Medaxes
Association for accessible medicines

STAKEHOLDER CONTRIBUTION BY MEDAXES

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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"TRIS" Notification number: 2025/0768/BE (Belgium)

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I. Introduction

Medaxes is the Belgian trade association representing pharmaceutical companies committed to accessible healthcare, and specifically the optimal use of baseline medicines, including generic medicines, biosimilars and off-patent medicines. Medaxes represents companies that are active in the development, production and distribution of these essential medicines and that play a central role in ensuring the continued availability and affordability of medicines for Belgian patients.

Medaxes hereby submits this contribution in response to the TRIS notification "2025/0768/BE", by which Belgium notified to the European Commission 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"). The notification was submitted on 18 December 2025.

Medaxes fully supports the objective of anticipating and preventing shortages of critical and essential medicines, and has actively engaged in discussions with the Federal Agency for Medicines and Health Products (FAMHP) during the development of this initiative, including during the pilot phase launched in November 2023. However, as set out in detail below, the Draft Royal Decree as currently notified raises serious issues, which in our view contravene EU law.

This contribution is structured as follows. Section II describes the relevant factual background. Sections III through VI set out the legal concerns, addressing in turn: (i) the absence of a proper evaluation of the pilot project; (ii) the disproportionate scope of the monitoring obligation; (iii) the insufficient protection of commercially sensitive data; and (iv) the inadequate implementation timeline. Section VII presents Medaxes' conclusion.

II. Background

A. The pilot project and its absence of formal evaluation

The Stock Monitoring Tool (hereafter "SMT") traces its origins to the COVID-19 pandemic, during which real-time stock data proved indispensable for ensuring the availability of critical medicines. Building on this experience, the Belgian Federal Agency for Medicinal and Health Products (hereafter "FAMHP") launched a formal pilot project in November 2023, under which weekly stock data were collected from relevant supply chain actors for a limited list of active substances.

Medaxes, together with other industry stakeholders, participated actively and constructively in the design and operation of this pilot project. The pilot was explicitly risk-based in both scope and frequency, and was understood by stakeholders to serve as a testing ground for evaluating the usefulness of real-time stock monitoring as a tool for proactively managing shortage situations.

However, despite repeated requests by Medaxes and other stakeholders during consultation rounds, the FAMHP has to date not published any formal evaluation of the pilot phase. No assessment has been made publicly available as to how many shortages were in fact prevented by the daily monitoring of the limited list of critical medicines, nor has any analysis been published to show that the pilot phase demonstrated structural shortcomings requiring a broader permanent regime. This absence of evidence is directly relevant to the legal assessment of the Draft Royal Decree, as set out in Section III below.

B. The Draft Royal Decree

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, generalised SMT applicable to a very broad scope of medicinal products and imposing daily reporting obligations on all actors across the supply chain.

Specifically, the Draft Royal Decree extends the scope of the monitoring obligation far beyond the pilot project, to cover:

- all prescription-only medicinal products for human use;
- all reimbursable medicinal products for human use;
- any non-prescription medicinal products sharing the same ATC-5 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.

The Draft Royal Decree also substantially increases reporting frequency and content. All in-scope actors – including marketing authorisation holders (hereafter "MAHs"), wholesale distributors and

pharmacies – are required to report on a daily basis: (i) end-of-day stock levels, classified by CTI-ext code; and (ii) volumes supplied or dispensed. In addition, MAHs and wholesale distributors must report the date and volume of their next two anticipated deliveries as soon as this information is known.

The entry into force is scheduled for 1 July 2026, without any transitional arrangements. Medaxes notes that the scope of the Draft Royal Decree was amended in early February 2026 – after the TRIS notification was submitted – to exclude advanced therapy medicinal products (hereafter "ATMPs"), medicinal gases and radiopharmaceuticals and to remove the obligation to monitor products that have ceased to be marketed in Belgium, for a period of two years following their withdrawal. This post-notification amendment has not been formally re-notified to the Commission, raising additional procedural concerns.

III. Absence of a formal evaluation of the pilot project: no evidence base for the proposed measure

A measure restricting the free movement of goods within the EU internal market can only be justified if the Member State concerned demonstrates that the restriction is based on a legitimate objective and is appropriate and necessary to attain that objective. This requires, at a minimum, that the measure is grounded in evidence of a genuine and current public health need.

In the present case, Belgium has failed to produce any such evidence. The FAMHP launched the pilot project precisely to test whether proactive stock monitoring would contribute meaningfully to shortage prevention. Yet, no evaluation of the pilot has been published and no data has been provided to show that the pilot materially reduced the number or clinical impact of shortages. Nor has any analysis been made available demonstrating that the pilot revealed systematic deficiencies in existing Belgian shortage-management tools that can only be addressed by a broad, permanent daily monitoring regime.

This evidentiary gap is particularly problematic in light of the FAMHP's own published statistics, which indicate that medicine shortages in Belgium are in fact decreasing under the existing framework. According to the FAMHP Annual Report 2024, the number of notifications of temporary unavailability fell from 3,841 in 2023 to 3,321 in 2024, and the vast majority of shortage situations are resolved rapidly, with alternatives available for patients. Only a limited subset of situations is classified as "critical", meaning that no adequate alternative is available.

Against this background, the transition from a narrowly defined, risk-based pilot covering a limited number of active substances to a permanent daily monitoring regime covering almost all Belgian medicinal products – without any published evaluation and without demonstrated evidence of necessity – is, in Medaxes' view, legally unsustainable. Belgium cannot rely on the protection of public health under Article 36 TFEU without concrete evidence that there is a genuine and current risk that the existing instruments are insufficient to address.

The Court of Justice of the European Union has consistently held that national measures restricting the free movement of goods must be actually justified by objective circumstances, and that the reasons relied upon by the Member State must be accompanied by appropriate evidence or by an analysis of the appropriateness and proportionality of the restrictive measure, substantiated by specific evidence (see, inter alia, Case C-499/23, Commission v. Hungary, judgment of 13 November 2025, para. 73, and the case-law cited therein). No such evidence has been provided in connection with the Draft Royal Decree.

IV. Disproportionate scope of the monitoring obligation

A. The monitoring scope is far broader than the stated public health objective

The stated objective of the Draft Royal Decree is to allow authorities to anticipate and prevent medicine shortages and to develop a strategy for ensuring the continuous supply of medicines to patients. The companion Draft Law notified simultaneously under TRIS reference 2025/0771/BE is even more explicit: its explanatory memorandum justifies the related ministerial intervention powers as being intended to "*guarantee access to essential medicinal products*".

Yet the monitoring scope of the Draft Royal Decree is not confined to essential or critical medicines. It extends to all prescription-only and reimbursable medicinal products, as well as OTC medicines sharing the same ATC-5 code. This covers, in practice, the vast majority of authorised Belgian medicinal products.

This mismatch between the stated objective – protecting access to essential medicines – and the breadth of the monitoring obligation is, in itself, a strong indicator of disproportionality. A measure that subjects the entire medicinal product market to permanent daily stock surveillance, when the public health concern that motivates it relates to a limited subset of critical products, cannot be considered proportionate within the meaning of Article 36 TFEU.

Medaxes further notes that the prescription-only or reimbursement status of a medicine is not a reliable indicator of shortage risk or of the potential clinical impact of a shortage. Many prescription (baseline) medicines are widely available, well-established, and have alternatives. Conversely, some non-prescription products may be critical for specific patient groups. The prescription/reimbursement criterion is thus an overly broad proxy for shortage relevance, one that captures large numbers of products for which no justification for intensive monitoring has been demonstrated.

B. Existing tools and the "only once" principle

Medaxes also draws attention to a specific concern regarding the interaction between the Draft Royal Decree and the European Medicines Verification System (hereafter "EMVS"). The FAMHP already has access to real-time and accurate data on available stocks in Belgium via the EMVS for prescription and

reimbursable medicinal products. Imposing a separate daily stock reporting obligation for these same products duplicates existing data flows and is not only disproportionate, but also contrary to the "only once" principle, under which public authorities should not request data from operators that they already have access to through other systems.

Belgium already operates a comprehensive set of shortage management tools, including "PharmaStatus" (the real-time shortage reporting platform), the Unavailability Working Group, the Authentic Source for Medicines ("SAM"), and statutory supply obligations. These existing instruments have demonstrably contributed to reducing shortages. These tools and sources already provide sufficient relevant information with significantly less administrative burden, and are hence better suited, awaiting further EU regulations, for the objective of preventing clinically significant shortages.

C. The reporting obligation conflicts with EU harmonisation efforts and the principle of loyal cooperation

The EU has made a clear and consistent legislative choice in favour of a centralised, risk-based and interoperable approach to shortage monitoring, with the European Medicines Agency (hereafter "EMA") at its core. Regulation (EU) 2022/123 already establishes the European Shortages Monitoring Platform (hereafter "ESMP") as the central EU reporting tool and charges the EMA with coordinating shortage management for critical medicinal products.

The EU Pharma Package, for which a political agreement was reached on 11 December 2025, will further reinforce this framework by introducing harmonised reporting obligations for shortages, mandatory shortage prevention plans for MAHs, and a Union list of critical medicinal products. The proposed Critical Medicines Act, endorsed in first reading by the European Parliament on 20 January 2026, is explicitly risk-based and selective, aiming to mobilise enhanced measures specifically for the subset of medicines whose shortage is most dangerous.

The Draft Royal Decree does not align with this evolving EU framework. It is not conceived as an interface with the ESMP and does not use data fields, thresholds or formats that are harmonised at EU level. It operates as a specific Belgian reporting layer that runs parallel to – rather than complementing – the EU architecture. As a result, companies operating cross-border are required to feed data into ESMP, PharmaStatus and the new Belgian application simultaneously, using different formats and specifications.

Furthermore, under the principle of sincere cooperation enshrined in Article 4(3) TEU, Member States must refrain from measures that could jeopardise the attainment of the Union's objectives.
The Court of Justice has repeatedly confirmed that this obligation applies even where an EU act has not yet been formally adopted, as long as a concerted EU strategy exists (see Case C-246/07, Commission v. Sweden). Given that both the EU Pharma Package and the Critical Medicines Act explicitly address the prevention and management of medicinal product shortages, it is premature for Belgium to introduce a broad standalone national monitoring regime at this stage. Belgium should

await the entry into force of the harmonised EU framework and design any national complementary measures in strict alignment therewith.

D. The reporting obligation conflicts with EU harmonisation efforts and the principle of loyal cooperation

The pilot project operated on a weekly reporting frequency, which was already considered ambitious. The Draft Royal Decree now requires daily reporting – including on weekends – for a vastly larger number of products and actors. This represents a dramatic increase in reporting burden without any demonstrated justification.

From a public health perspective, the key objective is to detect meaningful trends or sustained deteriorations in supply. Daily reporting duties are not only more burdensome, but also less likely to generate reliable data: smaller companies may lack the IT infrastructure to automate daily uploads, leading to gaps, weekend delays and manual submissions of doubtful accuracy. The FAMHP, in turn, would be required to process enormous volumes of data on a daily basis – including data on products presenting no shortage risk whatsoever – at significant cost to both the agency and the companies concerned.

V. Insufficient protection of commercially sensitive data

The Draft Royal Decree requires the reporting of highly sensitive commercial data, including daily stock levels, sales volumes and forward-looking delivery information. This information is of significant strategic and competitive value. Its disclosure or misuse could have far-reaching consequences for companies' commercial positions, particularly for smaller operators.

Medaxes notes with concern that the Draft Royal Decree, as notified, does not provide sufficient guarantees that this data will be used exclusively for shortage monitoring purposes and will not be shared with third parties – including in the context of public transparency or open government obligations[1]. The purpose limitation clauses in the current text are insufficiently specific and do not adequately foreclose secondary uses.

[1] The concern that commercially sensitive data reported under the Draft Royal Decree may ultimately become subject to public disclosure is not merely theoretical. It has been implicitly confirmed by the Belgian Council of State, Section Legislation, in its opinion on the parliamentary document underlying the legal basis for the Stock Monitoring Tool (Parl. Doc., 2022-2023, No. 55K3346001, p. 385, https://www.dekamer.be/FLWB/PDF/55/3346/55K3346001.pdf): in that opinion, the Council of State examined the confidentiality assumption attributed to data reported to the FAMHP pursuant to the SMT. The Council concluded that the presumption of confidentiality does not constitute a general exception to the right of public access to administrative documents. Rather, the presumption merely triggers the application of Article 6, § 1, 7°, of the Law of 11 April 1994 on public access to government information, which requires a balancing exercise to be carried out by the FAMHP between the public interest in disclosure and the interest of the reporting parties in maintaining the confidentiality of the data. The Council of State further noted that the presumption of confidentiality established by the provision must be considered rebuttable.

Moreover, it is currently unclear whether the FAMHP has in place the appropriate infrastructure, cybersecurity protocols and certifications required to ensure the security of the data collected. The retention period of ten years prescribed by the Draft Royal Decree is manifestly disproportionate to the stated monitoring objective, and increases the risks associated with unauthorised access, data breaches or future repurposing.

VI. Inadequate implementation timeline and legal uncertainty

The Draft Royal Decree foresees entry into force on 1 July 2026, without any transitional arrangements. This timeline is manifestly insufficient given the scale of the IT development required. As the data that must be reported under the Draft Royal Decree relates to stocks at production sites, cross-border distribution flows and country-level allocation decisions, it is not readily extractable from existing systems in most companies. Dedicated integrations and automated reporting pipelines must be designed, built, tested and validated – a process that can take many months from the date on which final technical specifications are available.

Medaxes notes that, as of the time of writing, the scope of the Draft Royal Decree is still not stable. As mentioned above, the FAMHP amended the scope in early February 2026, after the TRIS notification was submitted, to exclude ATMPs, medicinal gases and radiopharmaceuticals and to remove the obligation to monitor products that have been withdrawn from the Belgian market for a period of two years – without re-notifying the amended text to the Commission. This amendment demonstrates that the Royal Decree has not yet reached a definitive form. In this context, it is wholly unreasonable to expect companies to commit significant resources to IT development in advance of legal certainty as to the final scope of the obligation.

The government has indicated that the transition period is already underway and that companies can begin testing. However, without certainty about the final text of the Royal Decree – which may be further modified as a result of this TRIS procedure – it is disproportionate to require companies to undertake major system developments at this stage. Investing in IT infrastructure built around a scope that may subsequently change constitutes an unjustifiable financial risk, particularly for smaller operators with limited resources.

VII. Conclusion

Medaxes fully supports efforts to prevent and manage medicine shortages, and remains committed to constructive engagement with the Belgian authorities and the Commission. However, the Draft Royal Decree as currently notified is, in Medaxes' view, incompatible with EU law on several grounds, and its implementation in current form would generate significant and unjustified burdens on the generic and biosimilar medicines industry – burdens that, paradoxically, risk undermining the very availability of medicines they are meant to protect.

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