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ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

TRIS-PROCEDURE COMMENTS PHARMA.BE

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Author/Auteur/Auteur Caroline Ven

TRIS-procedure with reference 2025/0768/BE entitled Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to establishing a Stock Monitoring Tool

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EXECUTIVE SUMMARY

pharma.be, the Belgian association of the innovative biopharmaceutical industry representing around 130 companies active in Belgium, submits this note in response to the TRIS-notification 2025/0768/BE by Belgium concerning the Draft Royal Decree establishing a national Stock Monitoring Tool (***Draft Royal Decree***).

pharma.be fully recognises that medicine shortages constitute a public health concern and supports proportionate and effective monitoring measures. It has actively and constructively contributed to the Federal Agency for Medicines and Health Products (***FAMHP***) 2024 risk-based pilot, participates on an ongoing basis in the FAMHP's Unavailability Working Group, and continues to support the functioning and further improvement of existing tools such as PharmaStatus. However, the Stock Monitoring Tool as currently envisaged is excessively broad, misaligned with ongoing EU harmonisation efforts and incompatible with core EU internal market principles.

First, the Draft Royal Decree risks undermining the existing and evolving EU harmonised framework on shortages. Regulation 2022/123 has already established a European Medicines Agency (***EMA***) centred architecture, including the Medicines Shortages and Safety Steering Group (***MSSG***) and the European Shortages Monitoring Platform (***ESMP***). This framework is being reinforced by the EU Pharma Package and the proposed Critical Medicines Act, focusing on critical medicinal products. Creating a stand-alone and far-reaching national reporting layer that is not limited to critical or essential medicines and is not designed as an interoperable interface with harmonised EU reporting standards, risks duplication, fragmenting IT-systems and diverting regulatory and operational resources. It is, in any event, premature for Belgium to proceed with such a national regime while EU-level harmonisation is still underway.

Second, the Draft Royal Decree raises serious concerns under Articles 34 and 36 of the Treaty on the Functioning of the European Union (***TFEU***). The breadth and design of the Stock Monitoring Tool, including its interaction with the parallel Draft Law containing provisions concerning medicinal products and health products (TRIS-reference 2025/0771/BE) empowering the Minister to order redistribution, prioritisation and quantitative limits on supplies, are liable to influence cross-border allocation and supply decisions. As such, it constitutes a measure having equivalent effect to a quantitative restriction. In its current form, it is not justified under Article 36 TFEU and fails the proportionality test, as it is neither suitable nor necessary to achieve its presumed objective. An impact assessment conducted among pharma.be members confirms the significant and disproportionate burden in practice.

In light of the above, pharma.be respectfully invites the European Commission (***Commission***), in the framework of the TRIS-procedure, to block the Draft Royal Decree insofar as it conflicts with and pre-empts the harmonisation pursued by the upcoming EU Pharma Package and the proposed Critical Medicines Act. At a minimum, pharma.be respectfully urges the Commission to issue a detailed opinion requesting Belgium to amend the Draft Royal Decree so as to eliminate any obstacles to the EU internal market. The final section of this note therefore contains suggestions which, if taken on board, would enable Belgium to implement a lawful and effective Stock Monitoring Tool consistent

with EU law and with Belgium's own stated objective of safeguarding access to essential medicinal products.

1. INTRODUCTION

1. pharma.be is the Belgian association of the innovative biopharmaceutical industry, representing around 130 companies active in Belgium (***pharma.be*** or ***we***).

We write in view of the Draft Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to establishing a Stock Monitoring Tool (the ***Draft Royal Decree***) that Belgium notified to the Commission on 18 December 2025 via the TRIS-notification (reference 2025/0768/BE)[1].

2. The present note, addressed to the Commission, outlines the reasons why Belgium should not be allowed to proceed with the Draft Royal Decree in its current form. The proposed measure would introduce a far-reaching national stock monitoring system of medicinal products that risks undermining existing and forthcoming EU-level harmonisation efforts and constitutes an unjustified restriction on the free movement of goods within the EU internal market.

3. The structure of the note is divided into three main parts.

The first part sets out the factual and regulatory context of the Draft Royal Decree.

The second part examines the compatibility of the Draft Royal Decree with EU law, both in terms of its potential pre-emption of existing and forthcoming EU harmonisation efforts concerning medicinal product shortages and supply security, and in light of possible infringements of EU internal market principles, in particular those governing the free movement of goods and market access.

The third and final section proposes targeted amendments to the Draft Royal Decree aimed at addressing the concerns identified in this note.

2. BACKGROUND

2.1 Existing Belgian tools and measures

4. Belgium operates a **closed distribution system**, which means that medicines for human use are dispensed to patients exclusively via pharmacies. Wholesalers and wholesaler-distributors may only supply authorised actors within the distribution chain and cannot supply patients directly. Pharmacists therefore have a central overview of dispensing patterns and local availability and play a key role in managing potential shortages, including through substitution, magistral preparations and the reporting of supply issues to market authorisation holders (***MAHs***) and to the Federal Agency for Medicines and Health Products (***FAMHP***)).

[1] European Commission, Notification Detail: Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to establishing a Stock Monitoring Tool, 2025/0768/BE, 18/12/2025.

5. In addition to this structural feature, Belgium has developed a **comprehensive framework of tools** and measures to address medicinal product shortages, including:

- PharmaStatus[2]: the real-time platform through which MAHs and parallel distributors must report commercialisation starts, temporary unavailability (≥ 14 days) and discontinuations. For each shortage, the platform provides a criticality assessment and expert recommendations. PharmaStatus also serves as a publicly accessible tool allowing healthcare professionals and other stakeholders to consult up-to-date information on the availability of medicinal products. Since 2021, pharmacists and wholesalers can also use PharmaStatus to signal suspected shortages or supply issues directly to MAHs and the FAMHP.[3]
- Unavailability Working Group: a multi-stakeholder expert group regularly convened by the FAMHP, bringing together representatives of the competent authorities, industry (including pharma.be), health insurance funds, healthcare professionals and patient organisations. The group discusses structural trends in unavailability and possible rule-making. Individual shortages are addressed separately in dedicated product-specific task forces, convened as needed for the medicinal product concerned.[4]
- Authentic Source for Medicines (***SAM***): a central database containing information on availability and recommended alternatives. Since 1 January 2020, integration of SAM into ambulatory prescribing software has been mandatory. At the time of prescribing, physicians can verify whether a medicinal product is unavailable and which alternatives are recommended, thereby enabling proactive switching to suitable therapies in cooperation with pharmacists.[5]
- Law of 20 December 2019[6]: MAHs are subject to a statutory obligation to supply wholesaler-distributors and pharmacists within three working days. The Law of 20 December 2019 also provides a legal basis for the adoption of additional measures by implementing decree to limit or mitigate unavailability.[7] This includes the option of derogations under Article 105/1 of the Royal Decree of 14 December 2006[8] and restrictions on export in the case of shortages based on the Royal Decree of 19 January 2023 (***Royal Decree on Export***).[9]

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2 https://farmastatus.be/ .
3 https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products.
4 https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products.
5 https://www.famhp.be/en/human_use/medicines/medicines/information_about_medicines/authentic_source_of_medicines_sam
6 Law of 20 December 2019 amending various legal provisions concerning shortages of medicinal products (***Law of 20 December 2019***).
7 https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products.
8 Royal decree of 14 December 2006 on medicinal products for human use (***Royal Decree of 14 December 2006***); https://www.famhp.be/en/human_use/medicines/medicines/information_about_medicines/unavailability_of_medicines/article_1051.
9 Royal Decree of 19 January 2023 implementing article 12septies, second paragraph, of the Law of 25 March 1964 on medicines (***Royal Decree on Export***); https://www.afmps.be/fr/usage_humain/medicaments/medicaments/declarations_enregistrements/autorisation_dexportation_de.

6. According to the most recent statistics published by the FAMHP, these existing Belgian instruments have proven effective in managing medicinal product shortages.

In its annual report 2024, the FAMHP reports the following;

> "*After several years of increase, 2024 marks a positive break: the **number of** notifications on the **temporary unavailability** of medicinal products **has fallen** from 3 841 (in 2023) to 3 321. This **can be explained by the numerous measures implemented** by the FAMHP, in collaboration with stakeholders in the sector and European partners. While some shortages persist, **most are now rapidly solved, and alternatives are often available** or recommendations are made to provide patients with the best care possible.*"[10] (own emphasis)

The annual report 2024 further clarifies:

> "[I]*n **most cases**, the **unavailability** of a specific packaging **does not have a major impact on patient treatment**. In 2024, a particular packaging was actually unavailable in 1 214 cases (>36 %), but in each one, at least three alternatives with the same active ingredient, desired dosage and the same method of administration were available at all times. In 325 cases (10 %), one or two alternatives were available.*"[11] (own emphasis)

Only a limited number of situations are classified as "critical", meaning that no suitable alternative is available and/or that the clinical impact is significant. It is precisely in such cases that derogations and other exceptional measures are deployed.[12]

2.2 Pilot project of the Stock Monitoring Tool

7. The FAMHP first introduced stock monitoring during the COVID-19 pandemic, when accurate and timely stock data proved essential to ensure the availability of critical medicines.[13]

8. **In 2023**, the system was further expanded, and a formal **pilot phase** was launched. Under this pilot, weekly stock data were requested from relevant stakeholders for a limited and clearly defined subset of medicinal products (eight active substances), selected due to their clinical importance and risk of shortage.[14]

The pilot was **explicitly risk-based, both in scope and frequency**, and aimed at assessing the practical usefulness of the tool for proactively managing shortage situations of a subset of essential

10 https://www.famhp.be/en/news/fewer_medicines_temporarily_unavailable_in_2024.
11 FAMHP, Annual Report 2024, p. 56.
12 FAMHP, Annual Report 2024, p. 24 and 59.
13 https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products.
14 https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products; https://www.FAMHP.be/fr/news/projet_stock_monitoring_tool_phase_pilote_pour_la_surveillance_des_stocks_afin_de_mieux; https://www.fagg.be/nl/news/project_stock_monitoring_tool_pilootfase_voor_monitoring_van_voorraden_om_beter_te_anticiperen.

medicines. It was widely welcomed by stakeholders as a constructive and pragmatic initiative, and pharma.be actively and constructively contributed to its design and operation.

9. However, **without any publicly available evaluation** of the pilot phase and before its effectiveness and proportionality had been formally assessed, the Belgian authorities initiated steps to transform this limited and risk-based exercise into a permanent and generalised Stock Monitoring Tool (see, *infra* section 2.3.1).

2.3 TRIS-notifications: Draft Royal Decree and Draft Law

2.3.1 Draft Royal Decree

10. On 18 December 2025, Belgium notified the Draft Royal Decree to the Commission under TRIS procedure 2025/0768/BE. The Draft Royal Decree seeks to establish a permanent Stock Monitoring Tool aimed at "*offering a comprehensive and in-depth view of the availability of a series of medicinal products authorised on the Belgian market*".[15]

11. The scope of the Stock Monitoring Tool, in contrast to the pilot project which was limited to only eight active substances, now relates to:[16]

- **all prescription-only** medicinal products for human use;
- **all reimbursable** medicinal products for human use;
- any **non-prescription** medicinal products **with the same ATC code** as prescription-only or reimbursable medicinal products; and
- medicinal products that have ceased to be marketed in Belgium, for a period of two years following their withdrawal from the market.

12. The Draft Royal Decree also substantially increases the reporting frequency. Whereas the pilot required weekly reporting, the proposed system would require **daily reporting** by actors across the entire supply chain of:[17]

- the reference date of the **stock data**;
- an overview of the **end-of-day stock**, classified by CTI-ext code; and
- the **volume supplied** or dispensed.

In addition, MAHs and wholesale-distributors holding a Belgian wholesale authorisation under Article 12ter §1, third subparagraph of the Law of 25 March 1964 on medicinal products (***Law of 25 March***

[15] European Commission, Notification Detail: Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to establishing a Stock Monitoring Tool, 2025/0768/BE, 18/12/2025.
[16] Article 1 Draft Royal Decree.
[17] Article 2 and 3 Draft Royal Decree.

1964) would be required to report on a daily basis the date and volume of their **next two anticipated deliveries**.[18]

13. Although the Draft Royal Decree has not yet been adopted, it introduces a far-reaching and structurally new monitoring system that has not been tested for the vast majority of products and operators concerned. Nevertheless, its **entry into force** is scheduled for **1 July 2026** (*i.e.,* in just over 4 months from the date of this note), without providing for any transitional arrangements or phased-in application.[19]

2.3.2 Draft Law

14. On the same date as the Draft Royal Decree, Belgium also notified via TRIS a Draft Law containing various provisions concerning medicinal products and health products (***Draft Law***).[20] The Draft Law introduces specific additional measures to address medicinal product shortages.

Under the proposed amendments, the Minister or his/her delegate would be empowered to intervene **when the FAMHP determines** that the stock of a medicinal product available on the Belgian market is insufficient to meet patients' needs, or that such a **shortage is imminent or probable**. Such determinations would presumably be based on the data collected through the Stock Monitoring Tool envisaged in the Draft Royal Decree.

15. In situations when a shortage is deemed imminent or probable, the **Minister** or his/her delegate would be **authorised to adopt a range of preventive and corrective measures**, including (i) ordering the redistribution of remaining stock, (ii) requiring that available stock be prioritised for hospitals or specific healthcare professionals, and (iii) imposing quantitative supply limitations on wholesaler-distributors and/or pharmacies.[21]

16. Importantly, the explanatory memorandum to the Draft Law, as communicated under TRIS, justifies these powers as follows:

> "*The preliminary draft allows for preventive and proportionate interventions, such as the redistribution of stocks or the limitation of distribution,* ***in order to guarantee access to essential medicinal products*** *and protect public health.*"[22] (own emphasis)

The stated objective of the Draft Law is therefore to safeguard access to *essential medicinal products*. By contrast, the monitoring scope of the Draft Royal Decree is much broader and is not confined to those products for which intervention measures would realistically be envisaged under the Draft Law.

18 Article 5 Draft Royal Decree.
19 Article 10 Draft Royal Decree.
20 European Commission, Notification Detail: Draft law containing various provisions concerning medicinal products and health products, 2025/0771/BE, 18/12/2025.
21 Article 9 Draft Law.
22 European Commission, Notification Detail: Draft law containing various provisions concerning medicinal products and health products, 2025/0771/BE, 18/12/2025.

This divergence between the objectives pursued by both instruments and the breadth of the monitoring mechanism are part of the proportionality concerns developed below (see, *infra* section 3.2.2(b)).

3. EU LAW CONCERNS

3.1 Pre-emption of EU harmonisation efforts

17. In the context of combatting medicine shortages and ensuring supply security, several recent legislative and policy initiatives that are either already adopted or at an advanced stage of development, show a clear and consistent EU choice in favour of a centralised, risk-based and interoperable monitoring of shortages, with the European Medicines Agency (***EMA***) and EU-level IT tools at its core.

It is against this background that the Draft Royal Decree must be assessed. By setting up a stand-alone and far-reaching national Stock Monitoring Tool applicable to a very wide range of medicinal products, with extensive and systematic reporting requirements, Belgium is creating an additional system in an area where the EU has already opted for centralised tools and is in the final stages of adopting further harmonised rules.

This raises a distinct and serious harmonisation concern that warrants Commission intervention within the TRIS-procedure, independently of the separate free-movement and market-access issues (see, *infra* section 3.2).

3.1.1 Existing EU framework

18. Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices (***Regulation 2022/123***)[23] establishes the core EU framework for monitoring and managing shortages. In particular, it:

- confers on the EMA a mandate to coordinate shortage management of specific medicinal products;[24]
- establishes the Medicine Shortages and Safety Steering Group (***MSSG***);[25] and
- provides the legal basis for the European Shortages Monitoring Platform (***ESMP***)[26], designed as the central EU reporting tool.

[23] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02022R0123-20250101).

[24] *Ibid*, 22; https://www.ema.europa.eu/en/about-us/who-we-are/executive-steering-group-shortages-medical-devices.

[25] *Ibid*, 22; https://www.ema.europa.eu/en/committees/working-parties-other-groups/medicines-shortages-single-point-contact-spoc-working-party.

[26] *Ibid*, 22; https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform-esmp.

19. While Regulation 2022/123 does not fully harmonise all aspects of national shortages policy, it clearly structures the field. EU Member States must exercise their remaining competences in a way that respects and reinforces this **EMA-centred architecture**, in line with the duty of sincere cooperation.

However, the Draft Royal Decree does not simply complement ESMP. It establishes a separate national Stock Monitoring Tool requiring routine and broad submission of stock and flow data to the Belgian authorities, using **parameters, thresholds and formats that are not aligned with the ESMP**. The proposed system is not conceived as an ESMP-compatible interface, but as an **autonomous and permanent Belgian reporting layer**.

20. While the ESMP and the proposed Stock Monitoring Tool do not pursue identical objectives (the former being a targeted EU coordination mechanism and the latter a generalised national inventory system), this distinction does not remove the **tension between the Draft Royal Decree and Regulation 2022/123**. On the contrary, by introducing a broad and daily stock reporting obligation that is neither interoperable nor clearly integrated with the ESMP and EU-defined critical medicine lists, Belgium **risks**:

- duplication of reporting flows: companies must feed data into ESMP (and national shortage notification platforms like PharmaStatus) and, separately, into a Belgian stock monitoring application that uses different concepts and formats, contrary to the aim of Regulation 2022/123 of streamlined, interoperable systems;
- fragmentation and reduced interoperability: the Stock Monitoring Tool is not designed as an ESMP compatible interface, but as an autonomous application with its own data fields and reporting logic. This undermines the EU level drive (explicit in Article 9(1)(c) and Article 13(6)(e) of Regulation 2022/123) to align data fields and achieve interoperability between EU and national systems; and
- distorted allocation of regulatory attention and resources: both operators and authorities would be required to dedicate significant capacity to servicing a permanent, broad Belgian stock monitoring regime, instead of focusing on the EU's risk-based, shortage-driven framework centred on critical medicines and public health emergencies. This concern is amplified by the fact that the EU is currently finalising a comprehensive and harmonised shortages framework under the broader Pharmaceutical Package and the forthcoming Critical Medicines Act (see, *infra* section 3.1.2).

3.1.2 Upcoming EU legislation

(a) EU Pharmaceutical Package

21. Beyond Regulation 2022/123, the EU institutions have reached a political agreement on a 'pharmaceutical package' to revise central instruments of the EU's pharmaceutical legislation and make medicines more available, accessible and affordable while supporting competitiveness and attractiveness of the EU pharmaceutical industry (***EU Pharma Package***). The EU Pharma Package includes proposals for a new Directive and a new Regulation that will replace Directive 2001/83/EC and Regulation (EC) No 726/2004.[27]

22. Although the final legislative texts are not yet publicly available, the existing documentation already indicates that the reform will, *inter alia*, provide for:

- **harmonised reporting obligations** concerning shortages;
- strengthened obligations for undertakings to prevent and mitigate shortages;
- a further reinforcement of the EMA's coordinating role; and
- the establishment of a centralised Union list of critical medicinal products, accompanied by vulnerability assessments of their supply chains.

23. This reform confirms that the EU legislator is on the brink of adopting detailed, harmonised rules governing shortages related monitoring and prevention for medicinal products. In this context, a national regime such as the Draft Royal Decree risks preempting EU level choices as to the scope and intensity of future reporting and monitoring obligations. Once the EU Pharma Package enters into force, Belgium may be compelled to substantially amend or repeal its Stock Monitoring Tool to ensure compatibility, thus creating legal uncertainty and unnecessary costs, related monitoring and prevention, pre-empting EU-level choices as to the scope and intensity of future reporting and monitoring obligations.

24. From a harmonisation perspective, it is **premature for Belgium to adopt** such a **far-reaching monitoring regime just as the EU legislator finalises uniform shortages rules**. The more consistent, efficient and logical course would be to await publication and implementation of the EU Pharma Package and to design any national measures as strictly complementary.

(b) Critical Medicines Act

[27] Council of the EU, "'Pharma package': Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector", 11 December 2025 (https://www.consilium.europa.eu/en/press/press-releases/2025/12/11/pharma-package-council-and-parliament-reach-a-deal-on-new-rules-for-a-fairer-and-more-competitive-eu-pharmaceutical-sector/); Council of the EU, "The pharma package: new EU rules on medicines" (https://www.consilium.europa.eu/en/policies/pharma-pack/); European Parliament, "Revision of the EU's basic pharmaceutical legislation, including medicines for children and for rare diseases." (https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-revision-of-the-pharmaceutical-legislation).

25. In addition, the proposed Regulation on strengthening the availability and security of supply of critical medicinal products and medicinal products of common interest (the ***Critical Medicines Act***), first presented by the Commission on 11 March 2025[28] and endorsed in first reading by the European Parliament on 20 January 2026[29], adds an important dimension to this harmonisation landscape.

The Critical Medicines Act aims to reduce medicine shortages by strengthening EU supply chains for medicinal products on the Union list of critical medicines.

26. Crucially, the Critical Medicines Act is **explicitly risk-based and selective**. While shortages can in principle affect a wide variety of medicines, the EU recognises that not all shortages present the same level of risk. Through the Union list of critical medicines[30] and the proposed Critical Medicines Act, the EU institutions have identified a subset of medicines whose potential shortage is particularly dangerous because it would cause serious patient harm and significantly challenge health systems.[31] For that subset, the EU intends to mobilise enhanced monitoring and supply-security measures.

In this context, **broad national monitoring regimes** such as that proposed in the Draft Royal Decree, which subjects virtually the entire medicinal product portfolio to the same level of scrutiny, **risk diluting and undermining the EU's own risk-based prioritisation**, by forcing operators and authorities to spread scarce capacity across the entire portfolio instead of concentrating it where EU policy expects it to be concentrated.

27. In fact, the broad scope of the Stock Monitoring Tool **contradicts even Belgium's own objectives**. The Draft Law that was notified in parallel to the Draft Royal Decree (see, *supra* section 2.3.2) explicitly provides that the Minister's new powers to adopt preventive and corrective measures, on the basis of information received through the Stock Monitoring Tool, are intended to "*guarantee access to essential medicinal products*".[32]

This mismatch between the stated **objective of the Draft Law of safeguarding access to *essential* medicinal** products and the breadth of the reporting obligation under the Draft Royal Decree further accentuates the serious proportionality concerns raised by the Stock Monitoring Tool envisaged (see, *infra* section 3.2.2(b)).

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28 Proposal for a Regulation of the European Parliament and of the Council laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795, COM/2025/102 final, 11 March 2025 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025PC0102&utm_source=chatgpt.com).

29 European Parliament, "Critical medicines: EU measures to boost competitiveness and tackle shortages", 20 January 2025 (https://www.europarl.europa.eu/news/en/press-room/20260116IPR32437/critical-medicines-eu-measures-to-boost-competitiveness-and-tackle-shortages).

30 https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines.

31 Commission, Communication addressing medicine shortages in the EU, COM(2023) 672 final, 24 October 2023, p. 6; https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_5191.

32 European Commission, Notification Detail: Draft law containing various provisions concerning medicinal products and health products, 2025/0771/BE, 18/12/2025.

28. An impact assessment which pharma.be conducted among its members further illustrates this disproportionality. According to the responses received, close to the entire Belgian portfolio of most respondents would fall within the scope of the Stock Monitoring Tool as currently drafted. By contrast, **if the reporting obligation were limited to** a targeted approach based on predefined criteria (*i.e.,* those products for which stock intervention measures would be adopted and for which periodic monitoring would be justified; (see, *infra* paragraph 67(i)) the **proportion of affected products would decrease significantly**, to a range between 0% and 30% of their portfolios.

Adopting a genuinely risk-based approach in the Draft Royal Decree would therefore not only align the Belgian regime more closely with the emerging EU legislative framework, but would also better reflect the objective that the Belgian authorities themselves seek to pursue.

29. Moreover, the impact assessment conducted by pharma.be highlights a recurring and fundamental concern among its members: the proliferation of diverging national reporting regimes. Several respondents stressed the **operational and financial burden of having to comply with standalone national stock monitoring systems, each with distinct criteria, reporting frequencies, data formats, and IT specifications**. In the absence of harmonisation, companies operating cross-border must adapt centralised supply chain systems to country-specific technical requirements, resulting in duplication of compliance efforts, fragmentation of data management, and increased costs. This concern is particularly acute in a sector where supply chains are highly integrated at European and global levels. A **unilateral Belgian system** that diverges from ongoing EU-level initiatives **risks** further **regulatory fragmentation and undermines the objective of a coordinated internal market response to medicine shortages**.

30. Overall, it would be **premature for Belgium to adopt such an extensive national monitoring regime while the Critical Medicines Act is still under negotiation** at EU level, as this risks creating legal and operational inconsistencies that may shortly require amendment in light of EU legislation. From the perspective of legal certainty, proportionality, and internal market coherence, it would be more appropriate for Belgium to wait for the completion of the EU legislative framework.

3.2 Infringement of EU internal market principles

31. 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."*[33]

In the interests of the current TRIS-notification[34], we are specifically concerned with the free movement of goods and market access.

[33] '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).

[34] European Commission, Notification Detail: Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to establishing a Stock Monitoring Tool, 2025/0768/BE, 18/12/2025.

32. The free movement of goods is enshrined in Article 34 TFEU, which prohibits quantitative restrictions on imports and all measures having equivalent effect. It is pharma.be's position that the measures imposed by the **Draft Royal Decree will affect the import and cross-border supply of medicinal products from other EU Member States into Belgium** and therefore fall within the scope of Article 34 TFEU.

33. For Article 34 TFEU to apply, it must be shown that the measure concerns: (i) goods, (ii) a cross-border element, (iii) a state measure, and (iv) a restriction in the sense of a hindrance to intra-Union trade or market access. These elements are clearly present here.

34. First, **medicinal products** for human use unquestionably **fall within the notion of goods**. According to settled case-law of the Court of Justice of the European Union (***CJEU***), goods are defined as products that can be valued in money and are capable of forming the subject of commercial transactions.[35] Medicinal products clearly meet this definition, as they are physical products, marketed commercially, and may be traded across borders within the pharmaceutical supply chain. The CJEU has consistently treated pharmaceutical products as goods for the purposes of Article 34.[36]

35. Second, the **Draft Royal Decree has a clear cross-border dimension**. Belgium imports significant quantities of medicinal products from other EU Member States, including under parallel import arrangements. Indeed, the proposed Stock Monitoring Tool under the Draft Royal Decree applies to medicinal products placed on the Belgian market irrespective of their origin, and expressly covers wholesale distributors placing products on the Belgian market "*whether or not they are established in Belgium*".[37] Foreign MAHs and wholesalers supplying Belgium will therefore have to implement Belgium-specific daily stock and flow reporting and must adapt their centralised logistics and IT-systems accordingly. This may influence their decisions whether, and to what extent, to supply the Belgian market. In addition, for operators that supply several EU Member States from integrated distribution hubs, the Belgian Stock Monitoring Tool is also liable to affect allocation decisions between Belgium and other EU Member States.

36. Third, the **Draft Royal Decree constitutes a state measure** within the meaning of Article 34 TFEU. It is a binding regulatory act adopted by the Belgian federal authorities. Its notification under the TRIS procedure confirms its character as a technical regulation attributable to the Belgian State.

37. Fourth, the **measure constitutes a restriction** within the meaning of Article 34 TFEU. The CJEU has repeatedly held that Article 34 TFEU applies not only to measures that are overtly discriminatory, but also to any national rule which is "*capable of hindering, directly or indirectly, actually or potentially, intra-Community trade"*.[38]

In this regard, the Draft Royal Decree introduces mandatory stock monitoring and reporting obligations for stakeholders in the distribution chain that apply to a broad scope of medicinal products for human

35 Case 7/68, *Commission v Italy,* EU:C:1968:51.
36 See, e.g., case C-322/01, *DocMorris*, EU:C:2003:664.
37 Article 2 Draft Royal Decree.
38 Judgment of 11 July 1974, *Procureur du Roi v Benoît and Gustave Dassonville*, Case 8-74, EU:C:1974:82, para.5.

use marketed in Belgium, including those imported from other EU Member States (see, *supra* paragraphs ***11-***12).

Compliance entails significant administrative and technical burdens, particularly for cross-border operators required to adjust existing systems to Belgian-specific formats and timelines. Such obligations are liable to affect economic operators' decisions as to whether, and under what conditions, they supply the Belgian market, thereby restricting market access.

38. Against this background, it is submitted that the proposed measure constitutes a restriction on import and market access within the meaning of Article 34 TFEU, as further examined below.

3.2.1 Restriction on imports (Article 34 TFEU).

39. According to Article 34 TFEU, *"*[q]*uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States*." The Draft Royal Decree cannot in itself be regarded as a quantitative restriction on imports as it does not impose a quota or a total ban on imports, but it does qualify as a measure having equivalent effect (***MEE***).

40. 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*."[39]

The Commission further clarified in its guidance on Articles 34-36 TFEU:

> *"Article 34 TFEU applies* […] *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* […]. *This* […] *stems from the fact that the imported goods are required to comply with two sets of rules – those laid down by the Member State of manufacture, and those laid down in the Member State of importation."* [40]

Thus, **administrative and reporting requirements can constitute MEEs when they create additional burdens on cross-border trade**. Even indistinctly applicable measures fall within Article 34 TFEU when they hinder market access in practice.

In the present case, the combined effect of (i) the exceptionally broad product scope, (ii) the extensive data requirements (including forward-looking delivery information), and (iii) the high reporting frequency (daily reporting), within a Belgium-specific IT framework, creates precisely such an additional burden. Wholesalers and MAHs supplying Belgium from other Member States must adapt centralised logistics and IT systems to comply with Belgian-specific requirements, thereby duplicating work, processes and costs. The impact assessment conducted by pharma.be confirms that this entails significant operational adjustments and financial expenditure.

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

40 European Commission Notice, Guide on Articles 34-36 of the Treaty on the Functioning of the European Union (TFEU) (2021/C 100/03) p. 47.

41. By way of illustration, a wholesaler established in another EU Member State (*e.g.*, the Netherlands) supplying both its domestic market and Belgium would, in light of the Draft Royal Decree and the impact assessment feedback, be required to:

(i) Implement or adapt IT systems capable of tracking and reporting stock movements and next-two-days deliveries on a daily basis, specifically for products destined for Belgium;

(ii) maintain separate data management systems for Belgian supplies as compared to supplies to other EU Member States; and

(iii) bear the ongoing operational costs associated with these Belgium-specific obligations.

42. In particular, the impact assessment further demonstrates that these Belgium-specific requirements would **weigh disproportionately on smaller operators** and on **products with relatively limited Belgian market shares.** Virtually all respondents indicated that manual reporting would be unworkable, making automation indispensable. However, not all operators have the financial capacity to implement such systems. Some respondents explicitly noted that the cumulative compliance costs may exceed the commercial value of supplying the Belgian market, potentially leading to withdrawal decisions or reduced cross-border flows. Such effects fall squarely within the concept of hindrance to intra-Union trade.

43. Moreover, the reporting obligations under the Draft Royal Decree are not neutral in their practical consequences. The **data collected through the Stock Monitoring Tool** would **serve as the factual basis for** the exercise of **intervention powers under the Draft Law** as notified under TRIS-reference 2025/0771/BE (see, *supra* section 2.3.2). These powers include (i) ordering the redistribution of remaining stock, (ii) requiring that available stock be prioritised for hospitals or specific healthcare professionals, and (iii) imposing quantitative supply limitations on wholesaler-distributors and/or pharmacies.[41] The Draft Royal Decree will therefore not only increase the compliance burden, with the practical consequences as set out above, but also underpins binding measures that directly affect the distribution and allocation of medicinal products, in favour of the Belgian market.

44. All the elements above show that the Draft Royal Decree does not amount to a neutral, purely internal administrative measure. It **creates concrete and foreseeable barriers to the importation and cross-border supply of the concerned medicinal products**. The measure therefore clearly qualifies as an indistinctly applicable measure having equivalent effect within the meaning of Article 34 TFEU, restricting import of lawfully marketed medicinal products from other EU Member States.

Such a restriction is prohibited unless it can be justified under Article 36 TFEU and passes the proportionality test. The following section will demonstrate why the restrictive measure imposed by the Draft Royal Decree is not justified and is disproportionate.

[41] European Commission, Notification Detail: Draft law containing various provisions concerning medicinal products and health products, 2025/0771/BE, 18/12/2025, Article 9.

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

(a) Legitimate objective: no evidence of risk to health and life of humans

45. 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*."[42]

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 EU Member States.

46. Given the reasons stated in the TRIS-notification message, Belgium would likely seek to justify its proposed measure on the grounds of *"* […] *the protection of health and life of humans* […]*"*.[43] However, as Article 36 TFEU constitutes a derogation from the basic rule of free movement of goods, it must be interpreted strictly.

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.

47. Specifically, according to the statistics published and conclusions drawn by the FAMHP, medicinal product **shortages are already decreasing** owing to existing Belgian instruments. The FAMHP also highlights that in the overwhelming **majority of cases, continuity of care is ensured** through authorised therapeutic alternatives, pharmacist substitution, officinal preparations or other targeted interventions.

Only a limited number of cases are classified as "critical", meaning that no suitable alternative is available and/or that the clinical impact is significant. It is in such cases that derogations and other exceptional measures are deployed (see, *supra* paragraph 6). This confirms that Belgian authorities already differentiate between critical and non-critical shortages and that most situations are handled without any need for broad, continuous stock surveillance.

42 Judgment of 16 December 2008, *Lodewijk Gysbrechts, Santurel Inter BVBA*, C-205/07, EU:C:2008:730, para. 45.
43 'Consolidated version of the Treaty on the Functioning of the European Union', Article 36.

48. Against this background, the **Draft Royal Decree** is **not** designed as **a targeted response to a documented, systemic failure of existing instruments**. Rather, it **represents an unjustified expansion** from a situation in which only a small fraction of shortages is critical and is addressed through tailored measures (see, *supra* section 2.1), to a permanent, nationwide, daily monitoring regime covering virtually the entire market of medicinal products. The scope extends to all prescription and reimbursable medicines, as well as non-prescription medicines sharing the same ATC code (a category presumed to cover 76 additional molecules), and even products no longer marketed. Belgium has not produced evidence that the current, residual level of risk, confined to a limited subset of critical shortages, requires such a drastic expansion of monitoring and reporting.

49. This **evidential deficit is particularly acute in relation to the pilot project**, as set out above (see, section 2.2). The FAMHP launched a pilot stock monitoring tool, specifically to assess how useful the tool would be in proactively managing shortages. Yet, Belgium has not published any evaluation report of this pilot, nor provided any data or analysis showing that: (i) the pilot materially reduced the number or impact of critical shortages; or (ii) the pilot revealed structural shortcomings that can only be remedied by a full market, daily monitoring regime.

50. Therefore, in the absence of concrete evidence that there is real and current risk to health and life of humans that would necessitate a far-reaching Stock Monitoring Tool as envisaged by the Draft Royal Decree, **Belgium cannot rely on Article 36 TFEU to justify the restriction imposed by the Draft Royal Decree**.

(b) Proportionality test

51. Even if the Belgian authorities had proven the existence of the legitimate objective of protecting public health, *quod non*, the restrictive measure proposed must in any event 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[44], as discussed below.

(i) The proposed measure is not suitable for the objective sought

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

Belgium must show that the Draft Royal Decree is genuinely suitable and appropriate to contribute to the prevention and management of medicine shortages. That requires a plausible causal link between the specific design of the Stock Monitoring Tool and an improvement in patient access and availability. On the basis of the available information, such a link has not been established.

[44] 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.

53. First, Belgium has produced **no evidence** that a broad, high frequency **stock monitoring** of the kind **envisaged in the Draft Royal Decree will in fact prevent shortages**. Shortages of medicinal products are predominantly driven by upstream factors such as manufacturing disruptions, quality defects, scarcity of active substances, global allocation decisions, regulatory constraints and sudden demand surges. The Stock Monitoring Tool, if designed correctly, *quod non,* may signal symptoms (*e.g.,* declining stock levels), but it does not address the underlying structural causes. Without evidence that shortages are currently occurring because authorities lack inventory data, the suitability of a generalised stock inventory system remains unsubstantiated.

54. Second, **pharmaceutical companies already have strong commercial and regulatory incentives to avoid stock-outs**. Shortages entail reputational harm, financial loss, contractual penalties and increased operational costs. Companies therefore operate sophisticated internal forecasting, allocation and mitigation systems. In Belgium, they are moreover subject to existing legal obligations to notify unavailability through PharmaStatus and to cooperate with the FAMHP and the Unavailability Working Group. There is no indication that shortages of clinical relevance are currently going undetected due to an absence of stock-level data.

55. Third, Belgium has not shown why, **if additional monitoring is desired**, it would not be **more suitable to invest in and further develop PharmaStatus** (and its link to SAM), and to **improve an existing shortage reporting system that is closely aligned with the logic of ESMP**, rather than creating a new, parallel Stock Monitoring Tool focused on inventory levels. A shortage driven, event-based enhancement of PharmaStatus would be far more directly connected to the objective of preventing clinically relevant shortages than a generalised, permanent stock inventory exercise.

56. Fourth, even assuming that stock monitoring in principle could be useful, the concrete design of the Stock Monitoring Tool is such that it is **unlikely to generate the reliable, comprehensive information** that the Belgian authorities appear to expect.

The product scope is extremely broad. The pharma.be impact assessment shows that, for most respondents, almost the entire Belgian portfolio would be covered. At the same time:

- some companies do not currently have IT systems capable of extracting and transmitting the required data at daily frequency for this breadth of products;
- some companies will in practice not report, or will report late or partially (*e.g.*, no weekend uploads, delayed updates), particularly smaller operators with limited IT capacity; and
- the obligation to provide "next two deliveries" on a rolling daily basis concerns a parameter that stakeholders uniformly describe as volatile and operationally unstable, often only defined or adjusted weekly.

As a result, the Stock Monitoring Tool risks producing incomplete and unreliable data. In other words, the Stock Monitoring Tool is structurally not suited to provide the "full range of data" that the legislator envisages. By contrast, a regime with a limited, risk-based scope, reduced frequency (*e.g.*, weekly) and realistic implementation timelines would be much more likely to yield accurate, usable data for the products that matter most.

57. Fifth, even assuming the reported data is comprehensive and correct, *quod non,* due to the broad scope and high reporting frequency, the volume of daily data generated under the Draft Royal Decree would be considerable. The FAMHP would be required to process and assess **vast quantities of information** on a daily basis. There is no **evidence that the FAMHP** even **has the operational capacity to review, interpret and act upon such data in real time**. Important signals may be obscured in data overload. By contrast, a targeted approach based on predefined criteria (see, *infra* paragraph 67(i)) would drastically reduce the number of products concerned and enable focused, meaningful analysis.

58. Sixth, a measure intended to safeguard availability cannot be regarded as suitable if it is **liable, in practice, to reduce availability**. As already mentioned, the pharma.be impact assessment shows that the administrative burden and related costs of a Belgium-specific IT development and reporting are significant, especially for smaller companies. Operators supplying several EU Member States from integrated hubs anticipate that, for low volume products or for smaller Belgian market shares, the additional burden may cause the continued supply to Belgium to become economically unattractive. It is foreseeable that some **operators may** rationally **reduce or withdraw supply**. A measure that creates incentives to exit or downscale supply undermines its own objective and cannot be considered suitable within the meaning of Article 36 TFEU.

59. Seventh, even assuming that the instrument could be useful once fully implemented, *quod non*, the **extremely short implementation timeline further undermines suitability**. Companies estimate that they require between 6 and 18 months from final technical specifications to design, build, validate and test automated reporting systems. The Draft Royal Decree foresees entry into force on 1 July 2026, without transitional arrangements. [45]

In practice, many operators will not be operationally ready at that time. An under-implemented system risks generating inaccurate data, diverting resources from actual shortage management, and creating confusion rather than clarity. A more appropriate approach would involve a realistic transition period (at least 12–18 months), combined with a narrowed, risk-based scope and adjusted reporting frequency.

60. For all these reasons, the **Draft Royal Decree, as notified, cannot be regarded as suitable** for achieving the objective of preventing and managing medicinal product shortages within the meaning of Article 36 TFEU. More targeted and proportionate alternatives, as proposed in section 4 below, would better serve the stated public health objective.

(ii) The proposed measure is not necessary for the objective sought

61. For a measure to be proportionate, even if it satisfies the suitability criterion, *quod certe non*, 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**.[46] We will evaluate this again based on the presumed public health objectives stated by Belgium.

[45] Article 10 Draft Royal Decree.
[46] Judgment of 3 December 1998, *Bluhme,* Case C-67/97, para. 35.

62. First, the **product scope** of the Stock Monitoring Tool is **manifestly excessive**. As acknowledged by the FAMHP's own statistics and analysis (see, *supra* paragraphs 6 and 47), the vast majority of reported shortages do not threaten continuity of care. Only a limited subset of cases are classified as "critical".

In this context, it is not necessary to impose permanent, daily monitoring on all prescription-only medicines, all reimbursable medicines, and any non-prescription medicines sharing the same ATC code. A proportionate, risk-based alternative would confine systematic monitoring to those products for which shortages may realistically cause serious patient harm, by establishing predefined criteria that trigger the application of stock-monitoring requirements to medicinal products within the existing PharmaStatus application (see, *infra* paragraph 67(i)).

The pharma.be impact assessment confirms that such a risk-based limitation of scope would dramatically reduce the reach of the tool without undermining the ability to manage critical shortages (see, *supra* paragraph 28). Limiting the scope would automatically reduce the number of actors subject to the Draft Royal Decree, thereby lowering the burden without any loss in public-health protection.

Belgium has not shown why this obvious, risk-based alternative, monitoring only those products for which shortages are truly critical, would be insufficient. A full-market monitoring regime therefore goes well beyond what is necessary for the objective sought.

63. Second, the Draft Royal Decree mandates **daily reporting** of stock levels and flows for all in-scope products, **including on weekends**. This is **significantly more onerous** than the 2024 pilot, which operated on a weekly basis for eight high risk substances.

From a public health perspective, the key objective is to detect meaningful trends or sustained deteriorations in availability. Weekly reporting for a defined set of essential or critical medicines (see, *infra* paragraph 67(i)) would: (i) allow FAMHP to monitor stock trajectories and spot potential shortages in sufficient time to intervene, (ii) significantly reduce the operational burden on companies; and (iii) improve data data reliability by avoiding rushed submissions.

By contrast, daily reporting is not only more intrusive but also less realistic. Many companies, particularly SMEs and smaller affiliates, lack the IT infrastructure to automate daily reporting within the proposed timeframe. In practice, gaps, weekend delays or manual uploads are foreseeable, resulting in inconsistent data. Moreover, the FAMHP would be required to process large volumes of data relating to low-risk products, potentially obscuring genuinely critical signals. Belgium has thus failed to demonstrate that imposing daily reporting across the board is necessary, especially when weekly reporting would be sufficient to achieve the same level of protection.

64. Third, the **obligation to report the "next two deliveries"** on a daily basis is equally **unnecessary**. Feedback from the impact assessment indicates that delivery schedules are inherently volatile (see, *supra* paragraph 58). Daily updates therefore provide limited additional predictive value while significantly increasing compliance complexity. Belgium has not shown that such granular reporting materially enhances shortage prevention compared to less burdensome alternatives.

65. **Belgium has not** demonstrated that it has **seriously considered** these **less restrictive alternatives**, nor has it stated why such alternatives may be inadequate. The measure under the **Draft Royal Decree therefore** fails the proportionality test and **cannot be regarded as necessary** within the meaning of Article 36 TFEU.

4. CONCLUSION

66. **pharma.be** fully recognises that medicine shortages could be a serious problem when no alternatives are available for patients therefore does not in any way oppose appropriate measures to prevent and manage such critical shortages of essential medicines. On the contrary, pharma.be **supports the development of an improved, well-designed monitoring system** that would operate as part of the existing PharmaStatus application. It is also important to recall that pharma.be supported the pilot project introduced by the FAMHP in 2024 and actively contributed to its implementation.

Our objection is therefore not directed against stock monitoring as such, but **against the specific design of the Stock Monitoring Tool laid down in the Draft Royal Decree**, in particular insofar as it would impose high frequency reporting obligations for a very wide range of medicinal products, far beyond what is necessary or proportionate.-frequency reporting obligations for a very wide range of medicinal products, far beyond what is necessary or proportionate.

67. All the **concerns** identified in the present note **could be addressed if** the Draft Royal Decree were amended as follows:

(i) Product scope: introduction of predefined criteria that trigger the application of stock-monitoring requirements to medicinal products

Systematic stock monitoring should be **limited to medicinal products with clearly defined criteria** for which shortages are genuinely likely to have a serious public health impact. Such criteria could be based on objective criteria **comparable to those already applied under the Royal Decree on Export**.

(ii) Removal of the **obligation to report the "next two deliveries"**.

Feedback from the impact assessment indicates that delivery schedules are inherently volatile (see, *supra* paragraph 58). This data provides limited additional predictive value while significantly increasing compliance complexity. Belgium has not shown that such granular reporting materially enhances shortage prevention compared to less burdensome alternatives.

(iii) Reporting frequency: weekly rather than daily

The reporting frequency should reflect the objective of identifying structural or sustained supply risks, rather than short-term stock fluctuations. **Weekly reporting**, at least for products fulfilling the criteria, **would be sufficient to detect emerging shortages** in a timely manner and would be consistent with the approach adopted during the pilot phase.

A weekly regime would significantly reduce operational burdens, improve data quality and reliability, and enable both operators and the FAMHP to focus on meaningful signals. By contrast, daily reporting

across a broad product scope is neither necessary nor operationally realistic and risks generating excessive data without a commensurate public health benefit.

(iv) Implementation timeline: minimum one-year transition period

The **implementation date should be postponed providing for a realistic transition period of at least one year** from the adoption of final technical specifications.

The pharma.be impact assessment demonstrates that companies require substantial time to design, build, test and validate automated reporting systems, particularly when centralised cross-border IT infrastructures must be adapted. A rushed implementation risks incomplete or unreliable reporting and may inadvertently disrupt supply chains. A phased-in or staged implementation, prioritising the highest-risk products first, would further enhance legal certainty and effectiveness

68. With these amendments, Belgium could establish a lawful, proportionate and effective monitoring system that is aligned with EU harmonisation efforts, respects internal market principles, and genuinely supports the shared objective of safeguarding patient access to essential medicinal products.

69. In light of the above, pharma.be respectfully invites the Commission, in the framework of the TRIS-procedure, to **block the Draft Royal Decree** insofar as it conflicts with and pre-empts the harmonisation pursued by the upcoming EU Pharma Package and the proposed Critical Medicines Act.

At a minimum, pharma.be respectfully urges the Commission to **issue a detailed opinion** requesting Belgium to amend the Draft Royal Decree so as to eliminate any obstacles to the EU internal market.

70. Finally, pharma.be 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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