Working Document GIRP
Revision of the EU GPL – Council review 14 May 2024

Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

Article	Council text	GIRP proposed amendment
Article 56.3	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate **stock levels** and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate **stock levels** ~~and~~ **for** continued supplies of that medicinal product to wholesale distributors, pharmacies ~~or~~ **and** persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Further defining MAH Supply obligation for continuous availability of medicines
Article 56(3) in its current version foresees an obligation on pharmaceutical manufacturers / marketing authorisation holders to ensure a continuous and adequate supply to wholesale distributors, pharmacies or [i.e. alternatively] other parties entitled to supply medicinal products.

The word "or" enables marketing authorisation holders to pick and supply only one of the entities mentioned to fulfil their public service obligation. As such, wholesale distributors are not ensured access to the products marketed by a marketing authorisation holder but are still required on the basis of Articles 166 and 167 to continuously guarantee the supply of an adequate range of medicinal products in order to respond to the demand, i.e. the need in a specific geographical area. Therefore, the use of the word 'and' is preferred, as it appears in the current Directive 2001/83/EC Article 81 subparagraph 2.

The amendment proposed here aims to recognise the pharmaceutical full-line wholesaler's right-to-be-supplied without interfering with the share of products distributed directly to pharmacies (DTP) or any other models of distribution.

Seeing that in article 166 of the draft directive, pharmaceutical full-line wholesalers are required to continuously guarantee the appropriate and continued supply of medicines, GIRP reinforces our call to guarantee at European level the right to be supplied by marketing authorisation holders so full-line wholesalers can effectively comply with the

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requirements foreseen in the proposed directive. **Without such a measure, pharmaceutical full-line wholesalers are categorically unable to continuously guarantee the appropriate and continued supply of medicines.** Therefore, GIRP calls for the change from 'or' to 'and' in the article. **Correlation between stock levels and ensuring continued supplied.** GIRP proposes changing 'ensure appropriate stock levels and continued supplies' to 'ensure appropriate stock levels for continued supplies'. The revised formulation ensures that the stockholding obligation is imposed on MAHs and cannot be passed on by MAHs to downstream supply chain stakeholders who already respond to their own stock holding obligations through their PSOs.		
Article 166.1(l)	continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;	**Deletion**
Article 166.2 (New article)		**2. Member States shall designate wholesale distribution authorisation holders who, pursuant to article 56(3) shall continuously ensure the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in national legislation. The desginated wholesale distributors shall be granted an enforceable right-to-be-supplied by MAHs.**

Ensuring a framework allowing pharmaceutical full-line wholesalers to fulfil their PSOs

Article 166 (1)(l) establishes a regulatory obligation to supply for wholesale distributors which does not take into consideration the realities of the wholesale distribution sector.

In its current form, article 166(1)(l) does not account for the distinction between pharmaceutical full-line wholesalers and short-line wholesalers. The latter is unable to comply to 166(1)(l) while full-line wholesalers, responding to Public Service Obligations, continuously ensure the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe.

Through the inclusion of a new article 166.2 instead of 166(1)(l), GIRP's proposal maintains the objective of the obligation in 166(1)(l) while incorporating the realities of the market.

The inclusion of the reference to Article 56(3) reinforces the right of wholesale distribution authorisation holders - designated by national competent authorities and recognised as full-line wholesalers - to be supplied by marketing authorisation holders. These wholesale distributors are bound to fulfil the obligations of supply enumerated in the article.

The use of the word 'ensure' instead of 'guarantee' is necessary to provide consistency across the directive and ensure a coherent reading between article (4)(1)(70), article 56(3) and article 166(1a). Wholesale distributors, who are dependent on the supplies of MAHs and the fulfilment of their public service obligation, cannot be bound by a more stringent obligation than MAHs.

GIRP also proposes that the requirements set out in the provision be adopted specifically and cumulatively in the national legislation in each case.

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Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006		
Article 118	Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d) **and 120(1a)**, the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products. **In addition, the competent authority concerned may use information contained in the repositories in Article 67(2), second subparagraph, point (e), of [revised Directive 2001/83/EC].**	Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d) **and 120(1a)**, the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products. ~~**In addition, the competent authority concerned may use information contained in the repositories in Article 67(2), second subparagraph, point (e), of [revised Directive 2001/83/EC].**~~

GIRP strongly suggests returning to the original form of the article as proposed by the European Commission removing the reference to the repositories system referred to in Article 67(2), second subparagraph, point (e), of revised Directive 2001/83/EC, also know as the European Medicines Verification System (EMVS).

Built to protect patients from falsified medicines, the EMVS cannot provide an overview of supply available at national level and even less so, serve as an indicator of demand.

Overestimation of supply
On the supply side, the deficiency of the EMVS lies in an overestimation of available products of 3.6 billion packs due to multi-markets packs which are counted in the system for every country where they are uploaded whereas they can only be physically present in a single country.

In addition, data uploaded to the EMVS (and subsequently redistributed to NMVSs) are supposed to happen once a batch has cleared its Quality Control (QC) sign-off at which point, it can be supplied to the market. However, data related to the pack such as the serial number will happen before batch release and there can be a considerable delay between data upload and the release of the physical pack. The data in the system is not representative of the physical supply of product to the market (to wholesalers or pharmacies, nor indeed patients). This can thus lead to a further overestimation of supply.

No indication of demand
Most importantly, however, data about products decommissioned from the system in no way indicates national demand. Leaving aside the many cases where products are currently not decommissioned, due to non-compliance, the number of products decommissioned are in no way an indication of demand.

Therefore, numbers of decommissioned products would be highly misleading for demand estimations with a detrimental impact on patients. In order to accurately estimate demand, e-prescribing systems, which have been swiftly advancing especially during the COVID-19 crisis can serve as basis for the most accurate estimation. **Not fit-for-purpose** Although the EMVS is nearing the end of its implementation phase, there are still certain supply chain actors who remain to be connected to the system. Two markets have yet to join (Italy and Greece) and there are still ongoing disruptions stemming from the departure of one of the largest markets (UK).		
Article 120	**1a. Member States may require~~,~~ for ~~certain~~ centrally or nationally authorised medicinal products, that a~~A~~ wholesale distributor that is not the marketing authorisation holder and whose intention it is to obtain a medicinal product from a Member State (‘source Member State’) and to distribute this medicinal product in another Member State or third country (‘destination Member State) shall ~~notify~~notifies the competent authority of the source Member State of this intention. This notification shall include:** **(a) The name of the medicinal product and authorisation number;** **~~(b) Active substance(s);~~** **~~(c) Therapeutic indication(s);~~** **(d) Pharmaceutical form;** **(e) Strength;** **~~(f) Route of administration;~~** **~~(g) Destination Member State~~** **(g~~h~~) Pack size** **(h~~i~~) The quantity of the medicinal product obtained/which shall be obtained in the source Member State;** **(i) Destination Member State** **~~The competent authority of the source Member State shall identify which medicinal products shall be subject to the provision of paragraph 1a.~~**	**1a. Member States may require~~,~~ for ~~certain centrally or nationally authorised~~ medicinal products~~,~~ on the Union list of critical medicinal products, that a~~A~~ wholesale distributor that is not the marketing authorisation holder and whose intention it is to obtain a medicinal product from a Member State (‘source Member State’) and to distribute this medicinal product in another Member State or third country (‘destination Member State) shall ~~notify~~notifies the competent authority of the source Member State of this intention. This notification shall include:** **(a) The name of the medicinal product and authorisation number;** **~~(b) Active substance(s);~~** **~~(c) Therapeutic indication(s);~~** **(d) Pharmaceutical form;** **(e) Strength;** **~~(f) Route of administration;~~** **~~(g) Destination Member State~~** **(g~~h~~) Pack size** **(h~~i~~) The quantity of the medicinal product obtained/which shall be obtained in the source Member State;** **(i) Destination Member State** **~~The competent authority of the source Member State shall identify which medicinal products shall be subject to the provision of paragraph 1a.~~**

	Based on the notification referred to in this paragraph and on the information available pursuant to this Chapter, t~~T~~he source Member State may take measures to prevent or to mitigate shortages in the source member state. ~~any necessary, proportionate and appropriate measures to manage prevent or mitigate the shortage., on the basis of these declarations of intention to export.~~ **The measures referred to in this paragraph shall ~~should~~, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules.~~, particularly those concerning the free movement of goods and competition.~~** 2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned ~~as defined in Article 116(1)~~, entities including other marketing authorisation holders ~~as defined in Article 116(1)~~, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested ~~in a timely manner~~ **within the timeframe specified by the competent authority concerned.**	**Based on the notification referred to in this paragraph and on the information available pursuant to this Chapter, t~~T~~he source Member State may take any necessary, proportionate and appropriate measures to prevent or to mitigate shortages in the source member state.** **The measures referred to in this paragraph shall ~~should~~, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules.~~, particularly those concerning the free movement of goods and competition.~~** 2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned ~~as defined in Article 116(1)~~, entities including other marketing authorisation holders ~~as defined in Article 116(1)~~, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested ~~in a timely manner~~ **within a reasonable timeframe specified by the competent authority concerned.**

Enforcing notification measures on all centrally and nationally approved authorised products would impose an undue burden on wholesale distributors and consequently impede efficient and equitable access to medicines for European patients, especially in smaller and vulnerable markets.

With a view of harmonising obligations on supply chain stakeholders and ensuring consistency throughout the text, GIRP proposes to apply the import/export notification system to medicinal products on the Union list of critical medicinal products, in line with article 117.

Additionnally, consistently with the guidance of the European Commission Paper on the obligation of continuous supply to tackle the problem of shortages of medicines, GIRP calls for all measures taken based on the notifications to be necessary, proportionate and appropriate.

	Distributors who intend to import a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority of the Member State to which the medicinal product is to be imported of their intention to import that medicinal product.	Distributors who intend to import **significant volumes of** a medicinal product from another Member State shall notify ~~**the marketing authorisation holder and**~~ the competent authority of the Member State to which the medicinal product is to be imported of their intention to import that medicinal product.

Full-line wholesale distributors, in their efforts to mitigate the effects of medicines shortages, import medicinal products for supply to individual patients. This shortage prevention tool allows us to respond to individual patient needs and to mitigate the effects of shortages of critical medicines on patients. Due to the low volume of products being imported in each case and the frequency with which such imports take place, an obligation to report these imports would place a disproportionate strain on the wholesale distributor responding to the shortage in each case. Therefore GIRP proposes to limit the scope of this obligation to notify in cases of imports of **significant** volumes of medicinal products to maintain the efficacy of this shortage mitigating tool.

Import information is to be provided to the national competent authority for the sole purpose of the ensuring that only medicinal products in respect of which a marketing authorisation has been granted in accordance with Union law are distributed on their territory. Information to other actors for this purpose is unnecessary and irrelevant. GIRP opposes sharing unnecessary information with MAHs which will restrict the principles of the free movement of goods in the internal market.

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