EU law analysis of the proposed Swedish stockpiling obligation on parallel importers of medicinal products

1. Introduction

In April 2021, Affordable Medicines Europe was notified by its Swedish member, Läkemedelshandlarna, of a proposal for a Swedish law obliging marketing authorisation holders ("**MAHs**") and parallel importers to hold six months' worth of stock in Sweden as a means of preventing medicinal shortages.

There is a concern that if the proposed law comes into force, it may cause the Swedish parallel import industry to disappear due to the burdensome nature of the measures.

This paper analyses the legality of the proposed measure under EU law, namely Articles 34-36 of the Treaty on the Functioning of the European Union ("**TFEU**") which govern free movement of goods principles.

2. Factual background

On 9 August 2018, the Swedish Government established the "Healthcare Preparedness Inquiry" (hereinafter, the "**Inquiry**").[1] The Inquiry has been tasked with conducting a review of the preparedness of the Swedish healthcare system before and during serious events in peacetime and at times of heightened alert, and with submitting proposals for how the capacity of the healthcare system to tackle this type of event should be improved in the long term. The Inquiry is also to consider measures to prevent and address situations in which there is a shortage of medicines when supplies are not affected by a serious event.

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[1] Delbetänkande av Utredningen om hälso- och sjukvårdens beredskap (Interim report of the Inquiry into Health Care Preparedness), Stockholm 2021, SOU 2021:19, p.45.

The Inquiry submitted its Interim Report (the "**Interim Report**") in March 2021.[2] The Interim Report includes a *Proposal for a law on the obligation to stock medical products* (the "**Proposal**"). The most relevant elements of the Proposal for the purposes of this paper are as follows:

- The stated aim of the Proposal is *"[t]o achieve expanded stockpiling of such healthcare products required in crises and times of war for such healthcare that cannot be postponed […]".*[3]

- MAHs and parallel importers would have an obligation to maintain a certain stated level of stock in Sweden.[4] The amount of stock kept must correspond to **six months'** normal cycling.[5]

- Products held in stock shall correspond to the products sold in the previous calendar year.[6]

- The quantities to be stockpiled shall usually be calculated for each stockholder on the basis of the stockholder's average historical sales or purchases of the medicinal product.[7]

- The Government, or a Government-appointed body, has the discretion to prescribe a different period for the storage of a medicinal product than six months and to prescribe the calculation of quantities on the basis of other than the average historical sales or purchases of a health care product by the person liable to stockpile.[8]

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2 Delbetänkande av Utredningen om hälso- och sjukvårdens beredskap (Interim report of the Inquiry into Health Care Preparedness), Stockholm 2021, SOU 2021:19.

3 Interim Report, p.52.

4 Proposal, Chapter 3(1).

5 Proposal, Chapter 3(8).

6 Proposal, Chapter 3(8). This stock level may be adjusted if the consumption of a medical product decreases by 20 per cent or increases by 25 per cent during the period from 1 October of the previous calendar year to 31 March of the current year.

7 Proposal, Chapter 3(9).

8 Proposal, Chapter 3(15).

- Subject to a few exceptions,[9] **all prescription medicines in Sweden fall within the scope of the Proposal**. Generic medicines are exempted.

- While most prescription medicines would fall within the scope of the Proposal, **the Government "*may issue regulations on the medical products to be stocked*."**[10] The English language summary introducing the Proposal expands on this, stating: "*The Inquiry proposes that the National Board of Health and Welfare be tasked, in consultation with other actors concerned, especially municipalities, regions, the Swedish Medical Products Agency and the Swedish Armed Forces, with producing such data as is required to **enable the Government to decide on which healthcare products are to be stockpiled**. Such a mandate would also include **constantly assessing whether the scope of this range should be changed** considering Sweden's preparedness needs or medical developments*."[11]

- The stockholding must be carried out in Sweden.[12]

Despite the above, the Interim Report admits that parallel trade "*does not lend itself to a basis for good preparedness through stockholding. The current requirements therefore risk having economic consequences for parallel traders by reducing their ability to sell medicines in some cases*."[13] In addition the Interim Report states that

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[9] Proposal, Chapter 3(3). "*The obligation to stockpile according to § 2 does not apply to (1) medicinal products which are **covered by an exchange** pursuant to Section 21, first paragraph, of the Act (2002:160) on Benefits for Medicinal Products, etc, (2) medicinal products which, by decision of the Medical Products Agency or a court, are **interchangeable with another medicinal product**, if the consumption of the medicinal product does not amount to more than two per cent of the total consumption within the group of interchangeable medicinal products to which the medicinal product belongs, according to the calculation criteria set out in Section 9, (3) medicinal products whose authorised **shelf life is less than 24 months**, or (4) licensed medicinal products with the **same active substance, the same strength and the same pharmaceutical form** as a medicinal product which is authorised for sale in Sweden and which is normally available here*" (own translation from Swedish).

[10] Proposal, Chapter 3(13).

[11] Interim Report, p.53.

[12] Proposal, Chapter 3(10).

[13] Interim Report, pp.1121-1122.

"[t]*he expected savings of SEK 3-400 million are assumed to disappear completely*" as a result of the stockpiling obligation on parallel traders.[14]

Interested parties, such as Läkemedelshandlarna, will have an opportunity to provide comments on the Interim Report, including the Proposal, by 20 August 2021.

The Final Report is to be submitted to the Swedish Government by 28 February 2022.

3. Assessment of the Swedish Proposal under Articles 34 and 36 TFEU

The principle of the free movement of goods has been a key element in creating and developing the EU internal market. Articles 34 to 36 TFEU define the scope and content of the principle by prohibiting unjustified restrictions on intra-EU trade.

Article 34 TFEU encompasses imports of goods and products of any type.[15] The CJEU has repeatedly confirmed that parallel importations of medicines fall within the scope of Article 34 TFEU and has condemned State measures that restrict, without appropriate justification, parallel imports of medicines.[16] As the CJEU stated in *Glaxo* and in *Lelos*, parallel trade brings benefits not only to the health system but also to the final consumers of medicinal products, who have an increased choice of medicinal products at lower prices.[17]

Articles 34-36 TFEU deal with measures taken by the Member States. These provisions have been interpreted broadly to bind not only national authorities, but also all other authorities of a country, including local and regional authorities.[18]

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14 *Ibid*.

15 Case 7/68 *Commission v Italy*, ECLI:EU:C:1968:51.

16 Case C-15/74 *Centrafarm v Sterling*, EU:C:1974:114; cases C-267/95 and C-268/95, *Merck v Primecrown* EU:C:1996:468, para. 47.

17 Cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06, *GlaxoSmithKline Services v. Commission*, EU:C:2009:610, para. 62-64; C-468/06 *Sot. Lélos Kai Sia*, , EU:2008:504, para. 53.

18 Case C-1/90 *Aragonesa de Publicidad v Departamento de sanidad*, ECLI:EU:C:1991:327.

3.1 Articles 34 and 36 TFEU as the appropriate provisions for the legal assessment rather than Articles 49 or 56 TFEU

Certain national measures which fall within the rules governing the free movement of goods as laid down in Article 34-36 TFEU may at the same time fall within the scope of the provisions governing the freedom of establishment laid down in Article 49 TFEU and the freedom to provide (cross-border) services laid down in Article 56 TFEU.

When a national measure may affect more than one fundamental freedom, the Court of Justice of the EU ("**CJEU**") has often examined that measure in the light of one fundamental freedom only. For this purpose, it usually decides which of the fundamental freedoms prevails.[19]

While there is often no clear delineation, the European Commission ("**Commission**") has explained that where there is "*a significant impact on the making available of the product on the market*", Articles 34-36 TFEU may be more appropriate.[20]

In this case, as will be explained below, the Swedish Proposal would make it *de facto* harder – if not impossible – for imported medicines to be made available on the Swedish market. We therefore consider that Articles 34-36 TFEU would likely constitute more suitable provisions against which to analyse the Proposal.

3.2 The Proposal constitutes an infringement of Article 34 TFEU

Article 34 TFEU prohibits "*quantitative restrictions on imports and all measures having equivalent effect*" between Member States.

Article 34 TFEU applies both to national measures which overtly discriminate against imported goods as well as to national measures which in law seem to apply **equally to both domestic and imported goods, but in fact impose an additional burden on imports**.

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[19] Case C-20/03 *Burmanjer*, ECLI:EU:C:2005:307, para. 34.

[20] Commission Notice, Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) (2021/C 100/03), 23.3.2021, section 8.1.2.

Measures of equivalent effect to a quantitative restriction may also include any measures capable of **hindering market access**.[21] In this regard, the CJEU has stated:

> *"it is clear from the case law that a measure,* ***even if it does not have the purpose or effect of treating less favourably products from other Member States****, is included in the concept of a measure equivalent to a quantitative restriction within the meaning of Article 34 TFEU if it* ***hinders access to the market of a Member State of goods originating in other Member States****"* (emphasis added).[22]

This approach has been reflected in cases such as *Elenca,* in which the CJEU stated: "***the mere fact that an importer might be dissuaded from introducing or marketing the products in question in the Member State*** *concerned constitutes a restriction on the free movement of goods for the importer*".[23]

Finally in the Commission's 2021 Guide on the application of Articles 34-36 TFEU, it is stated that "[n]*ational requirements regulating the* ***stocking or storage of imported goods*** *may also amount to a violation of Article 34 TFEU if these measures affect imported goods in a discriminatory manner compared to domestic products*" (emphasis added). [24]

According to the information received from Läkemedelshandlarna, the Proposal will negatively affect parallel imported products more severely than originator products in two key respects:

1) Parallel importers have **no control over the availability** of the medicinal products that they parallel trade, given that they have no production of their own. Originator manufacturers, on the other hand, can far more easily plan in advance their levels of production to take into account stockpiling requirements.

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[21] Case C-110/05 *Commission v Italy*, ECLI:EU:C:2009:66, para 37, Case C-456/10 *ANETT*, ECLI:EU:C:2012:241 and Case C-148/15 *Deutsche Parkinson Vereinigung*, ECLI:EU:C:2016:776

[22] Case C-428/12 *Commission v Spain*, ECLI:EU:C:2014:218, para. 29.

[23] Case C-385/10 *Elenca*, EU:C:2012:634, para.22, and case law cited therein.

[24] Commission Notice, Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) (2021/C 100/03), 23.3.2021, section 4.2.

2) The **margins of parallel importers are much smaller** than those of manufacturers, as the former trade their products at full market value and must rely on price differences between countries, the krone exchange rate and the open market. In addition, with these small margins parallel importers have to pay for repackaging of imported products. A 6-month stockpiling obligation would therefore constitute a far great financial burden on parallel importers than manufacturers.

Although the same stockpiling requirements apply to both originator MAHs and parallel importers, the proposed measure imposes a far greater *de facto* burden on parallel importers and thus parallel imported goods.

In line with the wording of the CJEU in *Elenca*, parallel importers "*might be dissuaded from introducing or marketing the products in question"* in Sweden if the Proposal is brought into force.

Indeed, forced with the prospect of holding 6 months' of stock in Swedish territory, in a context of uncertain supply and demand, with small margins and no production, parallel importers would likely be strongly dissuaded from marketing products in Sweden, given the highly uncertain economic incentives to do so.

Moreover, the Interim Report itself admits that "[t]*he current requirements therefore risk having economic consequences for parallel traders by* ***reducing their ability to sell medicines in some cases***."[25]

In light of the above, **Swedish Proposal, once entered into force, would constitute a measure having equivalent effect to a quantitative restriction on imports, and thus would breach Article 34 TFEU**.

[25] Interim Report, pp.1121-1122.

3.3 The infringement is not justified under Article 36 TFEU and Article 81 of Directive 2001/83/EC

3.3.1 Article 36 TFEU

Article 36 TFEU lists the defences that could be used by EU Member States to justify national measures that impede cross-border trade: "*The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property*."

Article 36 TFEU allows national measures to take precedence over the free movement of goods only when they serve **legitimate aims** recognised by EU law, such as the protection of human health. Although taking measures to avoid medicinal shortages can be considered a legitimate way to protect public health,[26] **national authorities bear the burden of proof that the measures are based on genuine health concerns**,[27] which the CJEU has interpreted very narrowly in its case-law.[28] In addition, they have to prove the existence of a seriously considered health policy.[29]

Finally, and most importantly, the **national measure must be proportionate to the legitimate aim sought** and must not constitute means of arbitrary discrimination or disguised restriction. According to the case law of the CJEU, the proportionality test can be broken down into two cumulative sub-tests: (i) a **"suitability test"**, i.e. the means should be suitable to achieve the pursued end, and (ii) the **"necessity test"** which implies that the measure at stake may survive judicial scrutiny only on condition

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[26] Case C-324/93 *Evans Medical and Macfatlan Smith*, EU:C:1995:84, para. 37.

[27] Case C-90/86 *Zoni*, EU:C:1988:403. See also C-274/87 *Commission v Germany*, EU:C:1989:51, C-97/83 *Melkunie*, EU:C:1984:212 and C-473/98 *Toolex*, EU:C:2000:379.

[28] Case C-118/86 *Openbaar Ministerie v Nertsvoederfabriek Nederland*, EU:C:1987:424, para. 138

[29] Case C-40/82 *Commission v United Kingdom*, EU:C:1984:33.

that it is the least restrictive measure and there exists no less burdensome means of achieving the legitimate aim sought.[30]

3.3.2 Article 81 of Directive 2001/83/EC

Directive 2001/83/EC establishes harmonized rules regarding distribution of pharmaceutical products.[31] Paragraphs 2 and 3 of Article 81 of Directive 2001/83/EC state that:

> *"2. The holder of a marketing authorization for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State in question are covered.*
>
> *3. The arrangements for implementing this Article should, moreover, be justified on the grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules,* ***particularly those concerning the free movement of goods and competition****."*

Article 81 of Directive 2001/83/EC establishes an obligation to ensure continuous supply of authorized medicinal products to a given national market, which is imposed on MAHs as well as distributors "*within the limits of their responsibilities*". Pursuant to the third paragraph of Article 81, it is for each Member State to implement this obligation in national law having recourse to proportionate measures in relation to this objective and "*in compliance with the Treaty rules,* ***particularly those concerning the free movement of goods and competition***" (emphasis added). Member States shall ensure that national measures adopted are consistent with the obligations flowing from Article 81 of Directive 2001/83/EC.[32]

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30 Case C-296/15 *Medisanus d.o.o. v Slosna Bolnisnica Murska Sobota*, EU:C:2017:431, para 99.

31 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; OJ L 311, 28.11.2001, p. 67) ("**Directive 2001/83/EC**").

32 Case C-468/06 *Sot. Lélos Kai Sia*, EU:2008:504, para. 75.

Directive 2001/83/EC seeks to ensure free circulation of medicines within the EU internal market. In this regard, the preamble of Directive 2001/83/EC states that "*this objective* [i.e. protection of public health] *must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community*."

As a result, Articles 36 of the TFEU and 81 of Directive 2001/83/EC share the same logic: Member States may adopt measures intended to protect public health as long as these are motivated by a reason of public interest and respect the principles of necessity and proportionality.[33]

3.3.3 The stockpiling obligations on parallel importers are disproportionate under Articles 36 TFEU and 81 of Directive 2001/83/EC

It is for the Member State that claims to have a reason justifying a restriction on the free movement of goods to demonstrate specifically the existence of a reason relating to the public interest, the need for the restriction in question and the proportionality of the restriction in relation to the objective pursued. The justification provided by the Member State must be accompanied by appropriate evidence or by an analysis of the appropriateness and proportionality of the restrictive measure adopted by that State, and precise evidence enabling its arguments to be substantiated.[34] This **burden would therefore fall on Sweden** to show that the Proposal satisfies that requirements of Article 36 TFEU.

While the protection of human life and health is a legitimate aim, the Proposal's stockpiling obligation on parallel importers **fails the proportionality test** as (1) the obligation is not a **suitable** means of attaining the stated public health objective and (2) the obligation is not restricted to what is **necessary** to attain the legitimate aim of protecting public health.

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[33] Case C-296/15 *Medisanus d.o.o. v Slosna Bolnisnica Murska Sobota*, EU:C:2017:431, para 83.

[34] Case C-14/02 *ATRAL*, EU:C:2003:265, para. 69 and C-254/05 *Commission v Belgium*, EU:C:2007:319, para. 36.

3.3.3.1 Suitability test

Chapter 1 of the Proposal states:

> "*1. The provisions of this Act are intended to **protect human life and health** and to **maintain the capability of total defence in situations where the supply of medical products is not sufficient to meet the needs of the health care system in Sweden** or to ensure that Sweden is able to comply with international agreements.*
>
> *2. The provisions of the Act shall apply to medical devices used in the performance of health care for human beings as defined in Chapter 5. 9 of the Health and Medical Care Act, it must be possible to carry out such services even in the event of a **peacetime crisis or war**" (emphasis added).*[35]

In essence, the scope of the measure is to ensure that there are adequate supplies of medicines in Sweden during periods of peacetime crisis or during wartime, with the ultimate aim of protecting public health.

According to Chapter 3(1)(2) of the Proposal, the storage obligations are only incumbent on **MAHs** and **parallel importers**. Manufacturers of **generic products are exempted**.[36]

Specifically including parallel imported medicinal products within the scope of the Proposal is not a suitable *means* to meet the *ends* of ensuring that there are adequate supplies of medicines during war or crisis.

First, generic products, which make up over 50% of total pharmaceutical shares in Sweden,[37] are excluded from the scope of the obligation. In addition, parallel imported medicinal products make up only about 10% of the prescription medicines market.

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[35] Own translation from original Swedish: "*1 kap. Inledande bestämmelser. 1 § Bestämmelserna i denna lag syftar till att skydda människors liv och hälsa och upprätthålla totalförsvarets förmåga i situationer då försörjningen av sjukvårdsprodukter inte är tillräcklig för att tillgo- dose behoven i hälso- och sjukvården i Sverige eller för att säkerställa att Sverige ska kunna fullgöra internationella överenskommelser.*"

[36] See exemptions at Chapter 3(3) of the Proposal.

In this sense, due to the low market share of parallel imported medicines in the total pharmaceutical market (around 2%), the **stockpiling obligation on parallel imported goods will have no effect** on Sweden's capacity to supply medicines during moments of war or crisis. In times of crisis, Sweden's prescription medicine needs will be easily met by the 6-month stock reserves of pharmaceutical manufacturers, who have a 90% market share, and total control over national production.

Even if this were insufficient, *quod non*, a **more proportionate approach** would be to mandate MAHs to increase stocks by 10% to take into account parallel import volumes.

Second, while stating that "*the study considers that parallel traders should have the same obligations as MAHs with regard to being obliged to stock medicinal products*" the Interim Report at the same time admits that "*many parallel traded medicines are traded on a spot market. **Such trading does not lend itself to a basis for good preparedness through stockholding**. The current requirements therefore risk having economic consequences for parallel traders by reducing their ability to sell medicines in some cases*."[38] Given that parallel trade "does not lend itself to a basis for good preparedness through stockholding", it is clear that this measure is not suitable to achieve its aim of protecting public health via stockpiling.

Third, the Interim Report concludes that sales of generics and parallel imports are both "spot-markets" and are therefore ill-suited for stockpiling obligations. However, the Proposal excludes generics from the usual stockpiling obligation but nevertheless includes parallel imports within the scope. This again illustrates why the stockpiling obligation on parallel importers is not a suitable measure to protect public health, otherwise generics would have also been included.

In light of all these reasons, **a stockpiling obligation on parallel imports, in any form, is not a suitable means of attaining the stated objective of protecting public health during periods of crisis and war. It therefore fails the suitability test**.

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[37] See https://www.statista.com/statistics/1090149/sales-share-of-generic-pharmaceuticals-in-sweden/

[38] Interim Report, pp.1121-1122.

3.3.3.2 Necessity test

Even if it were held that the stockpiling obligation on parallel importers were to be a suitable measure for attaining the objective of ensuring an adequate supply of medicines in times of crisis or war, *quod non*, the measure would in any event be disproportionate as it would **fail to satisfy the necessity test**. In other words, **the measure is not restricted to what is necessary to attain the (legitimate) aim of protecting public health**.

- A stockpiling obligation applying to all medicinal products regardless of the threat of shortage

According to Chapter 3(3) of the Proposal, the stockpiling obligations apply to all medicinal products with the exception of those products falling under one of the four exceptions. This includes normally available generic medicines, medicinal products whose authorised shelf life from production is less than 24 months, and certain interchangeable medicines amounting to more than two per cent of the total consumption within the group of interchangeable medicinal products to which the medicinal product belongs.

It therefore appears that the vast majority of medicines fall within the scope of this Proposal.

The Proposal, however, seems to indicate that there will not be an indiscriminate application of the stockpiling obligation on all products. Indeed, according to the English language summary introducing the Proposal, "[t]*he Inquiry proposes that the National Board of Health and Welfare be tasked, in consultation with other actors concerned, especially municipalities, regions, the Swedish Medical Products Agency and the Swedish Armed Forces, with producing such data as is required to* ***enable the Government to decide on which healthcare products are to be stockpiled****. Such a mandate would also include* ***constantly assessing whether the scope of this range***

should be changed *considering Sweden's preparedness needs or medical developments*."[39]

This is reflected somewhat at Chapter 3(13) the Proposal, which states that "[t]*he Government may issue regulations on the medical products to be stocked*."[40]

In its current form, the Proposal is merely allowing the Government to issue regulations in the future regarding the medicinal products to be stocked, but this is not compulsory ("**may** issue regulations"). In other words, if the Government chooses not to establish a list of medicines subject to a stockpiling obligation, which under the Proposal it is entitled to do, the default situation will apply, whereby the vast majority of medicines would be indiscriminately subject to the stockpiling obligation, regardless of the likelihood of such medicines being in low supply during period of war or crisis.

In addition, the proposal does not contain any details on the **exact criteria** which the Government would have to apply in order to select which medicines will be subject to the stockpiling obligation. The following factors, at a minimum, would need to be taken into account in the determination as to which medicines should stockpiled:

- The list of stockpiled medicines covers only specific medicines in respect of which there is a **threat of shortage** in crisis or wartime periods;
- The **threat of shortage would need to be real**. In other words, if that medicine were not stockpiled, it would adversely affect the availability of the medicine in a crisis or war situation as there would be no substitute to this medicine;
- The need for the inclusion of that medicine would need to be **objectively justified**. In other words, it must be demonstrated by "hard" data which are continuously collected by the State authorities from the relevant market players (MAHs, distributors and pharmacies);

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39 Interim Report, p.53.

40 Proposal, Chapter 3(13).

- The Government would need to **balance the conflicting interests at stake**, namely that of protection of public health and that of free movement of goods; and

- There would need to be an **appeals process** as regards the medicines subject to the stockpiling obligation, both at the proposal and final decision stage.

However, at the moment there are no such criteria outlined in the Proposal, meaning that the Government would seemingly be free to choose which medicines would be subject to the stockpiling obligation on the basis of no evidence whatsoever, and with no right of appeal for the given parallel importer (or MAH).

In addition, following the Proposal, the Government, or a Government-appointed body, has the **complete discretion** to prescribe a different period for the storage of a medicinal product than six months and to prescribe the calculation of quantities on the basis of other than the average historical sales or purchases of a health care product by the person liable to stockpile.[41]

In light of the above, the measure is not restricted to what is necessary to attain the aim of protecting public health, given that the vast majority of medicines are indiscriminately subject to the stockpiling obligation by default, regardless of the likelihood of such medicines being in low supply during period of war or crisis.

The measure is therefore **disproportionate**.

- Obligation that the amount of stock kept corresponds to six months' normal cycling

The Proposal sets out that parallel importers must stockpile medicines in a quantity equivalent to six months' consumption of the product in Sweden, unless otherwise prescribed.[42]

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41 Proposal, Chapter 3(15).

42 Proposal, Chapter 3(8).

First, the Proposal does not indicate how the six-month period was determined as the necessary period. In any case, and in the absence of any evidence to the contrary submitted by Sweden, a six-month stock holding obligation does not appear to be proportionate, as it does not seem to be limited to the **minimum duration necessary**.

In other words, if a smaller stockpiling obligation would be equally effective in protecting public health during times of crisis or war, then the measure fails to **satisfy the necessity test and would therefore be disproportionate**.

3.4 Unilateral national stockpiling obligations are contrary to recent European Commission initiatives

The European Commission itself has strongly condemned stockpiling of medicines in the context of the COVID-19 crisis. According to its Communication titled "Coordinated economic response to the COVID-19 Outbreak", it states:

> *"Some Member States have already adopted or are preparing national measures which affect the availability of essential products. If not well designed,* ***such measures risk exacerbating rather than alleviating problems****, in particular if they focus on limiting cross-border supplies of the products in question rather than directing them to those who most need them both in the national territory and throughout Europe, while* ***avoiding stockpiling****, panic purchases and wastage through non-priority or even counter-productive uses within the Member State in question."*

Moreover, **the Swedish Proposal goes completely against a new legislative proposal from the Commission related to crisis preparedness and management for medicinal products and medical devices**.[43]

Indeed, rather than recommending Member States to stockpile medicines during moments of crisis, the Commission's proposal aims to strengthen the role of the European Medicines Agency, which will serve as a central hub to help **monitor,**

[43] Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devicesc, 2020/0321 (COD).

quantify and mitigate shortages of crucial medicines during a crisis, **to be more efficient and avoid duplication at different levels in the EU**.

In this respect, the Commission proposal states that the "*framework should **reduce the risk of uncoordinated stockpiling** of such products and **allow for the continued flow of goods across the single market** so that they reach the areas that need them most as the impact of public health emergencies peaks at different times across the Union*."

Moreover, the Commission proposal states:

> *"Potential or actual shortages of (nationally and centrally authorised) medicines and medical devices in times of crises can lead to the risk of **disproportionate national stockpiling** or restrictions to single market movements being placed on such goods. **Such measures can have a negative impact on the free movement of goods**."*

The European Commission would clearly view the Swedish Proposal's attempts to segment the EU internal market, by requiring that huge volumes of medicines have to sit unused in warehouses instead of freely circulating to places where they are needed most, would be a **disproportionate** approach to preventing medicines shortages in times of crisis.

4. Notification requirement under the TRIS Directive

In light of the above, it is clear that the Swedish Proposal as it applies to parallel importers constitutes an unlawful restriction on imports under Article 34 TFEU. Moreover, the measure cannot be justified under Article 36 TFEU given that it is neither suitable nor necessary (i.e. is disproportionate) to protect public health in times of war or crisis.

Irrespective of whether or not the Swedish authorities consider the measure to constitute a restriction of imports, it nevertheless has a **legal duty to notify the Proposal** under Directive 2015/1535 on technical standards (the "**TRIS Directive**").[44]

The TRIS Directive lays down a procedure for administrative cooperation in respect of new 'draft technical regulations' capable of affecting the free movement of goods.

The system was crafted with a view to eliminating the fragmentation of the internal market. The consequences of a measure being deemed a draft technical regulation are, among other things, (i) the need for prior notification to the European Commission; and (ii) the applicability of the standstill obligation.

The Swedish proposal may be considered a draft technical regulation which requires notification. The TRIS Directive contains a very broad definition of what constitutes a 'technical regulation':

> *"'technical regulation' means technical specifications and other requirements or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative provisions of Member States, except those provided for in Article 7, prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider*."[45]

This definition also applies to technical regulations in draft form, such as the Swedish Proposal.[46]

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44 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. 1–15.

45 TRIS Directive, Article 1(1)(f)).

46 TRIS Directive, Article 1(1)(g) : *"'draft technical regulation' means the text of a technical specification or other requirement or of a rule on services, including administrative provisions, formulated with the aim of enacting it or of ultimately having it enacted as a technical regulation, the text being at a stage of preparation at which substantial amendments can still be made."*

The Swedish Proposal falls under this definition as it could be categorised either (i) as a rule relating to services or (ii) as a prohibition on the marketing of a product or the provision of a service/establishment as a service provider, *inter alia.*

According to Article 5, "***Member States shall immediately communicate to the Commission any draft technical regulation*** *[…] Where appropriate, and unless it has already been sent with a prior communication,* ***Member States shall simultaneously communicate the text of the basic legislative or regulatory provisions*** *principally and directly concerned to the Commission, should knowledge of such text be necessary to assess the implications of the draft technical regulation*."

The Commission shall then notify the other Member States of the draft technical regulation and all documents which have been forwarded to it. The Commission and the Member States may make comments to the Member State (Sweden) which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

Article 6 establishes a **standstill obligation for the notifying Member State**; Member States shall postpone the adoption of a draft technical regulation for **three months** from the date of receipt by the Commission of the notification. During this period, a bilateral discussion with the authorities of the Member States may be held.

If the draft technical regulation is found in breach of EU internal market law, the standstill period can be extended up to six months. An extension up to 18 months can even be imposed by a blocking decision if the Council adopts a position on the same matter covered by the notified draft regulation.

Should Sweden enact the Proposal without either notifying it to the Commission or respecting the standstill obligation, the Proposal would be unenforceable against third parties in the Swedish legal system.

Any attempt to avoid notification would be in **direct violation of Article 5(1) of the Directive as well as of the general obligations of loyal cooperation provided for by Article 4(3) of the Treaty on European Union**.

5. Conclusions

- In light of the above, it is clear that the Swedish Proposal's stockpiling obligations on parallel importers constitute an unlawful restriction on imports under Article 34 TFEU.

- The measure cannot be justified under Article 36 TFEU given that it is neither suitable nor necessary (i.e. is disproportionate) to protect public health in times of war or crisis.

- In addition, the Proposal runs counter to current European Commission initiatives relating to shortages as a result of the COVID-19 crisis as well as the Commission's November 2020 proposal to strengthen the role of the European Medicines Agency in coordinating actions to deal with medicinal shortage in times of crisis.

- Finally, Sweden must notify the Proposal immediately to the European Commission in order to fulfil its requirements under the TRIS Directive.

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Brussels, 13 May 2021

Angel Givaja

Partner

Brussels (E-List) Bar