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ANALYSIS

Pharma & Healthcare

The new obligation to supply medicines at the request of Member States: analysis of Article 56a of the Medicines Directive

Article 56*a* of the new Medicines Directive introduces a mechanism allowing EU Member States to require marketing authorisation holders to supply authorised medicines within their territory to meet the needs of their patients.

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1. Introduction

Equal access to medicines in all Member States is one of the fundamental objectives of the European Union's pharmaceutical policy. Practice has shown, however, that on numerous occasions, the placing on the market of authorised medicinal products does not occur uniformly throughout the Union's territory, or is significantly delayed. This problem, which is particularly acute for smaller Member States or those with less commercially attractive markets, has led to the inclusion in the new directive — which will replace the current Community code on medicinal products for human use adopted by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2021 on the Community code relating to medicinal products for human use ("Medicines Directive") — of an innovative legal mechanism that allows Member States to *require the marketing authorisation holder to place the medicinal product on the market and supply it within their territory*.

The new Medicines Directive lays down new supply obligations for marketing authorisation holders

The provision under review here is part of the European Union's new pharmaceutical regulatory framework, on which an agreement was reached on 11 December 2025.

2. Rationale and justification for the new obligation

The introduction of this obligation responds to a reality: marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States often due to commercial reasons. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access.

Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions and various resolutions of the European Parliament[1].

3. Substantive content of the supply obligation

3.1. *Member State's power to require marketing*

The new legal regime provides that, with a view to facilitating access to a medicinal product covered by a valid marketing authorisation within the territory of a Member State subject to regulatory protection, a Member

[1] See this ***link***

State may request the marketing authorisation holder of that medicinal product to place it on the market of that Member State and supply it so that the needs of patients in that Member State in question are covered as specified by the Member State. This power also applies to medicinal products that enjoy market exclusivity in accordance with the provisions of the Regulation amending Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

This provision establishes a power that allows Member States to act in situations where an authorised medicinal product is not available to patients within their territory, despite the existence of a valid marketing authorisation. It is, therefore, an instrument that complements the general obligations of the marketing authorisation holder to ensure the appropriate and continuous supply of medicinal products.

The European legislator has provided for various methods through which a Member State may issue its request to the marketing authorisation holder. Specifically, the Member State may require the holder to take one or more of the following: *a*) submit a valid pricing and reimbursement application, in accordance with national law; *b*) fulfil specific requirements for marketing authorisation holders in procurement procedures, in accordance with national and Union law; and *c*) establish a roll-out plan, as referred to in paragraph 3.

The arrangements to implement these requirements must be proportionate to the objective pursued and in compliance with Union law. This requirement of proportionality constitutes an essential safeguard for the marketing authorisation holder, preventing Member States from imposing excessive or disproportionate burdens.

The rollout plan is one of the most significant tools introduced by the new regime. This document will include information about the supply of the medicinal product by the marketing authorisation holder over a given period in the Member State concerned. The roll-out plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may when justified require the marketing authorisation holder to update the roll-out plan.

When a Member State applies this Article, it must communicate it to the marketing authorisation holder, together with the required compliance modalities, within one year from the marketing authorisation for that medicinal product. The communication must contain an explicit reference to Article 56a.

When applying this Article, the Member State and the marketing authorisation holder must cooperate in good faith and undertake best efforts to

ensure, within the limits of their responsibility, the availability and supply of the medicinal product concerned. This obligation to cooperate in good faith is essential for the proper functioning of the mechanism, since the effectiveness of the system depends largely on the active collaboration of both parties.

The new Directive expressly provides that this Article shall not affect the application of national legislation and procedures, including pricing and reimbursement, public procurement and any other procedures, aiming at making available and supplying the medicinal product concerned within their territory at any time following the marketing authorisation. Likewise, the right of marketing authorisation holders to make available and supply the medicinal product concerned in a Member State by carrying out the relevant procedures pursuant to national law is preserved, regardless of whether that Member State has made a request.

3.2. *Consequences of non-compliance: loss of market protection*

One of the most significant features of the new regime is the provision for significant legal consequences in the event of non-compliance by the marketing authorisation holder. Where within 3 years after a Member State submitted its request the marketing authorisation holder has not, within the limits of its responsibilities, made the medicinal product available and has not supplied it continuously within that period so that the needs of patients in the requesting Member State in question are covered, the market protection for that medicinal product and, if applicable, the prolongation of the market exclusivity in the case of orphan medicinal products shall not apply within that Member State.

This consequence means that, in the Member State concerned, the reference medicinal product will lose the regulatory market protection that would normally prevent the marketing of generic, biosimilar, hybrid, or biohybrid medicinal products during the established protection period. This is a penalty of considerable financial significance, since market protection constitutes one of the main incentives for investment in the research and development of new medicinal products.

The Member State must make public, without undue delay, the information regarding the loss of protection. For medicinal products authorised in accordance with the centralised procedure, the Member State must also notify the European Medicines Agency.

The new regime also provides that a marketing authorisation application may be validated and assessed by the national competent authorities or the European Medicines Agency six years after the start of the data protection period of the reference medicinal product, where the medicinal product is a generic or biosimilar medicinal product to a reference medicinal product and where a Member State has made publicly available information with regard to

that reference medicinal product's loss of protection. Notwithstanding, the marketing authorisation validated and assessed in accordance with this procedure shall not be granted prior to the expiry of the regulatory data protection period.

3.3. *The limitation of Article 166(5): protection against circumvention of the system*

The new Directive provides an important safeguard to prevent the loss of market protection in one Member State from being used to circumvent the protection system in other Member States. This limitation stipulates that, in respect of a medicinal product where the protection or the prolongation of market exclusivity does not apply in a Member State as a result of a failure to comply with the supply obligation, the wholesale distribution holder or any person or entity engaged in sale at a distance of medicinal products shall not make the generic, biosimilar, hybrid or biohybrid medicinal product available on the market of another Member State where market protection and, where applicable, market exclusivity do apply.

The purpose of this provision is to prevent generic, biosimilar, hybrid, or biohybrid medicines that may be legally marketed in a Member State where market protection does not exist from flowing into other Member States where such protection remains in force, which would constitute a circumvention of the incentive system established to reward pharmaceutical innovation.

Where such a generic, biosimilar, hybrid or biohybrid medicinal product is intended for export to another Member State in which protection periods do not apply as a result of non-compliance with the supply obligation, the wholesale distribution authorisation holder shall keep specific records available to the competent authorities of the Member States for a period of three years.

This record-keeping obligation serves a dual purpose: on the one hand, it allows authorities to monitor the flow of these medicines and verify that they are indeed destined for Member States where protection does not apply; on the other hand, it provides a basis of evidence in the event that violations of the prohibition on introducing these products into protected markets are detected.

3.4. *Exceptions to the supply obligation*

The new regime recognises that there may be situations where compliance with the supply obligation is materially impossible or extremely difficult for the marketing authorisation holder. Therefore, it is provided that marketing authorisation holders shall comply with the obligations set out in Article 56a, except for exceptional and unforeseeable circumstances, including those related to disruptions of supply, or duly justified circumstances fully outside the marketing authorisation holder's control, the consequences of which could not have been avoided even if all best and reasonable measures had been taken.

In such a case the marketing authorisation holder shall provide an explanation of the case and circumstances and justify the reasons for non-compliance. This provision introduces an element of flexibility into the system, preventing the mechanism for loss of protection from operating automatically in situations where non-compliance is not attributable to the holder.

3.5. *Coordination and monitoring mechanisms*

Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee. The Pharmaceutical Committee may exchange views on the national measures envisaged when the obligations under this Article are not me.

4. Conclusions

The introduction of the obligation to supply upon request by Member States represents a significant shift in the balance of rights and obligations between marketing authorisation holders and the Member States of the European Union.

The design of the system, which provides for the loss of market protection as a consequence of non-compliance, introduces a powerful incentive for marketing authorisation holders to respond to Member States' requests. At the same time, the restriction established to prevent generic, biosimilar, hybrid, or biohybrid medicines marketed in Member States where no protection exists from flowing into protected markets ensures the system's coherence.

However, the effectiveness of this new regime will depend largely on its practical implementation and on the willingness of Member State authorities and marketing authorisation holders to cooperate in good faith.

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