Preamble

Objective(s)

- Safeguarding the supply of medicinal products
- Mitigating or preventing shortages of medicinal products due to future supply bottlenecks

Supply bottlenecks and shortages of medicinal products, in particular with respect to medicinal products for human use that require a prescription, are a global problem that has been repeatedly encountered in the past and became increasingly apparent again in the light of the COVID-19 pandemic and the related delays in the supply chain. In addition, the situation has been exacerbated by an exceptionally high wave of infection (European/global) in the 2022/23 winter season.

Stockpiling defined medicinal products for human use in Austria is intended to prevent shortages of medicinal products caused by supply bottlenecks and to safeguard the supply of medicinal products in Austria.

Contents

The proposed legislation consists mainly of the following measure(s):

- Obligation imposed on marketing authorisation holders to stockpile medicinal products for human use
- Obligation imposed on marketing authorisation holders to notify the Federal Office for Safety in Health Care (BASG) (see Section 4 of the Ordinance)

Measure 1 obligates marketing authorisation holders to stockpile defined medicinal products for human use in Austria. This obligation covers medicinal products for human use that are actually placed on the market in Austria and that marketing authorisation holders also distribute.

Measure 2 imposes an obligation on marketing authorisation holders to notify the BASG. This obligation includes notification of annual demand as referred to in Section 2(2) of the Ordinance and notification if there is a shortfall below the mandated minimum storage quantity per medicinal product.

Material impacts

In accordance with the submission to the cabinet on 25 July 2023 and in order to safeguard the supply of medicinal products in Austria, an obligation is to be imposed on the pharmaceutical industry to keep in stock, for the longer term, sufficient quantities of medicinal products that are relevant for medical care in Austria. The additional costs incurred in this respect shall be borne by the public purse.

Financial impact on the federal budget and other public budgets:

The starting point is medicinal products that are critical for medical care. For these, a four-month period of stockpiling in Austria is envisaged in accordance with the Annex to the draft Ordinance (a total of 721 medicinal products). According to calculations by the Austrian National Public Health Institute, Gesundheit Österreich GmbH, approximately 75 marketing authorisation holders are affected. Based on this data and assuming that undertakings currently hold stocks for three months (3-4 months coverage/product according to industry data), the Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGPK) would have to cover additional costs for an additional month of stockpiling, at least in the initial phases after the entry into force of the Ordinances, in order to ensure the total stockpiling period of four months mandated by the Ordinance for the selected medicinal products. To start with, an initial compensation payment for a period of three years is envisaged, which is to be

evaluated at the end of this period. Due to transitional periods and the EU notification obligation, the Ordinance is only expected to enter into force at the end of 2024.

Parameters used (based on the product list in the Ordinance, 2022):

1. Basis for calculating the stock value: 100 % of the ex-factory price of the medicinal products concerned

2. Storage cost rate of 5 % for additional risk, administrative and maintenance costs and additional costs for storage-related insurance

3. Interest on tied capital 4 % (base Euribor) plus 0.25 percentage points (supplement)

4. Calculation based on one month of additional financial burden from stockpiling

Using these parameters and based on the ex-factory price of the 721 selected products, an annual total cost of approximately EUR 3 million will be incurred.

Possible deviation from the operating and financing budget:

Due to the lack of reliable business indicators from the industry, these calculations are based only on a rough estimate assuming careful, appropriate and economical financial management (see parameters). Evaluation after two years is envisaged, with adjustment at the end of this period if need be

Financing budget for the first five years

in EUR thousands	2023	2024	2025	2026	2027
Net federal financing	**0**	**0**	**-3,000**	**-3,000**	**-3,000**

Impact on businesses:

Supply bottlenecks and shortages of medicinal products, in particular with respect to medicinal products for human use that require a prescription, are a global problem that has been repeatedly encountered in the past and became increasingly apparent again in the light of the COVID-19 pandemic and the related delays in the supply chain. In addition, the situation was further exacerbated by an exceptionally high wave of infection in Europe/worldwide last autumn.

The Ordinance requires defined medicinal products for human use to be stockpiled, stockpiled quantities to be monitored and any shortfalls in the stockpiled quantities to be notified. The aim is to safeguard the supply of these medicinal products for human use to the population. To this end, marketing authorisation holders will have to notify any shortfalls in the required quantities. Such a shortfall could be caused, for example, by the following two situations: a) unforeseen increased demand due to supply to patients (e.g. waves of infection in autumn/winter) or b) a supply bottleneck that the marketing authorisation holder has already experienced.

All persons residing in Austria who have additional demand for medicinal products in the cases indicated above are affected.

This constraint on the free movement of goods and on marketing authorisation holders’ freedom to carry on a business serves the important and overriding interest of protecting public health (see Article 81 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, which sets the objective of the free movement of goods against the protection of public health). In line with the principle of proportionality, the stockpiling obligation is limited to the absolutely necessary extent (restricted to prescription-only medicinal products for human use, narrow and targeted objective criteria, time limit by specifying a product-specific stockpiling period) in order to safeguard an adequate and continuous supply of medicinal products to the population in an emergency.

This Ordinance is subject to a notification procedure within the meaning 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 (OJ L 241, 17.9.2015, p. 1).

The text has no significant impact on the other categories under § 17(1) of the Federal Budget Act 2013 [BHG 2013].

Relationship to European Union legislation

This constraint on the free movement of goods and on marketing authorisation holders' freedom to carry on a business serves the important and overriding interest of protecting public health (see Article 81 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, which sets the objective of the free movement of goods against the protection of public health). In line with the principle of proportionality, the stockpiling obligation is limited to the absolutely necessary extent (restricted to prescription-only medicinal products for human use, narrow and targeted objective criteria, time limit by specifying a product-specific stockpiling period) in order to safeguard an adequate and continuous supply of medicinal products to the population in an emergency.

Special features of the legislative procedure:

This Ordinance is subject to a notification procedure within the meaning 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 (OJ L 241, 17.9.2015, p. 1).

Data protection impact assessment as per Article 35 of the General Data Protection Regulation

None

Outcome-oriented impact assessment

Ordinance of the Federal Minister for Social Affairs, Health, Care and Consumer Protection concerning the stockpiling of medicinal products for human use

Submitting body:	BMSGPK
Project type:	Regulation
Current fiscal year:	2023
Entry into force/ effective date:	2024

Contribution to outcome objective or measure in the federal budget

The draft legislation contributes to the outcome objective ‘Ensuring the promotion, preservation and restoration of the health of the entire population with particular attention to infectious diseases, chronic and mental illnesses and taking into account specific target groups (e.g. children).’ of Subdivision 24 Health in the federal budget of 2023.

Analysis of the problem

Problem definition

Supply bottlenecks and shortages of medicinal products, in particular with respect to medicinal products for human use that require a prescription, are a global problem that has been repeatedly encountered in the past and became increasingly severe again in the light of the COVID-19 pandemic and the related delays in the supply chain. In addition, an exceptionally high wave of infection across Europe/worldwide in the 2022/2023 winter season has further exacerbated the situation.

The Ordinance requires defined medicinal products for human use to be stockpiled, stockpiled quantities to be monitored and any shortfalls in the stockpiled quantities to be notified. The aim is to safeguard the supply of these medicinal products for human use to the population. To this end, marketing authorisation holders will have to notify any shortfalls in the required quantities. Such a shortfall could be caused, for example, by the following two situations: a) unforeseen increased demand due to supply to patients (e.g. waves of infection in autumn/winter) or b) a supply bottleneck that the marketing authorisation holder has already experienced.

All persons residing in Austria who have additional demand for medicinal products in the cases indicated above are affected.

Do nothing scenario and possible alternatives

Particularly in light of experience during the COVID-19 pandemic, there is a need to stockpile medicinal products that are critical for medical care in Austria. The effectiveness of this measure has also been demonstrated by international examples; similar measures are either already in place in many EU Member States (including DE, FI, FR, PT, NL) or are currently being implemented.

Since supply bottlenecks are caused by many different factors and are therefore difficult to foresee, stockpiling of care-critical medicinal products for human use is urgently required from a health policy perspective in order to better mitigate the prevailing shortages, for example of essential (child) antibiotics and to safeguard patient care in Austria.

If no action is taken, there will still be a risk of patients not being adequately treated in the event of shortages of medicinal products – or not being treated at all in an extreme scenario.

Available studies/impact assessments

Stockpiling of (critical) medicinal products is a common measure used to manage and address supply bottlenecks which has already been introduced by a number of European countries for selected medicines. Some countries already had this measure in place before the COVID-19 pandemic (e.g. Lithuania, Switzerland), while others have introduced stockpiling obligations more recently (e.g. the Netherlands). Finland is considered to be an example of international best practice; for decades pharmaceutical companies and wholesalers in Finland have been under an obligation to stockpile. The Finnish system compensates companies for the increased storage costs. Before stockpiling was introduced, companies expressed their concerns that they would no longer be able to operate economically because of the higher costs. This has not been borne out by the evidence. Having said that, no study has been found that would have explicitly examined the market structure before and after the stockpiling was introduced.

Overview of countries with stockpiling

Survey of the PPRI network in spring 2020/Information on 24 European countries: Vogler S, Fischer S.: How to address medicines shortages: Findings from a cross-sectional study of 24 countries. Health Policy 2020; 124(12): 1287-1296, https://www.sciencedirect.com/science/article/pii/S0168851020302256

Studies – country examples

Finland:

For background information on the Finnish system: see the website of the Medicines Agency with a brief summary in English and link to the legislation (in Finnish): https://www.fimea.fi/web/en/supervision/mandatory_reserve_supplies and see the National Emergency Supply Agency (NESA) website for details of financial compensation: https://www.huoltovarmuuskeskus.fi/en/organisation/funding-and-legislation

Netherlands:

Biedermann 2020, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01421-0/fulltext

Analyses and evaluations on the topic

Articles by employees of the Finnish Medicines Agency:

Sarnola, K., Linnolahti, J. A regulatory perspective on the availability of medicines and medicine shortages in outpatient care: case Finland. Int J Clin Pharm 41, 825-830 (2019). https://doi.org/10.1007/s11096-019-00850-2

Youssef Zad Mandatory reserves system and the pricing of pharmaceutical products in Finland, 2020, https://jyx.jyu.fi/bitstream/handle/123456789/69770/1/URN%3ANBN%3Afi%3Ajyu-202006084027.pdf

Technopolis report commissioned by the European Commission:

Vis C, Pelsy F, Dijkstal F, Petrosova L, Davé A, Spit W, et al. Future-proofing pharmaceutical legislation: study on medicine shortages: final report. Brussels: European Commission Directorate-General for Health Food Safety, Publications Office, 2021. https://data.europa.eu/doi/10.2875/211485

No dedicated impact assessment at European level is known.

Internal evaluation

Date of internal evaluation: 2026

Evaluation documents and method: The period of two years was chosen in order to be able to carry out a representative assessment of the impact of the measures adopted. The data to be collected includes

notifications by companies who are required to stockpile as mandated by the Ordinance, as well as various feedback from any stakeholders. On the basis of this and other data to be determined, any adjustment to the Ordinance will be examined.

Objectives

Objective 1: Safeguarding the supply of medicinal products

Description of the objective:

Shortages of medicinal products due to supply bottlenecks, which could jeopardise the supply of medicinal products for human use to the population, are to be counteracted by organisationally suitable and economically acceptable measures.

A successful outcome would be:

Initial situation at the time of the outcome-oriented impact assessment	Target situation at the time of the evaluation
There are currently no sufficiently specific legal requirements for the stockpiling of medicinal products for human use. The purpose of the Ordinance is to specify in detail existing legal provisions, in particular Section 57a(1) of the Medicinal Products Act (AMG). As a result, stockpiling of critical medicinal products by marketing authorisation holders in Austria will be mandatory for the duration specified in the Annex for medicinal products (currently 4 months).	Due to this Ordinance on stockpiling, sufficient stocks of selected medicinal products for human use will be available so as to maintain the continuous supply of medicinal products to patients in Austria in the event of supply bottlenecks or to mitigate longer-term supply shortages accordingly. Such stockpiling is based on recommendations by an expert group put together for this purpose, which determines the medicinal products that are to be stockpiled and for how long. In addition, a suitable system for providing notification to the BASG is being implemented. The BASG is tasked with the necessary evaluations and analyses, which are to be made available to the BMSGPK.

Objective 2: Mitigating or preventing shortages of medicinal products due to future supply bottlenecks

Description of the objective:

In addition to the general improvement in safeguarding the supply of critical medicinal products (see Objective 1), the stockpiling of defined medicinal products in Austria is also intended to prevent future shortages of medicinal products. The aim here is to ensure that the population is supplied with medicinal products not only in the medium term but also in the long term.

A successful outcome would be:

Initial situation at the time of the outcome-oriented impact assessment	Target situation at the time of the evaluation
Although current supply bottlenecks can be tracked on the basis of the Ordinance Safeguarding the Supply of Medicinal Products, BGBl. (Federal Law Gazette) II No 30/2020, and a parallel export ban can be imposed where applicable, no stockpiling of medicinal products that have proven to be particularly critical, over and above usual	By means of an obligation to stockpile defined medicinal products for human use shortages of medicinal products caused by future supply bottlenecks can be mitigated and the risk of shortages in the supply medicinal products to patients in Austria can be minimised.

levels, is provided for.

Measures

Measure 1: Obligation imposed on marketing authorisation holders to stockpile medicinal products for human use

Description of the measure:

Marketing authorisation holders are required to stockpile defined medicinal products for human use in Austria. This obligation covers medicinal products for human use that are actually placed on the market in Austria and that marketing authorisation holders also distribute.

Implementation of Objective 1, 2

Measure 2: Obligation imposed on marketing authorisation holders to notify the Federal Office for Safety in Health Care (BASG) (see Section 4 of the Ordinance)

Description of the measure:

The notification obligation includes

1. notification of annual demand as referred to in Section 2(2) of the Ordinance

2. notification if there is a shortfall below the required minimum storage quantity per medicinal product

Implementation of Objective 1, 2

Impact assessment

Financial impact on all administrative units and social security institutions

Financial impact for the Federal Government

– Operating budget

in EUR thousands	2023	2024	2025	2026	2027
Transfer costs	0	0	3,000	3,000	3,000
Total costs	**0**	**0**	**3,000**	**3,000**	**3,000**

The starting point is medicinal products that are critical for medical care. For these, a four-month period of stockpiling in Austria is envisaged in accordance with the Annex to the draft Ordinance (a total of 721 medicinal products). According to calculations by the Austrian National Public Health Institute, Gesundheit Österreich GmbH, approximately 75 marketing authorisation holders are affected. Based on this data and assuming that undertakings currently hold stocks for three months (3-4 months coverage/product according to industry data), the Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGPK) would have to cover additional costs for an additional month of stockpiling, at least in the initial phases after the entry into force of the Ordinances, in order to ensure the total stockpiling period of four months mandated by the Ordinance for the selected medicinal products. To start with, an initial compensation payment for a period of three years is envisaged, which is to be evaluated at the end of this period. Due to transitional periods and the EU notification obligation, the Ordinance is only expected to enter into force at the end of 2024.

Parameters used (based on the product list in the Ordinance, 2022):

1. Basis for calculating the stock value: 100 % of the ex-factory price of the medicinal products concerned

2. Storage cost rate of 5 % for additional risk, administrative and maintenance costs and additional costs for storage-related insurance

3. Interest on tied capital 4 % (base Euribor) plus 0.25 percentage points (supplement)

4. Calculation based on one month of additional financial burden from stockpiling

Using these parameters and based on the ex-factory price of the 721 selected products, an annual total cost of approximately EUR 3 million will be incurred.

Possible deviation from the operating and financing budget:

Due to the lack of reliable business indicators from the industry, these calculations are based only on a rough estimate assuming careful, appropriate and economical financial management (see parameters). Evaluation after two years is envisaged, with adjustment at the end of this period if need be

The draft legislation does not have any financial implications for provinces, municipal authorities and social security institutions.

Businesses

Impact on cost and revenue structure

Businesses will incur additional costs due to the stockpiling obligation under this Ordinance, determined by the following parameters:

Parameters used (based on the product list in the Ordinance, 2022):

1. Basis for calculating the stock value: 100 % of the ex-factory price of the medicinal products concerned

2. Storage cost rate of 5 % for additional risk, administrative and maintenance costs and additional costs for storage-related insurance

3. Interest on tied capital 4 % (base Euribor) plus 0.25 percentage points (supplement)

4. Calculation based on one month of additional financial burden from stockpiling

These additional costs are based on estimates by the BMSGPK and can only be assessed after two years against the background of the notification requirements and the envisaged evaluation. There are no reliable figures from the industry.

Quantitative impact on the cost and revenue structure of businesses

Group affected	Number of cases	Charge/discharge per case/company	Total	Explanation
Marketing authorisation holders pursuant to Section 57a AMG	75	40,000	3,000,000	Estimated average additional costs p.a. per business concerned

Annex

Detailed presentation of the financial impact

Coverage

in EUR thousands	2023	2024	2025	2026	2027
Payments/amount to be covered			3,000	3,000	3,000

in EUR thousands	Detail budget concerned	From detail budget	2023	2024	2025	2026	2027
according to Medium-Term Budgeting Framework Act (BFRG)/Federal Budget Act (BFG)	24.		0	0	3,000	3,000	3,000

Explanation of coverage

The submission to the cabinet entitled ‘Immediate health reform package measures’ of 25 July 2023 contains the commitment to cover the costs incurred from the public purse. Around EUR 3 million per year is estimated for covering the additional costs caused by the envisaged Ordinance (around EUR 9 million in total for three years). A budgetary commitment would have to be clarified in the course of drawing up the budget for 2025 onwards.

Project – Transfer costs

Entity (in EUR)	2023	2024	2025	2026	2027
Federal Government			3,000,000.00	3,000,000.00	3,000,000.00

		2023		2024		2025		2026		2027	
Designation	Entity	Recip.	Cost (€)	Recip.	Cost (€)	Recip.	Cost (€)	Recip.	Cost (€)	Recip.	Cost (€)
Compensation for additional costs arising from the Ordinance (additional storage of medicinal products)	Federal Government					75	40,000.00	75	40,000.00	75	40,000.00

The starting point is medicinal products that are critical for medical care. For these, a four-month period of stockpiling in Austria is envisaged in accordance with the Annex to the draft Ordinance (a total of 721 medicinal products). According to calculations by the Austrian National Public Health Institute, Gesundheit Österreich GmbH, approximately 75 marketing authorisation holders are affected. Based on this data and assuming that undertakings currently hold stocks for three months (3-4 months coverage/product according to industry data), the Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGPK) would have to cover additional costs for an additional month of stockpiling, at least in the initial phases after the entry into force of the Ordinances, in order to ensure the total stockpiling period of four months mandated by the Ordinance for the selected medicinal products. To start with, an initial compensation payment for a period of three years is envisaged, which is to be evaluated at the end of this period. Due to transitional periods and the EU notification obligation, the Ordinance is only expected to enter into force at the end of 2024.

Parameters used (based on the product list in the Ordinance, 2022):

1. Basis for calculating the stock value: 100 % of the ex-factory price of the medicinal products concerned
2. Storage cost rate of 5 % for additional risk, administrative and maintenance costs and additional costs for storage-related insurance
3. Interest on tied capital 4 % (base Euribor) plus 0.25 percentage points (supplement)
4. Calculation based on one month of additional financial burden from stockpiling

Using these parameters and based on the ex-factory price of the 721 selected products, an annual total cost of approximately EUR 3 million will be incurred.

Possible deviation from the operating and financing budget:

Due to the lack of reliable business indicators from the industry, these calculations are based only on a rough estimate assuming careful, appropriate and economical financial management (see parameters). Evaluation after two years is envisaged, with adjustment at the end of this period if need be

Information on materiality

In the opinion of the submitting authority, this draft has no significant impact on the following impact categories, within the meaning of Annex 1 to the Basic Ordinance on Outcome-Oriented Impact Assessments [WFA-Grundsatzverordnung].

Impact category	Impact subcategory	Materiality criterion
Administrative costs	Administrative costs incurred for businesses	More than €100,000 in administrative costs per annum for all parties concerned

This impact assessment was prepared with version 5.12 of the EFC tool (hash ID: 273752596).