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**DG Growth, Unit B2**

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TRIS notification 2025/0768/BE

"Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to creating a Stock Monitoring Tool"
(notified on 18 December 2025)

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**Lasne, 19 February 2026**

**Opinion from the Belgian Association of the Consumer Healthcare Industry ('BACHI')**

I am writing to you in my capacity as representative of BACHI, the Belgian Association of the Consumer Healthcare Industry which represents companies active in the industry of over-the-counter (OTC) and pharmacy-based health products. BACHI asbl has its registered seat in Belgium, Chaussée de Louvain 431, 1380 Lasne and is registered at the Crossroad Bank for Enterprises under number 809.465.691.

Our Association wishes to submit an opinion on the Draft "Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to creating a Stock Monitoring Tool" *notified by Belgium* on the 18th of December 2025 under notification number 2025/0768/BE[1] (see Annex 1 – the ""**Draft Royal Decree**") as we believe that it is incompatible with European Union law. BACHI represents 50 industrial operators active in the medicines supply chain in Belgium and is directly concerned by the scope and obligations contained in this Draft Royal Decree.

In what will be detailed hereinafter, we set out that the Draft Royal Decree is found incompatible with EU law. The purpose of this opinion is to bring to the attention of the European Commission the incompatibilities of these aspects with EU law.

Yours Faithfully,

For BACHI

Marc Gryseels

Managing Director Bachi

[1] See Annex 2 to this opinion for the details of this TRIS notification.



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## *Executive summary*

In the present opinion, we set forth that the Draft Royal Decree under TRIS notification number 2025/0768/BE is incompatible with EU law on the following grounds:

(i) **Firstly**, the obligations of marketing authorisation holders with regard to the prevention and management of the risk of shortages of human medicines are harmonised at EU level. Consequently, as far as marketing authorisation holders are concerned, the Draft Royal Decree infringes the harmonised legal framework. With regard to other actors in the medicine supply chain, in accordance with the principle of equality, a measure that is stricter than that imposed by EU law on marketing authorisation holders – who are the front-line actors in the marketing of medicines – would not be permissible.

The draft reform of pharmaceutical legislation (COM/2023/193 final) confirms the relevance of this issue. Furthermore, when regulating in a particular area where a European rule is announced, Member States are bound by a certain degree of restraint, by virtue of the obligation of loyal cooperation, i.e. it cannot adopt a measure that could conflict with the future rule of European Union law or compromise the objectives it pursues (Case C-246/07).

(ii) **Secondly**, in the alternative, even if the Draft Royal Decree would not be regarded as regulating a matter already harmonised at EU level, the measures that it intends to impose on operators in the value chain of human medicines are not justified in terms of necessity or strict proportionality. In particular:

a. European Union intends to impose a completely different burden on operators for the monitoring and management of shortages and for the security of the supply of medicines. The emphasis is on the responsibility of operators, in particular the marketing authorisation holder, to prevent the risk of shortages, mitigate it and assess the risks associated with shortages through the elaboration of prevention plans.
b. Existing delivery deadlines already ensure rapid supply and notification mechanisms (medicinal products that cannot be delivered for at least 3 working days are already considered temporarily unavailable and should be notified to the national control authorities), and the Belgian official platform PharmaStatut.be already real-time monitoring of shortages.
c. The scope of the Draft Royal Decree is excessively broad as it applies to nearly all medicinal products, including non-prescription (OTC) medicines, for which historical data has not shown any shortage issue

Imposing daily stock reporting obligations on all supply-chain operators (i.e. daily sales, daily stock-on-hand, expected next delivery) , despite the fact that most products present no shortage risk, is therefore unnecessary and hence disproportionate.

Given the adequacy of existing procedures (EU and national procedures in place) and the disproportionate impact they would have on those involved in the supply and distribution of medicines, the Draft Royal Decree creates an obstacle to the free movement of goods that is not and cannot be justified in accordance with Article 36 TFUE.



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## I. Scope and subject-matter of the Draft Royal Decree

2. The Draft Royal Decree requires from various actors in the medicine supply chain to report - on a daily basis - to the Federal Agency for Medicines and Health products ("**FAMHP**") the status of medicine stocks as well as the daily sales. The announced objective of the measure is to allow national authorities anticipating and preventing medicine shortages, assessing patient needs and developing a strategy for the unavailability and continuous supply of medicines (Art. 7).

3. Its scope can be summarised as follows:

   a. *Material scope (Art. 1)*

      1° prescription-only medicinal products for human use;
      2° reimbursable medicinal products for human use;
      3° non-prescription medicinal products with the same ATC code as the medicinal products referred to in points 1° and 2°

      provided that they are:
      - authorised or imported, and marketed in Belgium, or
      - whose marketing in Belgium has ceased less than two years ago.

   b. *Personal scope of application (Art. 2)*

      1° Marketing authorisation holder, or where applicable, the wholesale distributor responsible for distribution on behalf of the marketing authorisation holder;
      2° Wholesale distributor authorised pursuant to Belgian law, whether established in Belgium or not;
      3° Wholesaler-distributor;
      4° Hospital pharmacy and pharmacy open to the public.

4. The Draft Royal Decree imposes the following information requirements:

   a. Daily reporting obligation (for all) (Art. 3)
      - Reporting of stocks on D-1 (overview of stocks and volume sold)

   b. One-off reporting obligation (upon entry into force of the Royal Decree) (for all, except for pharmacists) (Art. 4)
      - Reporting of average monthly volume for the last twelve months.

   c. Obligation to provide information on new stocks placed on the Belgian market (marketing autorisation holders and wholesale distributors) (Art. 5)
      - Obligation to report as soon as the information is known: date and volume of the next marketing, as well as subsequent marketing.

5. The information must be communicated via an application made available by the FAMHP, the operational details of which are not described in the Draft Royal Decree (Art. 6). The FAMHP retains the data for 10 years (Art. 8).



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## II. In principal: EU law harmonises the obligations of marketing authorisation holders with regard to the monitoring and notification of shortages

### *(i) Legal context*

6. The compatibility of the Draft Royal Decree with current and future European Union law, given the progress of the European pharmaceutical legislation reform project (COM(2023) 193 final - Political agreement of 11 December 2025), must be raised.

7. Broadly speaking, the scope for national intervention in an area that is also regulated at EU level depends on the degree of harmonisation of the area in question and, if the area is not harmonised, on the limits inherent in the fundamentals of EU law (in particular, the free movement of goods).

   In other words, a matter that is harmonised by European Union law cannot be subject to national measures, particularly when the European legal standard constitutes a complete harmonisation standard.

   Only when the matter is not harmonised by EU law may Member States adopt national measures, provided, however, that they do not impede the free movement of goods or, more generally, conflict with a higher legal norm (EU law, but also, in the case of the Royal Decree, the Constitution, the law or a general principle of law).

8. The fight against medicine shortages is a long-recognised public health issue within the European Union.[2] In this context, marketing authorisation holders and distributors of medicinal products are required, each within the limits of their responsibility, to ensure an adequate and continuous supply of these products to pharmacies and persons authorised to dispense medicinal products in order to meet the needs of patients in the Member State concerned (Article 81(2) of 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, transposed into Belgian law by *Article 12quinquies*(1) of the Law of 25 March 1964 on medicinal products).

9. Marketing authorisation holders are also required to provide, upon request, the authorities of the Member State in which the medicinal product is marketed with any information relating to sales volumes[3] (Article 23a(3) of the Directive, transposed into Belgian law by Article 6§*1sexies*(5) of the Law of 25 March 1964 on medicinal products).

   They must also notify these authorities of any definitive or temporary cessation of the marketing of a medicinal product, at least two months in advance (Art. 23a(3) of Directive 2001/83, transposed into Belgian law by Article *6§1sexies* para. 2 of the Law of 25 March 1964 on medicinal products).

[2] European Parliament resolution of 17 September 2020 on medicine shortages – how to tackle an emerging problem (2020/2071(INI)), OJ C 385, 22.9.2021, pp. 83–103.
[3] In particular in the context of pharmacovigilance.



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10. Furthermore, since the COVID-19 pandemic, which has exacerbated medicine shortages, Regulation (EU) 2022/123[4] has established systems for the monitoring, prevention and notification of shortages of medicines and medical devices considered to be critical.

    In particular, it establishes a "Steering Group on Medicines Shortages" which, in coordination with the national authorities responsible for medicines, establishes appropriate communication with marketing authorisation holders or their representatives, manufacturers, other relevant actors in the medicinal product supply chain and representatives of healthcare professionals, patients and consumers, in order to gather relevant information on actual or potential shortages of medicinal products considered critical during a public health emergency or a major event[5] (Art. 3.4).

    In particular, after the recognition of a public health emergency or the recognition of a major event:

    - The European Medicines Agency (EMA) may request marketing authorisation holders for medicinal products included in the lists of critical medicines to provide it with data on sales and market shares, as well as available stocks of the medicinal product concerned.

    - Member States may require wholesalers and other persons or legal entities authorised or entitled to supply the public with medicinal products included in the lists of critical medicines to provide them with relevant information and data, in particular on the stock levels of those medicinal products.

    (Articles 7, 10 and 11)

### *(ii) As far as marketing authorisation holders are concerned*

11. It appears from the opinions issued by the Legislation Section of the Belgian Council of State that EU law harmonises, with Article *23a* of the 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, the obligations of marketing authorisation holders with regard to the prevention and management of the risk of shortages[6].

[4] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a strengthened role for the European Medicines Agency in crisis preparedness and management in relation to medicinal products and medical devices.

[5] **A public health emergency** is defined as a public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU (Art. 2.a. of Regulation 2022/123). **A major event** is defined as an event that may pose a serious risk to public health in relation to medicinal products in several Member States; such an event involves a life-threatening or other serious threat to health of biological, chemical, environmental or other origin, or a serious incident that may affect the supply or demand of medicinal products, or the quality, safety or efficacy of medicinal products; such an event may lead to medicinal product shortages in several Member States and require urgent coordination at Union level to ensure a high level of protection of human health (Article 2(b) of Regulation 2022/123).

[6] The Legislation Section of the Council of State acts as an advisor to the Belgian legislator (in the broad sense: parliaments and governments). It provides expert opinions on whether a draft normative act complies with higher-ranking norms, in particular European Union law, as well as on its compatibility with norms of the same hierarchical level with which the draft may potentially conflict. With regard to the conformity of the draft norm with European Union law, the analysis conducted by the Legislation Section of the Council of State is generally thorough, in light of the primacy of EU law.



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We refer in particular the opinion issued by the Council of State in 2021 on the draft Article 100/1 of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use[7]:

> "*Article 37/1, § 1, paragraph 2, as drafted, as it is to be amended following examination of the legal basis, introduces an additional obligation on the holder of the authorisation and registration, parallel distributors and parallel importers (see comment 4.3.6 on this subject), which is not covered by* ***Article 23a of Directive 2001/83/EC. It remains to be seen whether, in view of the harmonisation achieved by this provision of the Directive****, it can still be envisaged that the parties concerned may be subject to the obligation to assess the notifications made to them. It would therefore be preferable for the authors of the draft to contact the relevant Directorate-General of the European Commission to ensure that such a provision can be considered to be in conformity with Directive 2001/83/EC.*"[8] (emphasis added; to the best of our knowledge, however, the Belgian government never contacted the Commission in that respect, and has not notified this draft Royal decree under the terms of Directive (EU) 2015/1535).

12. The models that the EMA has put in place with national regulatory authorities and market operators on a voluntary basis are particularly noteworthy (accessible via this link). They confirm the harmonised approach in the prevention and management of shortages of human medicinal products.

    We note in particular the guidelines Good practices for industry for the prevention of human *medicinal product shortages* (2023), which emphasise the responsibility of operators in procedures for anticipating the risk of shortages, in particular through the implementation of prevention plans (recommendation 4) and the strengthening of communication between operators (recommendation 8).[9]

    The prevention plan is designed as a tool enabling operators to fulfil their obligation to ensure an adequate and continuous supply of medicinal products, as prescribed by Article 81(2) of Directive 2001/83 (in the *Shortage Prevention Plan (SPP)* guidelines

[7] Article 101/1 of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use (inserted by Article 5 of the Royal Decree of 26 November 2021 implementing Article 6, § 1er *sexies* of the Law of 25 March 1964 on medicinal products, on the transparency of stocks of medicinal products intended for public service obligations and introducing various amendments) requires wholesalers-distributors to provide the FAMHP, on a monthly basis, with a detailed overview of stocks of medicinal products for human use, the destination (quantity) of medicinal products and the quantity of medicinal products purchased between the last day of the previous month (month X - 1) and the last day of the month preceding that month (month X - 2).

[8] Opinion 69.346/3 of 10 June 2021 on the draft Royal Decree of 26 November 2021 implementing Article 6, § 1ersexies of the Law of 25 March 1964 on medicinal products, on the transparency of stocks of medicinal products intended for public service obligations and making various amendments (Belgian Official Gazette of 10 December 2021, p. 118022).

[9] See also the Communication of 24 October 2023 from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, 'Addressing' medicine shortages, COM(2023) 672, p. 8, in which the Commission notes that these prevention and management measures imposed on operators are part of their obligation to ensure an adequate and continuous supply ("The proposed reform of pharmaceutical legislation introduces structural measures to improve the availability of medicines. Its key elements include a new European alert system with a faster mechanism for companies to report shortages and withdrawals, harmonised criteria for reporting, mandatory shortage prevention plans and coordinated shortage management by the EMA. This reform would strengthen and tighten the obligation on companies to ensure an adequate and continuous supply."



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(2024, p. 1: "*The implementation of shortage prevention plans (SPP) will facilitate the MAH's compliance with their obligations to ensure, within the limits of their responsibilities, an adequate and continuous supply to the market (Article 81 Directive 2001/83).*"). It should be noted that, at the operator level, prevention involves aggregating data on the market positions of medicines, flows, and the production and distribution chain.

13. The draft reform of pharmaceutical legislation, which aims at harmonising European Union law on the prevention of medicine shortages, incorporates the models developed by the EMA. In particular, the proposed regulation "laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules for the European Medicines Agency" strengthens the obligations of marketing authorisation holders to report shortages (Article 116) and requires them to establish a shortage prevention plan (Article 117). It provides for the development of guidelines by the EMA for marketing authorisation holders (Article 117(2)) and lays down a set of rules governing interactions between the operators concerned, in particular the marketing authorisation holder, the national supervisory authorities and the EMA (Chapter X, Articles 116 to 134).

14. With regard to the monitoring and management of shortages and security of supply, the proposed regulation aims to harmonise EU law. We refer in particular recital 137 of the proposed regulation:

> "*(137) In order to achieve greater security of supply of medicinal products in the internal market and thus contribute to a high level of public health protection, it is appropriate to align the rules on the monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and respective roles and obligations of the entities involved, in this Regulation. It is important to ensure the continuous supply of medicinal products, which is often taken for granted throughout Europe. This is particularly true for the most critical medicinal products that are essential to ensure continuity of care and the provision of high-quality healthcare and to guarantee a high level of public health protection in Europe.*".

For example, in the context of shortage monitoring and management, the national supervisory authority may request additional information from the marketing authorisation holder, in particular a risk mitigation plan, a risk assessment or a prevention plan (Article 118(2)). The data covered by these plans are described in Annex IV to the proposed regulation; they include data on substitute medicines, stocks and actual and projected flows (Part IV, for the mitigation plan).

15. To summarise, the proposed regulation "laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules for the European Medicines Agency", for which a political agreement has been reached on 11 December 2025 (hereafter "Proposed Regulation"), imposes specific obligations on marketing authorisation holders in terms of preventing shortages, assessing the risks associated with shortages and mitigating those risks, in relation to national supervisory authorities and the EMA. The broad scope of the areas covered (monitoring and management of medicine shortages; security of supply) and the precision of the rules imposed on the parties involved (operators; national regulatory agencies; EMA) are, in our view, an expression of the harmonisation of this matter at European Union level.



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16. In this regard, it is worth noting that when a Member State intends to legislate in a particular area where a European rule is announced, that Member State is bound by a certain degree of restraint, by virtue of the obligation of loyal cooperation, i.e. it cannot adopt a measure that could conflict with the future rule of European Union law or compromise the objectives it pursues.

17. EU law provides that, under the principle of sincere cooperation, Member States must refrain from any measure that could jeopardise the attainment of the Union's objectives (TEU, article 4.3). In light of this principle, the Court of Justice of the European Union has repeatedly held that it applies even when the Union act is not yet binding upon them (a directive before the expiry of the transposition period)[10], is not yet in force (an act before its publication)[11], or even when it is still in the process of being adopted (where the Commission has submitted a draft decision to the Council)[12].

### *(iii) As far as other operators are concerned*

18. The question of harmonising European Union law on the monitoring and management of medicine shortages has been raised with regard to marketing authorisation holders.

    We believe that it should also be raised with regard to other operators, at least from the perspective of the principle of equality.

    Indeed, although the regulatory framework (current and future) expresses in general terms the possibility of imposing on these operators an obligation to inform the national supervisory authority[13], we do not see why these operators should be subject to more stringent domestic rules than those imposed on marketing authorisation holders by European Union law, given that the latter are the operators primarily concerned with the prevention of medicinal product shortages.

19. The Draft Royal Decree seeks to impose a broad requirement to notify information and data which, under European Union law, clearly do not fall within the obligations that the marketing authorisation holder would directly assume towards the national supervisory authority in order to prevent the risk of shortages. Only for the management of an announced or actual crisis can the obligation to inform the national supervisory authority be extended.

### *(iv) Conclusion*

20. In conclusion, we believe that a reasonable reading of the current legislation leads to the conclusion that EU law harmonises the obligations of marketing authorisation holders with regard to the monitoring and notification of shortages. Consequently, the adoption of a domestic legal measure could not be accepted in their regard.

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[10] see ECJ, 18 December 1997, Inter-Environnement Wallonie, C-129/96, EU:C:1997:628, § 628.
[11] ECJ, Lietuvos Respublikos Seimo nariu grupé, C-2/18, EU:C :2019:962, § 55.
[12] ECJ, 20 April 2020, Commission v. Sweden, C-246/07, EU :C :2010 :203.
[13] See Article 120(2) of the Proposed Regulation: *'[For the purposes of monitoring notifications of shortages], where appropriate, at the request of the competent authority concerned, as defined in Article 116(1), entities, including other marketing authorisation holders within the meaning of Article 116(1), importers and manufacturers of medicinal products or active substances and their suppliers, wholesalers, associations representing interested parties or other natural or legal persons authorised or entitled to supply medicinal products to the public, shall provide any information requested in a timely manner.*



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21. With regard to other actors in the medicine supply chain, we consider that, in accordance with the principle of equality, a measure that is stricter than that imposed by EU law on marketing authorisation holders – who are the front-line actors in the marketing of medicines – could not be accepted.

22. The draft reform of pharmaceutical legislation (COM/2023/193 final) confirms the relevance of this issue, taking into account the obligation of loyal cooperation, i.e. that a Member State cannot adopt a measure that could conflict with the future rule of European Union law or compromise the objectives it pursues.

## III. In the alternative: the Draft Royal Decree is not proportionate to the objective pursued and breaches Articles 34-36 TFUE

### *(i) Legal background*

23. In the alternative, even if the Draft Royal Decree would not be regarded as regulating a matter already harmonised at EU level, it remains that the measures that the Draft Royal Decree intends to impose on operators in the value chain of human medicines are not proportionate to the objective pursued.

24. Article 34 of the TFEU prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States. This prohibition covers « *all commercial rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade* »[14].

    It is settled case law that national rules forming obstacles to the free movement of goods, even if those rules apply without distinction to all products, constitutes measures of equivalent effect.[15] Except where these can be justified on ground of a public-interest objective taking precedence over the free movement of goods in accordance with Article 36 of the TFEU, such rules are prohibited.

25. The principle of proportionality, as established under Article 36 of the Treaty on the Functioning of the European Union (TFEU), requires that any restriction of the free movement of goods must be strictly limited to what is necessary to achieve the legitimate objectives, such as the protection of public health. This means that national measures should not go beyond what is required, and must be carefully balanced against their impact on fundamental rights and freedoms.

    In that respect, the Court of Justice of the European Union has already stated that the objective of facilitating controls of products is not recognised public-interest objectives, capable of taking precedence over the free movement of goods. In case C-104/75 "*De Peijper*"[16], the Court has explicitly stated:

> « *8. In particular article 36 cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the*

[14] Point 74, CJEU, 28 January 2010, *Commission v. French Republic*, case C- 333/08, ECLI:EU:C:2010:44.
[15] CJEU, 20 February 1979, *Cassis de Dijon*, case C-120/78, ECLI:EU:C:1979:42 ; CJEU, 24 November 1993, *Keck and Mithouard*, cases C-267/91 and C-268/91, ECLI:EU:C:1993:905
[16] CJEU, 20 May 1976, *De Peijper*, case C- 104/75, ECLI:EU:C:1976:67.



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*said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be require.* ».

26. More precisely, it follows from the Court's case-law that the conditions for the admissibility of a measure restricting the free movement of goods must be interpreted strictly, and the reasons relied upon by the Member State must be justified in concrete terms (...) : the Member State must demonstrate that the measure is necessary to achieve the objective invoked, that it is capable of effectively attaining that objective, and that it does not go beyond what is necessary (...). It has recently reaffirmed these conditions in its judgement of 13 Novembre 2025, Commission v. Hungary, C-499/23, EU:C:2025:875( emphasis added) :

> « *69 A national measure contrary to Article 35 TFEU may be justified on one of the public interest grounds listed in Article 36 TFEU and by an overriding requirement in the public interest, provided that the objective which it pursues is legitimate and that the measure is proportionate to that objective (see, to that effect, judgments of 16 December 2008, Gysbrechts and Santurel Inter, C-205/07, EU:C:2008:730, paragraph 45; of 17 September 2020, Hidroelectrica, C-648/18, EU:C:2020:723, paragraph 34; and of 19 January 2023, CIHEF and Others, C-147/21, EU:C:2023:31, paragraph 48).*
>
> *70 To that end, it must be ascertained whether the measure **is appropriate for** ensuring the attainment of that objective and **does not go beyond what is necessary** in order to attain it. It should also be recalled in that connection that national legislation is appropriate for ensuring attainment of the objective relied on **only if it genuinely reflects a concern to attain it in a consistent and systematic manner** (see, to that effect, judgment of 11 June 2015, Berlington Hungary and Others, C-98/14, EU:C:2015:386, paragraph 64 and the case-law cited).*
>
> *71 As regards, in particular, a national measure which, according to the Member State concerned, is justified by an objective of public security, the Court has already held that, for the purposes of Article 36 TFEU, that measure **must be actually justified by objective circumstances corresponding to the needs** of public security (see, to that effect, judgment of 10 July 1984, Campus Oil and Others, 72/83, EU:C:1984:256, paragraph 36).*
>
> *72 Likewise, the Court has stated that, while Member States are still, in principle, free to determine the requirements of public policy and public security in the light of their national needs, those grounds must, in the EU context and, in particular, as derogations from a fundamental freedom enshrined in the TFEU, be **interpreted strictly**, so that their scope cannot be determined unilaterally by each Member State without any control by the EU institutions. Thus, public security may be relied on only if there is a genuine and sufficiently serious threat to a fundamental interest of society (see, to that effect, judgments of 18 June 2020, Commission v Hungary (Transparency of associations), C-78/18, EU:C:2020:476, paragraph 91*



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*and the case-law cited, and of 13 July 2023, Xella Magyarország, C-106/22, EU:C:2023:568, paragraphs 66 and 67).*

73 *In addition, the reasons which may be invoked by a Member State by way of justification* ***must be accompanied by appropriate evidence or by an analysis of the appropriateness and proportionality*** *of the restrictive measure adopted by that State, and by specific evidence substantiating its arguments (judgments of 7 June 2007, Commission v Belgium, C-254/05, EU:C:2007:319, paragraph 36 and the case-law cited, and of 19 January 2023, CIHEF and Others, C-147/21, EU:C:2023:31, paragraph 53 and the case-law cited).* » (see also ECJ, 19 January 2023, CIHEF e.a., C-147/21, EU:C:2023:31, § 53).

### *(ii) In the case at hand*

#### *a. The measures already in place provide a relevant basis for determining whether the Draft Royal Decree is compatible with the fundamental freedom it infringes*

27. The Draft Royal Decree aims at imposing obligations for operators within the value chain of human medicines. However, these measures appear excessive in relation to the aims pursued. Despite the stated objective of preventing and managing medicine shortages, existing mechanisms already provide sufficient tools for authorities to anticipate and respond to such risks. The current framework, fortified by recent developments at European level and the involvement of the European Medicines Agency (EMA), allows for effective management of shortages without imposing unnecessary burdens on operators.

28. The European regulatory framework (current and future) clearly outlines the mechanisms that must be put in place to prevent and manage medicine shortages and ensure security of supply, i.e. ultimately guarantee continuity of care. Although the current framework has revealed shortcomings, the way in which it has been implemented since the COVID-19 crisis and the involvement of the EMA in developing guidelines, together with the operators concerned, provides a relevant basis for determining whether or not a particular measure decided at Member State level is compatible with the fundamental freedom it infringes.

#### *b. The Draft Royal Decree goes beyond what is required*

29. **First**, the deadlines by which marketing authorisation holders are required to notify events leading to the unavailability of medicines already enable national control authorities to anticipate the risk of shortages and to mobilise the resources available on the market to reduce them or find alternative solutions.

30. **Second**, existing delivery deadlines already ensure rapid supply and notification mechanisms. Under Article 101, 5° of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use, wholesale distributors ("grossistes-répartiteurs") must deliver medicinal products within 24 hours of receiving an order.



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Other wholesalers must supply medicinal products to wholesale distributors within a maximum of 3 working days, provided this is done in the context of their public service obligations, and to persons authorised to supply medicines to the public (Article 12quinquies of the Law on Medicinal Products). Medicinal products that cannot be delivered for at least 3 working days are already considered temporarily unavailable.

Hence, a manufacturer or wholesaler that cannot deliver within this period must notify the FAMHP. This system already enables the authority to promptly alert relevant stakeholders and to take any necessary additional measures. It therefore already ensures timely and effective monitoring of potential shortages of medicinal products.

31. The Belgian official platform PharmaStatut.be already ensures real-time monitoring of shortages. Through this platform, pharmacists, manufacturers and wholesalers notify temporary unavailability or discontinuations of medicinal products. Notifications submitted by marketing authorisation holders or parallel distributors are published in real time, and the platform continuously updates the list of affected products.

32. This mechanism already enables national control authorities to:

    a. monitor potential shortages effectively. There is no indication that PharmaStatut is insufficient or that it has failed to provide timely and reliable information.
    b. request any relevant information as soon as a shortage is notified. This enables them to refine their knowledge of market availability and potential patient needs in order to take urgent measures to allocate existing resources to ensure continuity of care.

33. In addition, the scope of the Draft Royal Decree is excessively broad as it applies to nearly all medicinal products, including non-prescription (OTC) medicines sharing the same ATC code as prescription medicines. However, there is no evidence that OTC medicines present a risk of unavailability. Historical data from the FAMHP show that OTC products almost never become unavailable because multiple therapeutic alternatives exist.[17]

    This also follows from a decision tree, developed by FAMHP's experts. This decision tree indicates that if there are more than three options on the market for a same molecule, the issue does not qualify as a shortage and no intervention is necessary. [18]

34. **Conclusion**: the proposed measures do not appear necessary to achieve the objective of preventing and managing drug shortages that they pursue.

### *c. The measures proposed by the Draft Royal Decree are not duly balanced against their impact on fundamental rights and freedoms*

[17] See report here: https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products
[18] Idem, under "Actions and solutions", item 2.



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35. **First**, European Union intends to impose a completely different burden on operators for the monitoring and management of shortages and for the security of the supply of medicines. In particular, based on the experience gained since the COVID-19 crisis and the guidelines established by the EMA, the emphasis is on the responsibility of operators, in particular the marketing authorisation holder, who must prevent the risk of shortages, mitigate it and assess the risks associated with shortages through the plan. Risk anticipation is therefore placed at the level of the operator concerned. This is consistent with their obligation to ensure an adequate and continuous supply of medicines.

36. **At a second level of analysis**, we note that all the information that the federal government intends to make subject to the obligation to notify the national supervisory authority (FAMHP) relates to data (i) that operators must already manage in order to anticipate and manage the risk of shortages at their level and that (ii) the national supervisory authority (FAMHP) may request from them when a shortage is notified. This is concretely implemented and made available to the authorities and all interested stakeholder via the platform https://pharmastatus.be. We do not see how daily or monthly communication of this information could significantly improve the national supervisory authority's (FAMHP) ability to prevent and manage the risk of shortages.

    Imposing daily stock reporting obligations on all supply-chain operators, despite the fact that most products present no shortage risk, is therefore unnecessary and hence disproportionate. Such an obligation would impose a significant administrative and operational burden without contributing meaningfully to the prevention of shortages. In addition, this would create a duplicate notification system, at least for the wholesalers, adding unnecessary administrative burden without any demonstrable benefit.

37. **Conclusion:** the hoped-for benefits of such communication are far too small to justify a measure whose cumbersome nature will impact the capabilities of the operators concerned by diverting their resources to relatively ineffective administrative tasks.

### *d. Conclusion*

38. In view of the mechanisms already in place and those announced at European Union level, the measures planned by the Draft Royal Decree do not appear to be necessary nor proportionate because (i) existing mechanisms are sufficient to anticipate and manage the risk of medicines shortages and (ii) they place an excessive burden on operators in relation to the state's need for anticipation.

39. Eventually, we note, as an aside, that the federal government ultimately intends to transfer to the FAMHP the task of anticipation that operators currently perform and will perform even more reliably under the reform of European pharmaceutical law. To act in this way against the established mechanisms, the federal government would have to demonstrate a systemic failure of these mechanisms to accumulate anticipatory responsibilities by forcing the operators concerned to continuously communicate their commercial data to the FAMHP.

40. As such, the proposed measures are not justified in terms of necessity and strict proportionality, given the adequacy of existing procedures and the disproportionate impact they would have on those involved in the supply and distribution of medicines. The Draft Royal Decree, therefore, cannot be considered proportionate to the objective



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it seeks to achieve. Therefore, this obstacle to the free movement of goods is not and cannot be justified in accordance with Article 36 TFUE.

## IV. General Conclusion

41. In conclusion, we respectfully ask the Commission to take our comments into consideration and to communicate observations to the Belgian State in the context of the TRIS notification number 2025/0768/BE, drawing its attention to the fact that:

- **In principal**, the Draft Royal Decree infringes the harmonised framework on the obligations of marketing authorisation holders with regard to the prevention and management of the risk of shortages. With regard to other actors in the medicine supply chain, we consider that, in accordance with the principle of equality, a measure that is stricter than that imposed by EU law on marketing authorisation holders – who are the front-line actors in the marketing of medicines – could not be accepted. The draft reform of pharmaceutical legislation (COM/2023/193 final) confirms the relevance of this issue.

- **Alternatively**, the proposed measures are not justified in terms of necessity or strict proportionality, given the adequacy of existing procedures and the disproportionate impact they would have on those involved in the supply and distribution of medicines. The Draft Royal Decree, therefore, creates an obstacle to the free movement of goods is not and cannot be justified in accordance with Article 36 TFUE.

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List of Annexes:

1. Draft Royal Decree implementing Article 12nonies of the Law of 25 March 1964 on medicinal products for human use with a view to creating a Stock Monitoring Tool;
2. TRIS notification 2025/0768/BE (notified on 18 December 2025).



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