efpia
European Federation of Pharmaceutical Industries and Associations

Directive Article 56.3 (Commission Proposal)

"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 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."

Why is it important to maintain 'or' when referring to the obligation of the marketing authorisation holder to supply medicinal products to wholesalers, pharmacies or persons authorised to supply medicines to the public?
Why does the clause "within the limits of its responsibility" not address industry concern with respect to the obligation to supply since it could lead to serious distribution disruptions on some EU markets?

Different medicines may be supplied by different routes, and not all categories will be relevant for all medicines, nor all categories will be supplied by the marketing authorization holder directly in all cases (Figure 1). For example, hospitals are often directly and exclusively supplied by the marketing authorisation holder or manufacturer through public procurement contracts. It is important that Directive Article 56.3 and other Regulation provisions (e.g. Article 134) reflect this reality and all parties are equally responsible toward ensuring supply to the patients.

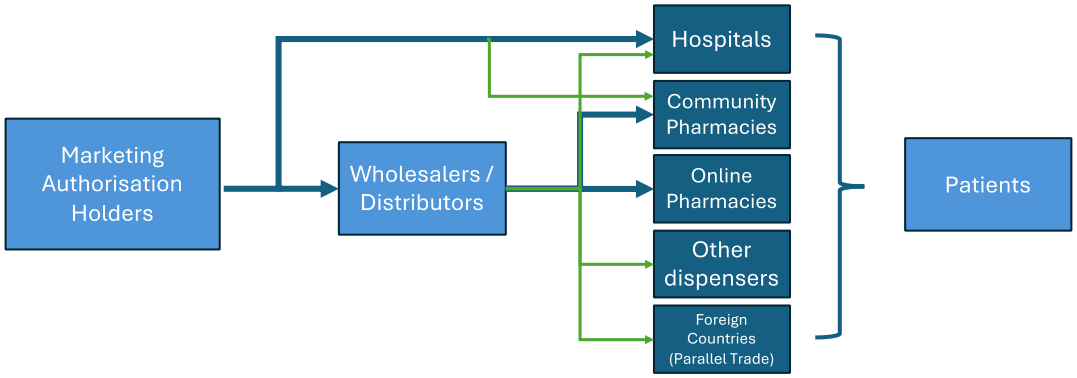

Figure 1. Pharmaceutical Supply Chains (excluding manufacturing process). Wholesalers are the principal distributors; however, hospitals (and in sometimes community pharmacies) frequently source their products directly from MAHs, bypassing wholesalers[1].
Adapted from [1]Chapman, S., G. Dedet and R. Lopert (2022), "Shortages of medicines in OECD countries", https://doi.org/10.1787/b5d9e15d-en

The clause "within the limits of its responsibility" does not address industry's concern that an obligation to supply all distribution chain actors could lead to serious distribution disruptions on some markets. It is of course consistent with our responsibilities as MAH to choose the best route to market

in order to deliver product to patients (taking into account the kind of product, the level of demand, transport conditions needed, etc.). That is why "or" makes sense. But if you change "or" to "and", it means the MAH might be asked to supply all customers at all levels in the supply chain at all times with all products, which by contrast does not make sense. The idea surely is to choose the best/most effective way to ensure products reach patients in each market, and such an obligation might prevent this. It would be a recipe for confusion and duplication if e.g. both pharmacies and wholesale distributors required to be supplied with the same products to meet the needs of the same patients creating a false impression of the total market demand and risking waste of product, time and cost. If we need to supply everyone, it means we won't have enough quantities to supply the most effective route for patients, so they will be the ultimate loser here.

Further, we should remember that wholesale distributors have their own obligation under art Directive 167.2 to supply pharmacies and persons authorized to supply medicines. If we put "and" instead of "or" in art 56.3, aren't we somehow undermining that separate obligation? What will compel wholesale distributors to play their part in making sure that the needs of patients in each member state are covered if the MAH already always has an obligation to supply all the customers that the wholesale distributor would deal with as well as an obligation to supply the wholesale distributor itself?

If the MAH has already supplied sufficient products to wholesale distributors, art 167.2 says that it should be for the wholesale distributors to make sure those medicines reach patients in the market via the distributor's downstream customers. But if art 56.3 is changed to say that the MAH must itself supply those downstream customers and the wholesale distributors, then the logic of the scheme breaks down. What market would the wholesale distributor have for its products if the MAH can be compelled to directly supply those downstream customers who supply patients in the member state? By contrast, with "or" reinstated, the MAH's obligations in art 56.3 would work smoothly alongside the wholesale distributor's obligations in art 167.2 in a coherent way for the benefit of patients in the relevant member state.

At the end of the day, the purpose of art 56.3 (and 167.2) is to make sure that the needs of patients in each member state are covered. As MAH, we can put enough products to fulfil the demand of patients in that market by supplying wholesaler distributors or pharmacies or persons authorized to supply medicines. Those are just alternative routes by which medicines reach patients and different routes suit different products. It does not help patients in a member state if demands for supply are duplicated – and the resulting confusion and misalignment with actual patient needs in the member state could potentially create the risk of shortages in other member states.

It should be reminded that the information stored in the European Medicines Verification System (EMVS) or repositories system referred to in Article 67, paragraph 2, second sub-paragraph, point (e) of the Directive provides for timely intelligence regarding the number of packs for all prescription products being supplied by manufacturers on the various Member States' markets, number of packs dispensed in national pharmacies and hospitals, number of packs exported (and/or imported), as well as on the level of stocks present in the supply chain at Member State level. The real time information in the EMVS data repositories can be analysed according to very granular time frames (per day, per week, per month etc.) as well as per region (postal codes). Wholesalers and traders, pharmacists and hospitals as well as National Competent Authorities have access to the data stored in National Medicines verification Systems.