Perrigo
Belgium

Gent, 19-03-2026

Subject: Position of Perrigo Belgium N.V. on the Draft Royal Decree implementing Article 12 nonies of the Law of 25 March 1964 — Creation of a Stock Monitoring Tool (SMT)

As a marketing authorisation holder (MAH) responsible for the continued and reliable supply of medicinal products in Belgium, we are fully committed to supporting public health and collaborating with authorities to prevent and manage potential medicine shortages. We recognise the importance of timely information and transparent communication in achieving these goals.

However, after reviewing the Draft Royal Decree notified under TRIS reference 2025/0768/BE, we have significant concerns regarding its compatibility with European Union legislation, operational feasibility, and proportionality. We respectfully submit the following observations.

1. EU Law Already Harmonises MAH Obligations for Shortage Prevention and Notification

The EU regulatory framework (current and forthcoming) already defines clear, harmonised obligations for MAHs regarding shortage prevention, monitoring and reporting:

- Directive 2001/83/EC establishes obligations for MAHs to ensure adequate and continuous supply, notify temporary or permanent cessations, and provide sales or stock data upon request by competent authorities.
- Regulation (EU) 2022/123 strengthens EU-level coordination mechanisms for monitoring and managing critical shortages, including mandatory information sharing during public health emergencies.
- The EMA's harmonised shortage prevention guidelines (e.g., Shortage Prevention Plans) already require MAHs to anticipate risks, assess supply vulnerabilities, and proactively manage availability.
- The proposed EU pharmaceutical legislation reform (COM/2023/193 final) clearly aims to fully harmonise rules on shortage monitoring and reporting at European level.

Based on these frameworks, MAHs already assume precise and extensive obligations related to continuous supply, risk prevention, and communication with national authorities and the EMA.

Conclusion: Imposing additional national obligations risks fragmenting the internal market, contradicting Article 23a of Directive 2001/83/EC, and undermining the EU's objective of harmonization.

2. Disproportionate Burden and Lack of Necessity

We recognize Belgium's legitimate aim of improving shortage management. However, the Draft Royal Decree would impose extensive daily reporting obligations on MAHs — including stocks, sales data, and future deliveries — for nearly all medicinal products, including OTC medicines.

We respectfully submit that:

2.1 Existing Belgian mechanisms are already effective

- PharmaStatus.be provides real-time publication of unavailability notifications.
- Existing national rules require notification within 3 working days when a product becomes unavailable.
- Wholesale distributors are already subject to strict delivery timelines (24 hours), allowing rapid identification of supply issues.

2.2 The scope is excessively broad

Applying daily stock reporting to all products — including OTC products with historically no shortage risk — is unnecessary and creates administrative overload and burden without public health benefit.

2.3 The measure duplicates existing obligations

MAHs already maintain detailed stock, distribution, and forecasting information as part of EMA-aligned shortage prevention plans. Re-reporting this daily does not improve shortage anticipation but would divert resources away from actual mitigation activities.

2.4 Proportionality concerns under Articles 34–36 TFEU

Given the burden, cost, and competitive sensitivity of daily stock/sales reporting, the measure may restrict the free movement of goods and is unlikely to meet the strict proportionality test required under EU law (necessity, suitability, least restrictive alternative).

3. Risk of Conflict with Future EU Legislation (Principle of Sincere Cooperation)

The European Commission and Council have already achieved political agreement on the upcoming pharmaceutical legislation reform, which will harmonise shortage monitoring obligations.
Under Article 4(3) TEU, Member States must refrain from adopting measures that could obstruct or pre-empt future EU-level rules.

The proposed Stock Monitoring Tool risks creating a national framework incompatible with the forthcoming EU system, leading to duplicative and potentially conflicting reporting requirements for operators.

4. Conclusion and Recommendations

We respectfully request that the Belgian authorities reconsider the Draft Royal Decree in its current form. In particular, we submit that:

1. The draft imposes obligations already harmonised at EU level for MAHs.
2. The scope and frequency of reporting (daily, all products) are excessive and disproportionate, lacking demonstrated necessity.
3. Existing European and Belgian mechanisms already allow effective anticipation and management of shortages.
4. The measure risks undermining the internal market and contradicting the principle of sincere cooperation with EU-level legislative developments.

We would respectfully recommend:

- Aligning any Belgian measures with the upcoming EU pharmaceutical legislation and EMA guidance.
- Prioritising targeted, risk-based monitoring for products with genuine shortage potential.
- Relying on existing mechanisms (PharmaStatus, current reporting obligations, MAH shortage prevention plans) instead of adding parallel systems.

We remain fully committed to constructive dialogue and to working with Belgian authorities to ensure robust, efficient and compliant processes that safeguard medicine availability for patients.

Beste regards,

Kady Karioredjo

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Signed on behalf of *Perrigo Belgium B.V.*

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