partly in cooperation with the MEB, and in taking such a decision.

The Inspectorate was asked to submit a supervision and enforceability test on a draft of the Regulation. **[TBC description of advice and processing].**

6. Consultation

A draft of the current legislative proposal has been submitted for Internet consultation on **xxx** for a period of four weeks. **[TBC description of reactions and processing].**

In addition, the Regulation was notified to the European Commission on **xxx. [TBC description of reactions and processing]**.

7. Entry into force

The aim is to bring this Regulation into force as soon as possible so that there is a formal legal basis for ‘shortage decisions’. A period between publication and entry into force is not necessary in this case, because all parties involved are aware and

[13] Article 100(1) of the Act.

[14] Article 15a(3) of the Health, Welfare and Sport (Mandate) Regulation.

experienced in applying for or granting such general waivers. This Regulation shall enter into force at the same time as Article II, Parts A and C of the Health, Welfare and Sport (Miscellaneous Provisions) Act 2024 by means of a Royal Decree.

II Explanatory notes by article

Article I, Part A (Article 3.17)

Article 3.17(1) has been amended to bring the wording back into line with the basis in the Act.

Article I, Part B (Article 3.17a)

Article 3.17a has been laid down anew. The Article sets out the conditions to be assessed when granting the general waiver. In short, for example, there must be a lack of an appropriate medicinal alternative. A general waiver may not, therefore, be granted when there is a shortage of a medicinal product from a specific manufacturer, but a similar medicinal product from another manufacturer is obtainable to a sufficient degree, for example a generic medicinal product.

In addition, the general waiver may be granted only for medicinal products that do indeed constitute an appropriate medicinal alternative to the medicinal product for which there is a shortage. This will often be a medicinal product with the same active substance, strength and form of administration. Whether there is an appropriate medicinal alternative is to be assessed by the Inspectorate – where necessary in consultation with other parties, such as the MEB – and may be assessed differently for different medicinal products. Finally, the medicinal product must have a marketing authorisation in another Member State of the European Union, in the United Kingdom or in a country with a *mutual recognition agreement*. This ensures, among other things, that these are medicinal products that have been pre-tested for, among others, quality, efficacy and safety.

It follows from the basis in the Act that the general waiver is of a temporary nature.[15] The Inspectorate may, however, extend the general waiver, indicating for each extension the period of time to which the extension applies. In addition, the Inspectorate may attach a restriction to the general waiver with regard to the indications (paragraph 2). That is to say, the medicinal products covered by the exemption may be dispensed solely for patients with those specific indications.

Paragraph 4 states that the manufacturer, wholesaler or pharmacist that supplies medicinal products from another country to pharmacists in the Netherlands on the basis of the general waiver must keep records. The quantity of the medicinal product, the number of patients for whom the medicinal product is intended and the adverse reactions observed must be recorded. This can provide valuable information on the effectiveness of the instrument of a decree regarding shortages. Manufacturers and wholesalers are no longer required to keep records of the names of doctors, as this is already being administered by pharmacists. With regard to the administrative obligations, this does not mean that separate records must necessarily be kept. It is important that the requested data can be made retrieved from the parties' records.

[15] Having regard to Article 40(3)(c) of the Medicines Act.