VAN BAEL & BELLIS

**TRIS-procedure with reference 2024/0266/BE entitled**

***Royal Decree amending the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances***

**16 July 2024**

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## 1. INTRODUCTION

1. We are writing on behalf of our client, the Belgian Association of Consumer Healthcare Industry (***BACHI***)[1], *i.e.,* the Belgian association representing the pharmaceutical industry in the non-prescription category. Specifically, we write in view of the draft Royal Decree amending the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances (the ***draft Royal Decree***) that Belgium notified to the European Commission (***Commission***) on 17 May 2024 via the TRIS-notification (reference 2024/0266/BE)[2].

2. The present note, addressed to the Commission, outlines the reasons why Belgium should not be allowed to proceed with this amendment, which would see pseudoephedrine (***PSE***)-containing medicines switch to a prescription-only (***Rx***) status to the detriment of patients whilst infringing the free movement of goods in the EU internal market.

The structure of the note can be divided into three main parts. The first part provides an overview of the context, detailing the TRIS-notification and the recent Pharmacovigilance Risk Assessment Committee (***PRAC***) review, along with its subsequent recommendations.[3] It highlights how the draft Royal Decree contradicts these EU-level recommendations, which subsequently were endorsed by the Commission and therefore have become legally binding.

The second part examines how the draft Royal Decree infringes the free movement of goods within the EU internal market. It scrutinises the lack of evidence supporting the Belgian authorities' claims justifying the draft Royal Decree and demonstrates the disproportionality of the proposed measure.

In the third and final section, we propose specific amendments to the draft Royal Decree to address the issues detailed in this note. Should the Commission wish to further examine the situation, given the glaring lack of evidence provided by the Belgian authorities, the note concludes with a list of essential questions that the Belgian authorities should answer. These questions aim to help the Commission to assess the (il)legitimacy of Belgium's current proposal.

## 2. CONTEXT

### 2.1 TRIS-notification of the draft Royal Decree

3. On 17 May 2024, Belgium notified to the Commission under the TRIS-procedure the draft Royal Decree that would change the status of ephedrine- and pseudoephedrine-based substances (hereinafter, ***PSE-containing medicines***) from 'free supply: TF' or 'upon written request: TD', to 'with a medical prescription' (hereinafter, the ***proposed measure***).

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1 A non-profit organisation organised under the laws of Belgium, with registered office at Millenium Business Center, Chaussée de Louvain 431E, 1380 Lasne, Belgium, filed with the Register for Legal Entities (*Rechtspersonenregister / Registre des Personnes Morales*) in Brussels under number 0809.465.691.

2 European Commission, Notification Detail: Royal Decree amending the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances, 2024/0266/BE, 17/05/2024.

3 Referral procedure under Article 31 on PSE-containing medicinal products, EMEA/H/A-31/1526.

4. PSE-containing medicines are authorised in the majority of the EU Member States and can be used alone or in combinations to help patients to treat nasal congestion which can occur as a symptom of colds and flus, and also allergies. PSE is widely known as an effective treatment, offering symptomatic relief for nasal or sinus congestion. As such, PSE-containing medicines are popular self-care treatments which have an important impact on the quality of life of patients suffering from nasal congestion.

Within the context of the draft Royal Decree and this note to the Commission, it is important to highlight that only *oral* PSE-containing medicines are marketed in Belgium. The proposed measure therefore will impact only the supply of oral PSE-containing medicines, limiting the scope of our analysis on the EU internal market infringements in section 3 below.

5. Belgium's rationale for making PSE-containing medicines subject to prescription is two-fold[4]:

(i) alleged risks related to the use of PSE-containing medicines were identified; and

(ii) the alleged use of PSE-containing medicines as a drug precursor.

Neither reason provided by the Belgian authorities is supported by any form of evidence to justify such a drastic and restrictive approach as changing the supply status of PSE-containing medicines from non-prescription to Rx, as will be evidenced below (see, *infra* section 3.3)

6. Before delving into the internal market infringements, we wish to highlight an important development at the level of the European Union that appears to have fuelled, at least partially, the current Belgian legislative initiative.

### 2.2 Recent 'PRAC' initiative and subsequent recommendations

7. On 9 February 2023, the PRAC, which is the safety committee of the European Medicines Agency (***EMA***), started a review of the benefit-risk balance of medicines containing PSE-substances under the Article 31 pharmacovigilance referral procedure of Directive 2001/83/EC[5] at the request of the French Medicines Agency (***ANSM***).[6] This request was made in light of recent concerns regarding the associated risks of PSE-substances, namely the risks of posterior reversible encephalopathy syndrome (***PRES***) and reversible cerebral vasoconstriction syndrome (***RCVS***).

8. PRAC conducted an extensive and thorough review, taking into account all available evidence. According to the EMA's press release covering the PRAC's recommendations, the PRAC sought advice from an expert group of general practitioners, otorhinolaryngologists (specialists in diseases of the ear, nose, throat, head and neck), allergologists (specialists in the treatment of allergies) and a patient representative. PRAC also reportedly considered information submitted by a third party representing healthcare professionals.

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4 Notification message to TRIS-notification 2024/0266/BE, https://technical-regulation-information-system.ec.europa.eu/en/notification/25892.

5 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, *Official Journal of the European Union* L 311/67-128, 28 November 2001.

6 Referral procedure under Article 31 on PSE-containing medicinal products, EMEA/H/A-31/1526. (https://www.ema.europa.eu/en/medicines/human/referrals/pseudoephedrine-containing-medicinal-products#overview).

9. Ultimately, the PRAC concluded that the benefit-risk balance of these products remains favourable, and only recommended the following risk minimisation measures:

- updating the product information of PSE-containing medicines to include the risks concerning PRES and RCVS and the new measures to be taken;
- adding PRES and RCVS to the list of safety concerns for the periodic safety update reports (***PSURs***);
- issuing a Direct to Healthcare Professional Communication (***DHCP***) to inform healthcare professionals of these risks and measures.

Importantly, the PRAC did **not** suggest altering the supply status of PSE-containing medicines, even though the question was explicitly reviewed.

10. The above PRAC recommendations subsequently were endorsed by the Committee for Medicinal Products for Human Use (***CHMP***) – the EMA's human medicines committee – as well as the Commission. The latter issued legally binding decisions across the EU on 25 and 27 March 2024. Indeed, the final stage of this review process is the adoption by the Commission of a legally binding decision which is applicable in all EU Member States – and thus naturally also legally binding in Belgium.

11. Despite these recent developments, the Belgian authorities still intend to switch PSE-containing medicines from their non-prescription status to Rx, thereby unnecessarily restricting the use of these medicines on the Belgian market. By doing so, Belgium is infringing the free movement of goods, as set out below.

## 3. INFRINGEMENT OF THE FREE MOVEMENT OF GOODS

### 3.1 EU internal market: PSE supply status

12. At the outset, it is important to note that, although there is a lack of harmonisation at the EU level for the supply status of PSE-containing medicines overall, *oral* PSE-containing medicines, such as the ones marketed in Belgium, remain available without prescription virtually throughout all EU Member States with each subject to its own risk minimisation measures when considered appropriate. According to the internal information available to BACHI and its members, and as confirmed by the Association of the European Self-Care Industry (***AESGP***), the EU Member States in which oral PSE-containing medicines have a non-prescription status include Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Spain, Portugal[7], Romania and Slovenia.

It is worth mentioning that even France, the country that initiated the Article 31 referral with the PRAC and that expressed a divergent opinion on the PRAC recommendations, ultimately decided to implement the recommendations as they were, without taking any additional measures, let alone something as drastic as switching to Rx.

[7] It is interesting to note that Portugal had switched the supply status for PSE-containing medicines from Rx to non-prescription through pharmacy dispensation in 2017.

Notably, several of these EU Member States where the supply status of PSE-medicines is non-prescription include Belgium's neighbouring countries and, as such, represent important trading partners for Belgium. Indeed, Luxembourg and Germany maintain a non-prescription supply status for PSE-containing medicines in general, as does France for oral PSE-containing medicines.

13. It will be argued below that the proposed measure represents a measure having equivalent effect to quantitative restrictions on imports and exports, as per Articles 34 and 35 of the Treaty on the Functioning of the European Union (***TFEU***), which is not otherwise justified under the relevant Article 36 TFEU justification of the protection of health and life of humans.

### 3.2 The proposed measure has an equivalent effect to quantitative restrictions on imports and exports

14. It may be recalled that the purpose of the TRIS procedure is to prevent creating technical barriers to trade in the internal market before they materialise. The EU's internal market can be understood as the following: *"[t]he internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties."*[8]

In the interests of the current TRIS-notification[9], we are concerned only with the free movement of goods.

15. The protection of the free movement of goods in the internal market is guaranteed by the Treaties, under both Article 34 TFEU (the provision concerning imports) and Article 35 TFEU (the provision concerning exports). It is our position that this proposed Belgian measure will have an impact on both the import of goods from other EU Member States to Belgium, as well as to the export of goods from Belgium to other EU Member States.

#### 3.2.1 Restriction on imports (Article 34 TFEU)

16. According to Article 34 TFEU, *"[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States*.".

Since the proposed Belgian measure cannot be regarded in itself as a quantitative restriction on import as it is not a quota or a total ban on import, it shall be argued instead that the measure represents a measure having equivalent effect (***MEE***).

17. MEEs were defined in the *Dassonville* case as follows: *"[a]ll trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions*."[10]

Product requirements that relate to designation, form, size, composition, labelling, packaging, marking, and presentation of goods are classic examples of indistinctly applicable MEEs to quantitative restrictions on trade between EU Member States. Such requirements can hinder, directly or indirectly, actually or potentially,

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8 'Consolidated version of the Treaty on the Functioning of the European Union', *Official Journal of the European Union*, C 326/47, 26.10.2012, Article 26(2).

9 European Commission, Notification Detail: Royal Decree amending the Decree of the Regent of 6 February 1946 regulating the storage and sale of poisonous and toxic substances, 2024/0266/BE, 17/05/2024.

10 Judgment of 11 July 1974, *Procureur du Roi v Benoît and Gustave Dassonville*, Case 8-74, EU:C:1974:82, para.5.

intra-EU trade by conflicting with the presumption of equivalence (mutual recognition) derived from Article 34 TFEU.[11]

18. Through established case-law, the general principle of the presumption of equivalence or mutual recognition[12] was developed. This principle dictates that goods lawfully produced and marketed in one Member State should be allowed to be sold in another Member State without further restriction. This principle is now codified in Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State (the ***Regulation***).[13]

The principle of mutual recognition is defined in the Regulation as follows: "*To benefit from the principle of mutual recognition, goods must be lawfully marketed in another Member State. It should be clarified that, for goods to be considered to be lawfully marketed in another Member State, the goods need to comply with the relevant rules applicable in that Member State, and need to be made available to end users in that Member State*" (own emphasis).[14]

In the context of the current TRIS-notification, we have established that oral PSE-containing medicines are generally marketed as being non-prescription throughout the EU Member States, with only very few exceptions (see, *supra* paragraph 12). Given that Belgium's proposed measure aims at changing the legal status of oral PSE-containing medicines marketed in Belgium to prescription-only, it would effectively prevent these medicines that are lawfully marketed with non-prescription status in the vast majority of other EU Member States from being recognised and freely sold in Belgium. This constitutes a *prima facie* breach of Article 34 TFEU.

19. Concretely, most of BACHI's members are MAHs that are marketing oral PSE-containing medicines in both Belgium as well as in other EU Member States where the legal status is generally non-prescription. If the proposed measure is implemented, these MAHs would face a situation where an oral PSE-containing medicine, lawfully marketed in another EU Member State, would suddenly be subject to the stringent rules concerning Rx medicines, including packaging requirements, in Belgium, thereby undermining the mutual recognition principle.

Importantly, packaging requirements under the Rx status are particularly burdensome, given that they must comply with Directive 2011/62/EU of 8 June 2011 (the ***Falsified Medicines Directive***)[15] which imposes unique identifying serial numbers, as well as tamper-evident measures (for example, a sticker to seal the pack so that it is visible when the pack has been previously opened).

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11 Joined cases C-267/91 and C-268/91, *Keck and Mithouard*, ECLI:EU:C:1993:905, para. 15; case C-123/00,*Bellamy and English Shop Wholesale*, ECLI:EU:C:2001:214, para. 18, case C-51/94, *Commission v Germany*, ECLI:EU:C:1995:352,para. 29. See also Article 2(c)(i) of Regulation 2019/515.

12 Judgment of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein,* Case 120/78, EU:C:1979:42, para.14; Judgment of 10 February 2009, *Commission of the European Communities v Italian Republic*, C-110/05, EU:C:2009:66, para. 34; Judgment of 18 October 2012, *Elenca Srl v Ministero dell'Interno*, C-385/10, EU:C:2012:634, para. 23.

13 Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, Official Journal of the European Union L 91/1, 29.03.2019.

14 *Ibid.*, Recital 15.

15 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, *Official Journal of the European Union* L 174/74-87, 1 July 2011.

20. As such, the proposed measure disrupts the generally uniform supply status of oral PSE-containing medicines throughout the EU and constitutes an MEE that restricts the import of lawfully marketed medicines from other EU Member States into Belgium. Such restriction is expressly prohibited under Article 34 TFEU.

3.2.2 Restriction on exports (Article 35 TFEU)

21. Article 35 TFEU states that: *"[q]uantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States."* As is the case for imports, the proposed measure also represents an MEE to restrictions on export.

The 'Dassonville formula' mentioned above in paragraph 17 has since also been applied in cases concerning Article 35 TFEU[16].

22. As per the *Groenveld* case, Article 35 TFEU in particular *"concerns national measures which have as their specific object or effect the restriction of patterns of exports and thereby the establishment of a difference in treatment between the domestic trade of a Member State and its export trade."*[17]

Since the case of *Gysbrechts*, these measures no longer need to be directly discriminatory in order to be considered an MEE to restrictions on exports, but can also be indirectly discriminatory: "[…] *even if a prohibition such as that at issue in the main proceedings is applicable to all traders active in the national territory, its actual effect is none the less greater on goods leaving the market of the exporting Member State than on the marketing of goods in the domestic market of that Member State."*[18]

23. The proposed Belgian measure to switch PSE-containing medicines from non-prescription status to Rx will be applicable to all traders active on the Belgian market but nevertheless will affect PSE-containing medicines being exported more than those for the domestic market, and therefore can be categorised as an MEE as per Article 35 TFEU.

24. As a concrete illustration, we can consider that marketing authorisation holders (***MAHs***) often produce medicines, including those containing PSE, in the form of so-called 'shared packages' for multiple EU markets. We will take the existing example of an MAH selling PSE-containing medicines in both Belgium and Luxembourg.

The use of shared packages in different EU Member States' markets, such as Belgium and Luxembourg, is only feasible because in both markets these medicines have the same legal status of non-prescription. However, the proposed Belgian measure to switch PSE-containing medicines to Rx would mean that it would no longer be possible to produce these shared packages.

MAHs who are currently marketing their PSE-containing medicines for both markets would now have to make separate packages to meet, on the one hand, the Rx packaging requirements in Belgium, and on the other hand, the non-prescription packaging requirements in Luxembourg and other EU Member States where non-prescription is the supply status.

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16 Judgment of 3 March 2011, *Kakavetsos-Fragkopoulos AE Epexergasias kai Emporias Stafidas, formerly K. Fragkopoulos kai SIA OE, v Nomarchiaki Aftodioikisi Korinthias*, C-161/09, EU:C:2011:110, paras. 27 and 29.

17 Judgment of 8 November 1979, *P.B. Groenveld BV v Produktschap voor Vee en Vlees*, Case 15/79, EU:C:1979:253, para.7.

18 Judgment of 16 December 2008, *Lodewijk Gysbrechts, Santurel Inter BVBA*, C-205/07, EU:C:2008:730, para. 43.

As such, it is foreseeable that the implicated Belgian MAHs will not be able to meet these new, costly hurdles of satisfying the Rx packaging requirements for Belgium as well as, in parallel, the non-prescription packaging requirements when exporting their goods to non-prescription markets such as Luxembourg. As a result, they will simply be forced to discontinue supplying their oral PSE-containing medicine to the Luxembourg market.

25. The significance of this in terms of the impact on intra-EU trade cannot be overstated. *"[T]he vast majority (around 90%)"*[19] of medicinal products available in Luxembourg derive from the Belgian market. This switch to Rx in Belgium will therefore act to cut off trade between Luxembourg and one of its key providers of oral PSE-containing medicines. This is clearly a technical barrier to trade in the internal market which will have the unacceptable consequence of limiting access to oral PSE-containing medicines in the EU, and in particular in Luxembourg.

The proposed switch to Rx for PSE-containing medicines in Belgium is therefore capable of hindering intra-EU trade due to the introduction of burdensome packaging requirements for Belgian MAHs that are marketing these medicines in Belgium, as well as in other markets where non-prescription status applies.

26. Therefore, the proposed measure represents an MEE as per both Article 34 TFEU and Article 35 TFEU and, consequently, is prohibited under EU law, unless it can be justified by Belgium under Article 36 TFEU, *quod non*. In the next section, we will demonstrate that Belgium has failed to justify the proposed measure under this provision.

### 3.3 The proposed restrictive measure is not justified and is disproportionate (Article 36 TFEU)

3.3.1 Legitimate objective: no evidence of risk to the health and life of humans

27. Measures falling within the scope of Articles 34 and 35 TFEU may be justified by the EU Member State in question by relying on an Article 36 TFEU derogation: *"[a] national measure contrary to Article 29 EC may be justified on one of the grounds stated in Article 30 EC, and by overriding requirements of public interest, provided that the measure is proportionate to the legitimate objective pursued*."[20]

Therefore, the proposed measure could only take precedence over the free movement of goods if Belgium can demonstrably serve one of the interests listed in Article 36 TFEU and show that the measure is proportionate, respects fundamental rights, and does not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

28. Given the reasons stated in the TRIS-notification message (see, *supra* paragraph 5), Belgium would likely seek to justify its proposed measure on the grounds of *" […] the protection of health and life of humans […]"*.[21] However, as Article 36 TFEU constitutes a derogation from the basic rule of free movement of goods, it must be interpreted strictly.

29. Regarding the draft Royal Decree and its proposed measure, Belgium has failed to produce any evidence that the alleged health concerns raised are in fact legitimate, as set out below.

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19 Le Gouvernement du Grand-Duché de Luxembourg, Ministère de la Santé, Direction de la Santé, 'Guideline on BE/LU packages : Human medicinal products, Version : V2.1 (2023-09)', <guideline-on-be-lu-pack.pdf (public.lu)>, p.2.

20 Judgment of 16 December 2008, *Lodewijk Gysbrechts, Santurel Inter BVBA*, C-205/07, EU:C:2008:730, para. 45.

21 'Consolidated version of the Treaty on the Functioning of the European Union', Article 36.

*3.3.1.1 No evidence of increased risks related to the use of PSE-containing medicines*

30. The first reason stated by Belgium for the proposed measure is that "*risks related to its use were identified*".

Considering the fact that PSE-containing medicines have been on the market for many decades with well-known and documented potential side effects, these risks have been continuously managed with risk minimisation measures to ensure a positive benefit-risk balance.

We must, therefore, consider that the *"identified risks"* referred to in the TRIS-notification refer to the risks of PRES and RCVS that were highlighted by the ANSM in its Article 31 referral to the PRAC. There has been no indication of any other risks or concerns following the PRAC assessment.

31. Indeed, the ANSM had initiated the Article 31 referral because a small number of cases of PRES and RCVS reportedly had been identified in individuals using PSE-containing medicines, which prompted the PRAC to undertake a comprehensive analysis of these newly identified health risks in relation to the safe supply and use of PSE-containing medicines.

However, it is important to note that instances of PRES and RCVS attributed to PSE-containing medicines are exceedingly rare. For instance, according to *NèreS* – a trade association representing the pharmaceutical companies manufacturing and selling selfcare products in France – only 18 cases of PRES or RCVS have been reported over the past 16 years throughout Europe, with no recorded fatalities. Importantly, these are 18 cases from a grand total of 1.16 billion boxes dispensed. Moreover, *NèreS* reported that out of these 18 cases, in 16 cases no direct causal link with PSE could be established.

This assessment is supported by an *ad hoc* expert group convened during the PRAC review, which also considered "*the risk of PRES and RCVS to be low and that PRES and RCVS could also be caused by other factors, including respiratory viruses*".

32. The PRAC's thorough evaluation of all available evidence led to the conclusion that the benefit-risk balance of PSE-containing medicines remains favourable. PRAC did not find it necessary to recommend switching PSE products to prescription-only, and there were no indications from the Belgian authorities of new developments justifying such a drastic measure. Therefore, switching PSE-containing medicines to Rx status cannot be objectively justified as necessary to mitigate the associated risks of PRES and RCVS. This is further demonstrated by the fact that no EU Member State, except for Belgium, has opted to classify PSE-containing medicines as prescription-only following the PRAC review.

*3.3.1.2 No evidence of non-prescription PSE-containing medicines as drug precursors*

33. The second reason provided by the Belgian authorities for the proposed measure is the alleged use of PSE as a drug precursor of methamphetamine and ephedrone, yet, without substantiating the claim with any evidence.

Indeed, Belgium should be providing concrete proof that PSE-containing medicines that are available without prescription via pharmacies are in fact being misused as drug precursors in Belgium, contributing to abuse and illicit drug use.

In this context, it is noteworthy that BACHI should not have to speculate or develop justifications on behalf of the Belgian authorities, as the burden of proof lies squarely with the EU Member States (in this case Belgium). Nonetheless, for the sake of thoroughness in this note, we consider the possibility that the proposed measure is motivated by a report issued by the Belgian Federal Agency for Medicines and Health Products (***FAMHP***) on 15 February 2024, which reviewed the supply status of PSE-containing medicines.[22]

34. This report quotes a Polish survey conducted between 2014 and 2015 as evidence that PSE is a non-prescription substance subject to misuse due to its availability on the internet and the presumed free or unrestricted access.[23]

First, it is important to emphasise here that the data being relied on by the FAMHP is now 10 years old and thus arguably outdated. Relying on a survey from a decade ago cannot reasonably be considered a valid justification for the drastic measures proposed by the Belgian government in 2024.

Second, it is wrong to assume that the ability to purchase medicines online would equate to free or unrestricted access. In Belgium, PSE-containing medicines can only be purchased via pharmacies, which of course includes e-pharmacies that are crucial in modern-day society to ensure the best standard of care for patients. It must be noted that, in Belgium, only licensed and publicly accessible (brick-and-mortar) pharmacies are allowed to sell medicines online. These e-pharmacies have also implemented the necessary measures to prevent abuse and illicit drug use. For instance, Newpharma, one of Belgium's largest online pharmacies, requires patients purchasing PSE-containing medicines to (i) complete a written request and (ii) limit the total number of tablets to a maximum of 30 tablets per order.

Third, in contrast to the drastic measure proposed by the Belgian authorities, Poland chose to adopt a more balanced and effective risk minimisation strategy to monitor the distribution of PSE-containing medicines. The Polish approach involves the "ZSMPOL – Integrated System for Monitoring the Trade of Medicinal Products," which has been mandatory since 1 April 2019. This system enables the Polish health authorities to track the supply chain of products subject to reporting requirements. By leveraging this integrated monitoring system, Poland ensures comprehensive oversight of the distribution and sale of PSE-containing medicines, thereby addressing potential risks without imposing undue restrictions. The image below illustrates how this system functions in practice, showcasing its capability to follow the supply of these medicines across the Polish market. This alternative approach highlights a viable solution that balances public health concerns with the principles of free movement of goods within the EU.

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22 FAMHP, "pseudoéphédrine et ephédrine : révision du statut de délivrance", 15 February 2024.

23 *Ibid.,* p. 9.

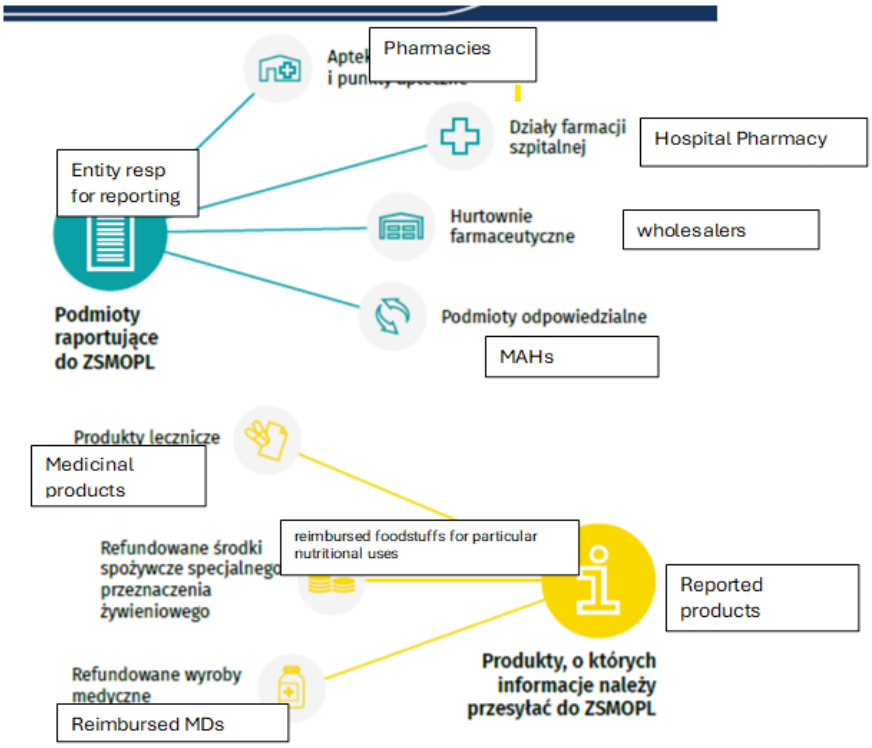


*Image: structure of the ZSMPOL – Integrated System for Monitoring the Trade of Medicinal Product*[24]

35. The FAMHP report also refers to *"attempts"* since May 2023 to purchase large quantities of PSE-containing medicines from Belgian pharmacies, ranging from a few boxes to thousands of boxes or purchases amounting to thousands of euros. Buyers reportedly tried to justify these large quantities as aid for Ukraine, with the FAMHP suspecting that the medicines were destined for illicit kitchen labs in Eastern Europe.[25] However, aside from the quantity control by e-pharmacies as stated in the previous paragraph, it is also important to note that pharmacies in Belgium in any case are prohibited from selling medicines for export, including to Ukraine.

Furthermore, the FAMHP report admits uncertainty regarding the actual success of these purchase *"attempts"*, suggesting a lack of concrete evidence on whether such transactions were completed or, on the contrary, prevented by vigilant pharmacists adhering to the regulations. To the extent the FAMHP refers to *"attempted"* purchases, we can reasonably assume that these attempts failed, which implies that the current system in place works well, with Belgian pharmacists preventing large, suspicious purchases. Even if, hypothetically, a few successful *"attempts"* were made, this would indicate potential fraudulent behaviour by certain pharmacists, an issue that needs to be addressed at the pharmacist level rather than imposing blanket restrictions on the MAHs of PSE-containing medicines. Ultimately, however, it can be assumed that pharmacists are highly qualified experts who will avoid selling massive quantities of PSE-containing medicines. The FAMHP is only able to claim a suspicion that some of these PSE medicines are headed for kitchen labs but has no concrete evidence to back up this assertion.

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24 https://www.gov.pl/web/gif/zintegrowany-system-monitorowania-obrotu-produktami-leczniczymi-zsmopl

25 *Ibid.,* p. 13.

BACHI and its members are also wondering whether this concern may stem from a misunderstanding. The Belgian authorities seem to only take into consideration the sales figures, potentially overlooking the operational practices of pharmacies in Belgium, especially those operating under a consolidated structure where bulk purchases are made to supply a large number of related branches. Based on the shared data and perspective of BACHI and its members, there have been no alarming trends or irregular purchases of PSE-containing medicines whatsoever.

36. Given these points, even if Belgium is basing its justification for the proposed measure on this *"evidence"*, its validity remains highly questionable and lacks sufficient ground to justify the stringent regulatory changes at issue.

3.3.2 Proportionality test

37. Even if the Belgian authorities had proven the existence of the legitimate objective of protecting public health, *quod certissime non*, the restrictive measure proposed in any case must pass the so-called proportionality test. This is a two-stage test which first considers the suitability of the measure, and second the necessity of the measure in relation to the objective pursued[26], as discussed below.

*3.3.2.1 The proposed measure is not suitable for the objective sought*

38. The test of suitability considers whether the proposed measure is suitable and appropriate to attain the intended objective.

(a) PRES and RCVS risks relating to the use of PSE-containing medicines

39. Regarding the first objective mentioned by Belgium, switching PSE-containing medicines to prescription-only status cannot be considered a suitable and appropriate measure for addressing the risks of PRES and RCVS.

40. In contrast to the lack of evidence provided by the Belgian authorities, existing evidence following the Article 31 referral to the PRAC shows that PRES and RCVS risks are extremely rare and do not pose significant risks to public health. The risk minimisation measures proposed by the PRAC, and subsequently endorsed by the CHMP and the Commission, ensure that the benefit-risk balance remains positive. Therefore, removing an effective source of self-care from all patients to combat very rare risks that can be offset by other means, is entirely inappropriate and thus disproportionate. Additionally, reducing the accessibility to PSE-containing medicines to this extent would not only burden many patients who rely on the non-prescription availability for quick relief from congestion and related symptoms, but would also cause inconvenience and increase the burden on healthcare providers as patients would need to visit doctors for prescriptions. The requirement for a prescription would increase the number of doctor visits, placing an additional strain on an already overburdened healthcare system.

[26] Judgment of 10 February 2009, *Commission v. Italy*, Case C-110/05, EU:C:2009:66, para. 59; judgment of 3 December 1998, *Bluhme,* Case C-67/97, para. 35.

41. What instead can be considered as suitable and appropriate measures, are the recommendations set out by the PRAC, as endorsed by the CHMP and the Commission. If the Belgian authorities truly believe that additional risk minimisation measures are required in Belgium, they must provide evidence of legitimate health concerns that are not met by the PRAC recommendations, whilst demonstrating the existence of a well-considered health policy.

(b) Illicit use of PSE-containing medicines as a drug precursor

42. The proposed measure is also not suitable and appropriate to tackle the alleged abuse and illicit use of PSE-containing medicines as drug precursors for the production of methamphetamine. According to the FAMHP report, the Belgian authorities appear to believe that significant quantities of PSE-containing medicines purchased without a prescription are ending up in illegal drug labs in Eastern Europe (see, *supra* paragraph 35). They suggest that switching these medicines to prescription-only status would effectively curb this issue at its source. However, the reliance on this strategy overlooks critical insights.

43. The FAMHP cites the European Union Drugs Agency (***EUDA***) to support its initiative, whereas the EUDA has clearly established that: "*Large-scale production of methamphetamine in the EU is furthered by a web of international connections providing access to logistical and transport infrastructure. European methamphetamine producers are increasingly outsourcing services such as the procurement of precursors […] of methamphetamine across the globe […].*" Furthermore, the EUDA confirmed that the PSE-containing medicines used in central Europe for methamphetamine production are predominantly sourced in large quantities from *outside* the EU.[27]

44. Therefore, restricting PSE-containing medicines to prescription-only status within Belgium would have a negligible impact on the abuse and illicit use of these medicines as drug precursors. Instead, such a measure would primarily penalise patients who rely on these medicines for legitimate self-care purposes.

45. The FAHMP report also relies on the fact that authorities have found five PSE drug labs in Belgium and 32 in the Netherlands[28], whilst overlooking the fact that no PSE-containing medicines are for sale in the Netherlands. This clearly shows that a switch to prescription status for PSE-containing medicines in Belgium will not have any effect on the precursor issue.

*3.3.2.2 The proposed measure is not necessary for the objective sought*

46. For a measure to be proportionate, it must also not exceed what is necessary to achieve the intended objective. A measure cannot be deemed necessary if the same result could be achieved by less stringent means.[29] We will evaluate this again based on the presumed objectives stated by Belgium.

(a) PRES and RCVS risks relating to the use of PSE-containing medicines

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27 EUDA, "Methamphetamine and criminal networks in Europe — flexible, adaptable and resilient", https://www.euda.europa.eu/publications/eu-drug-markets/methamphetamine/criminal-networks-europe_en.

28 FAMHP, "pseudoéphédrine et ephédrine : révision du statut de délivrance", 15 February 2024, p. 10.

29 Judgment of 3 December 1998, *Bluhme,* Case C-67/97, para. 35.

47. Regarding the first objective of addressing the PRES and RCVS risks associated with PSE-containing medicines, it has already been made abundantly clear that less restrictive means exist that would achieve the same objective.

We would like to highlight again that the PRAC has thoroughly examined this issue, including the question of whether it would be necessary or even beneficial to switch PSE-containing medicines to Rx. After evaluating all available sources, resources and expertise, the PRAC concluded that addressing the risks of PRES and RCVS does not necessitate such a drastic measure. The PRAC recommendations, as endorsed by the CHMP and the Commission, are deemed sufficient. As such, in going against the highest level of evidence and recommendations available, in way of the PRAC conclusions, Belgium is acting in an unjustifiably disproportionate manner.

48. That being said, BACHI highly values the importance of public health. We do not exclude the possibility that the Belgian authorities may have identified new or specific issues unique to Belgium. If this is the case, Belgium should clearly articulate these concerns so that additional risk minimisation measures can be developed. These measures should address the identified issues in the most appropriate and least restrictive manner.

(b) Illicit use of PSE-containing medicines as a drug precursor

49. Regarding the concerns about non-prescription PSE-containing medicines being used as drug precursors for illicit purposes, we have demonstrated that the proposed measure is inappropriate for addressing this issue.

As previously mentioned, if there had been *"attempts"* to buy large quantities of medicines containing PSE from pharmacies in Belgium which were unsuccessful, this would indicate that the current system works well and already constitutes an appropriate and less restrictive measure to tackle the issue.

50. Again, BACHI remains open to better understand any legitimate concerns the Belgian authorities may have with the current measures in place. We believe there can be less restrictive means to address this situation.

For instance, Belgium is a pioneer with the "*Dossier Pharmaceutique Partagé"*, collecting all information on medicines and other health products sold in a pharmacy to an individual patient. Making this dossier mandatory would not only contribute to the safe use of medicines and other health products, but also help flag the potential abuse of certain products, such as PSE-containing medicines.

## 4. REQUESTS TO THE COMMISSION

### 4.1 Proposed amendments to the draft Royal Decree

51. In light of the above, we do not believe that the draft Royal Decree should be implemented insofar as it concerns changing PSE-containing medicines to Rx.

As such, we strongly hope that the Commission will urge Belgium to amend the draft Royal Decree as follows:

| | Draft Royal Decree as notified | Amendments proposed by BACHI |
|---|---|---|
| Article 1 | *In Article 2, subparagraph 3, fifth indent, of the Decree of the Regent of 6 February 1946 regulating the storage and flow of poisonous and toxic substances, inserted by the Royal Decree of 5 April 2001, the words 'up to (k)' are replaced by the words 'up to and including (m)'.* | *In Article 2, subparagraph 3, fifth indent, of the Decree of the Regent of 6 February 1946 regulating the storage and flow of poisonous and toxic substances, inserted by the Royal Decree of 5 April 2001, the words 'up to (k)' are replaced by the words 'up to and including **(l)**'.* |
| Article 2 | *The following amendments are made to Article 3, in List IV, of the same Decree:*<br>*(1) subparagraph 3, as last amended by the Royal Decree of 10 June 2001, is supplemented by (l) and (m), which are worded as follows: '(l) ephedrine, stereo-isomers of ephedrine, salts of ephedrine, ephedrine esters, salts and esters of the stereoisomers of ephedrine, as such and in mixtures; (m) fusidic acid.';*<br>*(2) in subparagraph 5, replaced by the Royal Decree of 22 September 2000 and amended by the Royal Decree of 5 April 2001, the words 'up to (k)' are 'up to and including (m)'.* | *The following amendments are made to Article 3, in List IV, of the same Decree:*<br>*(1) subparagraph 3, as last amended by the Royal Decree of 10 June 2001, is supplemented by (l), which **is** worded as follows: '**(l)** fusidic acid.';*<br>*(2) in subparagraph 5, replaced by the Royal Decree of 22 September 2000 and amended by the Royal Decree of 5 April 2001, the words 'up to (k)' are 'up to and including **(l)**'.* |
| Article 3 | *Article 3 of the draft Royal Decree. In Annex I of the same Decree, the following amendments are made:*<br>*(1) in List III, the row 'Ephedrini hydrochloridum laevogyrum' is repealed;*<br>*(2) in List III, the row 'Ephedrinum' is repealed;*<br>*(3) in List IV, the words 'Ephedrine or phenylpropanolamine preparations intended to suppress appetite' are replaced by the words 'Phenylpropanolamine* | Article should be removed entirely. |

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|---|---|---|---|
| | | *preparations intended to suppress appetite';* | |
| | *(4)* | *in List IV a row is inserted below the row '- Ectylurem', worded as follows: ' - Ephedrinum'.* | |

52. If Belgium genuinely believes there are new health concerns that need to be addressed beyond the PRAC review and the overall scientific consensus, it must properly substantiate these concerns with concrete evidence. In the event that such justifications are validated, several alternative risk minimisation measures can be implemented to address these concerns effectively without resorting to prescription-only status. These measures may include, but are not limited to:

- **Integrating Electronic Pop-up Alerts:** Incorporating electronic pop-up alerts in pharmacy software systems, as proposed by the Pharmaceutical Group of the European Union[30], can serve as a reminder to pharmacists. These alerts can notify pharmacists of potential risks or contraindications associated with PSE-containing medicines, ensuring that they provide informed guidance to patients and prevent inappropriate sales.
- **Implementing Strict Quantity Limits:** Setting strict limits on the quantity of PSE that can be purchased, both in-store and online, is another effective measure. This can prevent stockpiling and reduce the risk of these medicines being diverted for illicit purposes. Such limits could be enforced through mandatory registration of purchases, ensuring that individual consumers do not exceed safe amounts within a given time frame.
- **Mandatory "*Dossier Pharmaceutique Partagé*":** Making the *Dossier Pharmaceutique Partagé* mandatory would allow for comprehensive tracking of all purchases of PSE-containing medicines made by a patient. This system would enable pharmacists to monitor a patient's medication history, flagging any patterns of misuse or overuse. This centralised record-keeping would facilitate better oversight and enable timely interventions if abuse is suspected.
- **ZSMPOL – Integrated System for Monitoring the Trade of Medicinal Products**: Belgium could also consider adopting an approach that is similar to the Polish online tracking and monitoring system, ZSMPOL (see, *supra* paragraph 34). Unlike the *Dossier Pharmaceutique Partagé* that focuses more on patient-level data, involving primarily pharmacists, the Polish system monitors the entire supply chain, involving pharmacists, MAHs and wholesalers, specifically designed for regulatory monitoring. This approach is more specifically aimed at increasing transparency and regulatory oversight of the entire supply chain.

By adopting these targeted measures, whether separately or in combination, Belgium can effectively address specific health concerns related to PSE-containing medicines, if applicable, without unnecessarily restricting access for patients who rely on these medicines for legitimate self-care. These measures strike an

[30] FAMHP, "pseudoéphédrine et ephédrine : révision du statut de délivrance", 15 February 2024, p.21.

appropriate balance between safeguarding public health and maintaining the accessibility of effective non-prescription treatments.

### 4.2 Questions to be addressed to Belgium

53. In the event that the Commission is not immediately persuaded to propose amendments to the draft Royal Decree as set out above, we would in any case urge the Commission to ask specific questions to the Belgian authorities to better assess the concrete objectives, legitimacy and proportionality of the proposed restrictive measure.

54. Please find below an overview of the questions that we deem necessary and relevant to the assessment of the current TRIS-notification:

- What specific criteria or thresholds are being used by Belgium to determine the necessity of switching PSE-containing medicines from non-prescription to Rx status?
- Can Belgium provide evidence related to any *increased* or *new* risks identified in the period following the PRAC evaluation? Does Belgium have any new or additional pharmacovigilance data beyond what was reviewed by the PRAC through the Article 31 referral that could justify the current legal initiative?
- If there is evidence of new or additional pharmacovigilance data, can Belgium specify to which PSE-containing medicines it relates? Notably, there are three different legal statuses in Belgium depending on the specific PSE-containing medicine: (i) 9 registered PSE products are available without a prescription upon written demand, (ii) 2 registered PSE products are freely supplied without a prescription, and (iii) 2 registered PSE products are only available on prescription. Not all PSE-containing medicines can therefore be equally compared. It is crucial to determine which products the new or additional pharmacovigilance data, if any, pertains to. If the data relates to products already under prescription status, there is no need to switch the remaining PSE-containing products to Rx. If it concerns specific products that are available without a prescription, targeted measures can be taken to address those particular cases without hindering the supply of the remaining self-care medicines.
- Can Belgium provide detailed statistics on the current usage patterns of PSE-containing medicines in Belgium, including any regional variations or trends that might justify the proposed measure?
- Can Belgium provide evidence of alleged attempts to purchase large quantities of PSE-containing medicines at pharmacies to use as a drug precursor?
- Can Belgium provide the number of confirmed cases of the alleged abusive or illicit use of PSE-containing medicines that are available without a prescription, including concrete sales volumes within (e-) pharmacies?
- Can Belgium elaborate on how many different pharmacies are involved in the alleged sales of PSE-containing medicines for illicit use?
- Which other, less restrictive measures did the Belgian health authorities take or seriously consider, in order to tackle the alleged problem of the illicit sales of PSE-containing medicines?
- Can Belgium illustrate concretely how a switch to Rx would effectively address the concerns it has, if the concerns are legitimate?

- How has Belgium engaged with stakeholders, including healthcare professionals, pharmacists and MAHs, in developing the proposed measure? What feedback was received, and how has it been addressed?
- What impact assessments have been conducted to evaluate the potential effects of the proposed measure on patient access to PSE-containing medicines and the healthcare system in Belgium?
- Can Belgium provide a comparison of the proposed measure with alternative regulatory approaches adopted by other EU Member States facing similar issues? How do the outcomes of those approaches compare with the anticipated outcomes in Belgium?
- What mechanisms are in place to monitor and evaluate the effectiveness of the proposed measure if implemented? How will success be measured, and what contingency plans exist if the measure does not achieve its intended objectives?

55. Finally, BACHI and its members would welcome any initiative, whether from the Commission or from the Belgian authorities, to further discuss the matter and address any questions or concerns collaboratively.

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