AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

Brussels, February 24th, 2026

Contribution Affordable Medicines Europe regarding TRIS notification 2025/0768/BE (Royal Decree establishing a Stock Monitoring Tool)

The Belgian authorities are planning to introduce a very broad monitoring tool in Belgium to support the administration in the prevention and management of shortages of medicinal products.

While Member States may introduce certain measures in the context of shortage prevention and management, such measures must remain fully compliant with European legislation. In this regard, we would like to highlight several concerns regarding the proposed legislation.

1. Scope and proportionality of the reporting obligation

Article 3 of the proposed Decree imposes an obligation on marketing authorisation holders (MAHs), wholesalers and pharmacies to report, on a daily basis, their stock levels and sales volumes to the competent authority for all prescription medicines, reimbursed medicines, and over-the-counter (OTC) medicines sharing the same ATC code as prescription or reimbursed products.

- **Excessive scope of the reporting obligation**

Firstly, the requirement to include *all* prescription and reimbursed medicinal products in a generalised manner is extremely broad. A daily reporting obligation covering the full range of these products does not appear proportionate to the stated objective of shortage monitoring.

Under Article 71(1) of Directive 2001/83/EC, medicinal products are subject to prescription status based on criteria such as the risk to patient safety when used without medical supervision or the potential danger arising from incorrect use. The objective of this provision is therefore the protection of public health through controlled access, not the management of availability or supply.

Consequently, the prescription or reimbursement status of a medicinal product is not, in itself, a relevant or reliable indicator of the potential imminent public health impact of a shortage. Many prescription medicines are well-established, widely available, and easily substitutable, whereas certain non-prescription medicines or specialised products may be critical for specific patient populations despite not being prescription-only.

- **Inconsistency with practices in other Member States**

In other Member States that have implemented shortage monitoring systems, reporting obligations are generally limited to critical or essential medicines or products identified as being at risk of shortage based on objective criteria (e.g., Denmark limits reporting obligations to critical medicines and requires reporting every two weeks).

These targeted approaches allow authorities to achieve effective shortage prevention while limiting unnecessary administrative burdens and avoiding the collection of excessive data. The Belgian proposal diverges significantly from this risk-based and proportionate approach.

- **Questionable necessity of daily reporting**

Although the Belgian authorities argue that the measure is appropriate to the objective pursued and does not go beyond what is necessary, the necessity of imposing *daily* reporting obligations for such a broad range of products is highly questionable.

It should be carefully assessed whether a more limited reporting obligation - focused on critical medicines and medicines identified as being at risk of shortage - would not achieve the same objective in a less burdensome and more proportionate manner, based on the already existing shortage reporting via the already existing pharmastatus.be platform. Such an approach would also respect the principles of proportionality and necessity under EU law.

- **Disproportionate administrative burden and market impact**

Furthermore, the daily reporting obligation for an extensive number of medicinal products imposes a significant administrative burden on all stakeholders concerned.

While the AFMPS indicates that reporting will be automated via a machine-to-machine IT platform, substantial implementation efforts will still be required. In particular, smaller MAHs, parallel importers and distributors, wholesalers and pharmacies may lack the technical infrastructure and resources necessary to fully automate data extraction and transmission. These actors may therefore be forced to rely on manual data collection and entry, leading to disproportionate compliance costs.

This burden risks forcing smaller operators to withdraw from the Belgian market, ultimately leading to reduced competition, increased dependency on a limited number of suppliers, and greater vulnerability of the supply chain to disruptions. Paradoxically, these effects could increase, rather than reduce, the risk of shortages.

- **Sensitivity of the data and data retention concerns**

Finally, the reporting obligation includes the transmission of highly sensitive data, not only relating to stock levels but also to sales volumes. Such information constitutes commercially sensitive data, the disclosure or misuse of which could have significant competitive implications.

Although the draft Decree currently limits the use of the data to the three purposes defined therein, the proposed retention period of ten years appears disproportionate to the stated objectives. A retention period of this length increases the risks associated with unauthorised access, data breaches, or future repurposing of the data beyond the original intent, not even mentioning access via public transparency obligation.

The data retention period should therefore be substantially reduced, and robust technical and organisational safeguards should be explicitly provided for to ensure strict access control, data security, and protection against unauthorised use.

2. **Reporting of future deliveries**

Article 5 of the draft Decree requires MAHs and wholesalers to inform the competent authorities of the expected date and volume of the next confirmed delivery, as well as the date and volume of the subsequent delivery.

The obligation to report the date and volume of the next two deliveries is, once again, very extensive and constitutes a significant intrusion into commercially sensitive information. This requirement is particularly problematic for parallel importers, who are also subject to the reporting obligation.

Unlike MAHs, which typically operate on the basis of planned production and distribution schedules, parallel importers rely on surplus stocks available in other Member States. As a result, they cannot plan future deliveries in the same manner or with the same degree of certainty. In many cases, parallel importers only become aware of the actual volume available once the product has been received.

The reporting obligation therefore imposes requirements that, in practice, cannot be fulfilled by parallel importers with the degree of certainty implied by the draft Decree. The wording of Article 5 does not appear to take these structural differences into account and should be adjusted accordingly in order to comply with the principle of proportionality.

Such a measure is liable to restrict parallel trade and may therefore constitute a measure having equivalent effect to a quantitative restriction within the meaning of Articles 34 and 35 TFEU. While restrictions on the free movement of goods may be justified on public health grounds under Article 36 TFEU, such measures must be appropriate, necessary, and proportionate to the objective pursued.

In the present case, the necessity and proportionality of requiring parallel importers to report the date and volume of two future deliveries - where such information is inherently uncertain or unavailable - are highly questionable. If maintained without appropriate differentiation or flexibility, this obligation risks unduly impeding lawful parallel trade, thereby undermining competition and patient access within the internal market.

3. Principle of loyal cooperation and ongoing EU legislative initiatives

The prevention and management of shortages of medicinal products are currently the subject of extensive legislative work at EU level, notably within the framework of the revision of the EU pharmaceutical legislation and the proposed Critical Medicines Act. These initiatives aim to establish a coherent and harmonised EU approach to shortage monitoring, prevention, and mitigation, including obligations relating to data collection, information sharing, and supply chain transparency.

In this context, the introduction of new national measures pursuing the same objectives may be precluded, even where the proposed EU legislation has not yet been formally adopted. Under Article 4(3) TEU, Member States are obliged to facilitate the achievement of the Union's tasks and to refrain from any measure that could jeopardise the attainment of the objectives of the Treaties.

The Court of Justice of the European Union has consistently held that this duty of loyal cooperation requires Member States, during an ongoing EU legislative process, to refrain from adopting measures liable to seriously compromise the result pursued by the forthcoming EU act. In *Inter-Environnement Wallonie* (C-129/96, para. 45), the Court confirmed that this obligation applies during the period preceding the transposition of a directive. Moreover, the application of Article 4(3) TEU is not contingent upon the prior adoption of a legally binding EU act. As clarified in *Commission v Sweden* (C-246/07, paras. 74–76), it is sufficient that a concerted EU strategy exists, including where the Commission has submitted legislative proposals that constitute the starting point for coordinated Union action.

Such a concerted EU strategy clearly exists in the present case. Both the revision of the EU pharmaceutical legislation and the proposed Critical Medicines Act explicitly address the prevention and management of shortages of medicinal products, including the establishment of EU-level mechanisms for monitoring availability and identifying medicines at risk of shortage. These initiatives are intended to avoid fragmentation, ensure consistency across Member States, and prevent the emergence of divergent national systems that could undermine the functioning of the internal market.

Against this background, the introduction of a comprehensive national monitoring tool, such as that envisaged by the Belgian authorities, risks prejudging and potentially undermining the objectives and effectiveness of the forthcoming EU framework. By establishing far-reaching reporting obligations at national level while EU rules on the same subject are still under being implemented, Belgium would risk creating regulatory fragmentation and increasing compliance burdens for economic operators active in multiple Member States.

Accordingly, the adoption of the proposed monitoring tool at this stage appears incompatible with the principle of loyal cooperation under Article 4(3) TEU, as it is liable to seriously compromise the achievement of a harmonised EU approach to shortage prevention and management currently being developed through Union legislation.

4. Subsequent changes to the notified legislation

On 10 February, the FAGG informed stakeholders that the scope of the notified draft Decree would be amended. Consequently, it is no longer intended to adopt the legislation in the form notified to the Commission. However, the amended draft has not yet been re-notified to the Commission.
In light of this, we respectfully urge the Commission to seek clarification from the Belgian authorities regarding the current status and content of the draft legislation. The amended draft Decree, incorporating all subsequent changes, needs to be formally re-notified to the Commission to ensure transparency and proper assessment.

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