AFFORDABLE MEDICINES EUROPE

WORKING IN PARALLEL FOR A BETTER DEAL

HMA/EMA GUIDE FOR SHORTAGES PREVENTION

CONSULTATION COMMENTS

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GENERAL REMARKS

Affordable Medicines Europe appreciates the opportunity given by EMA to provide comments to the draft "Good practices for the prevention of human medicinal product shortages". We consider the guidance can be a step in the right direction if a some comments are taken on board by the HMA/EMA Task Force.

First and foremost, we agree with HMA/EMA that shortages continue to be a problem in Europe. We also believe, that prevention and management plans are tools, that could help alleviate these problems. That said, it is important that we direct the various efforts to address this issue towards those stakeholders who can actually make a difference in relation to alleviating/preventing a shortage in a given situation. We fully support recommendations 1, 2, 3, 6, 7 and 9.

Overall, we consider that this guide does – in some areas – not strike the right balance between useful and targeted action for the relevant stakeholders, and burdens with broad requirements a number of stakeholders with no real value-added in relation the actual solution to this problem. We will outline these points in the specific remarks connected to the relevant recommendations below.

In relation to the national competent authorities' role, it is worth reminding that in the on-patent segment there are requirements on marketing authorisation holders (MAHs) to supply ordinary orders of wholesalers[1,2,3]. It is obvious that today NCA's are not using *all* the tools at their disposal in this context to avoid shortages related to commercial considerations *within* the scope of this guide (i.e., we are not referring to withdrawals). We encourage NCA's to include this part of their role as well in the guide (section 3.4).

Finally, we regret to see that section 4.10 on parallel trade tends to focus only on the possibility that exports may exacerbate shortages. Considering that export activities are performed by wholesalers who are under the public service obligation (PSO) and that exports in most EU Member States are regulated via export notifications/ban lists, we do not recognise the picture that exports are today a problem. Rather, we remind authorities, that stops to exports from one Member State will possibly lead to shortages in another. Here we call for solidarity in order not to overuse export restriction tools as we see some NCAs do today.

As an example, if exports of a given product have taken place for years from country A, and the MAH now notify a shortage, it is not that exports "exacerbate" that shortage. Looking at exports like this, only leads to a shortage in country B, where parallel imports of the given product have been an established part of the supply for years. Limiting exports to other Member States will never lead to address the actual shortage of supplies to Europe in total. On the contrary, it becomes a perverse reward to MAHs as they see their profits increase as parallel trade is eradicated. In this context it is pertinent to repeat what the European Court of Justice has said:

> *"parallel imports enjoy a certain amount of protection in Community law because they encourage trade and help reinforce competition".*[4]

At the same time, there is no recommendation on how to use parallel import and unlicensed import routes to address shortages, despite it being recognised in Section 3.4 as a solution for NCAs. Fact is, that parallel imports and unlicensed imports are one of the key tools to prevent shortages since, as established in the European Commission's study on shortages[5], the vast majority of shortages are national or regional. We hence consider it obvious and diligent to recommend establishing import procedures when shortages are foreseen or have materialised. We therefore strongly call for HMA/EMA to include an 11th recommendation to this effect. Below we propose a wording to that effect for inspiration.

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[1] *Joined Cases C-468/06 to C-478/06 Sot. Lelos kai Sia and Others, EU:C:2008:504.*

[2] *Corte d´Appello di Milano, Ordinanza 10 novembre 2005; Pres. ed est. MARESCOTTI; Soc. Farmacie Petrone c. Soc. Pharmacia Italia e Pfizer Italia*

[3] *Hellenic Competition Commission, Decision concerning GLAXOSMITHKLINE SA and GLAXOSMITHKLINE plc's supply policy of medicinal products LAMICTAL, IMIGRAN and SEREVENT in the Greek market, following the partial referral of the case back to the Hellenic Competition Commission (HCC) by the Athens Administrative Court of Appeals and the Council of State, 11 July 2018.*

[4] *Joined Cases C-468/06 to C-478/06 Sot. Lelos kai Sia and Others, EU:C:2008:504, para 37.*

[5] *European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M., et al., Future-proofing pharmaceutical legislation : study on medicine shortages : final report (revised), 2021,* https://data.europa.eu/doi/10.2875/211485

SPECIFIC REMARKS

Section 3.1 - MAH's

We consider it would be helpful to note in section 3.1 specifically that MAHs are under a public service obligation, as is mentioned in section 3.3 for wholesalers. We also suggest it pertinent to stress, that MAHs are the main responsible party for placing enough products on the European market (or the combined number of markets for which there is a marketing authorisation) in total.

Section 4.4 - Recommendation 4

According to Recommendation 4 actors in the supply chain, such as MAHs, manufacturers and wholesalers, should each have a shortage prevention plan specific to their role. Nevertheless the recommendation does not distinguish sufficiently between what is beneficial for MAH/manufacturer shortage prevention measures versus prevention measures taken by wholesalers.

We would like to underline that while we strongly support prevention plans as a crucial tool to address medicine shortages and we consider it important that MAHs/manufacturers are obliged to take such steps on a product-by-product basis. Hence, we fully support the part of recommendation related to MAHs/manufacturers.

We do, however, question the usefulness of e.g., product-by-product prevention plans at wholesale level. Furthermore, the sheer number of different products (SKUs) held by wholesalers makes such planning impossible in practice. We consider rather that wholesalers could be asked to have a general prevention plan for all products focused on processes such as reporting non-deliveries, unfulfilled orders, sharp increase in orders from healthcare professionals (in line with recommendation 8 essentially), as well processes focused on ensuring equitable supply etc. when shortages may occur (in line with recommendation 9 essentially). This would allow each wholesaler to have a general framework describing what they can do in their power, specifically to their role and nature, to prevent and mitigate shortages. We therefore strongly suggest rephrasing recommendation 4 with concerns to wholesalers.

Finally, we believe that asking parallel importers to make prevention plans will make little sense in relation to the aim of such plans – which is to restore the quantities needed for the EU market. Since parallel importers have no control of the supply of medicines, they could only simply refer to efforts pertaining to asking MAH's to increase their supplies. Therefore, requiring parallel importers to implement shortage prevention plans for each of the product they have in license would only introduce further administrative burden while not adding much value. Based on the wording of this provision, Affordable Medicines Europe would like to request that paragraph 2 of this recommendation specifies that parallel importers/distributors are excluded from its scope and therefore not subjected to this recommendation. We believe this isn't contributing to solving the problem of medicine shortages.

Rather, we suggest that this is left to national authorities to consider in dialogue with the national parallel import associations, based on the importance of parallel import to the national market and functioning of the national market in general. Our sector does recognise, that in some countries we make up a large part of the supply for some individual products. Therefore, we are also in such a constructive dialogue with these countries, and we are confident that suitable solutions will be found.

Section 4.5 – Recommendation 5

With regards to management plans our comments are similar to those for prevention plans. However, here we would stress an even bigger responsibility on the MAH/manufacturer in relation to producing and placing on the market the necessary stocks. At their root, almost all shortages require more stocks to be placed on the market as quickly as possible. Thus, management of the production supply chain product-by-product in cases of shortage is crucial.

At the same time, we do not consider management plans provide much value added at wholesale level, besides what is described above under recommendation 4 on prevention plans. Hence, we suggest a similar approach to prevention plans by wholesalers be taken for management plans for wholesalers – that is process oriented (e.g., establishing SOP's on how to ensure equitable distribution etc. that takes effect in shortage situations).

Section 4.8 - Recommendation 8

Generally, we do support the recommendation, but we would have liked to see an acknowledgement, that often the NCA is actually both the best and most natural interlocutor (also overcoming any competition concerns). We would therefore like to see a more active role for NCAs in some cases reflected in the recommendation as well.

Section 4.10 – Recommendation 10

As mentioned in the general remarks, Affordable Medicines Europe regrets the focus of recommendation 10. That said, our sector has clearly committed to, and is working every day, to ensure we do not cause or exacerbate shortage. We thank HMA/EMA as well for acknowledging that we are unlikely to be a cause of shortages. We also acknowledge that the aspect of exports and imports needs to be considered.

Firstly, we would like to suggest that the recommendation headline refers to "the risk of export exacerbating shortages". Parallel import/distribution is the act of placing on the market a medicine not originally labelled/boxed for that market. Hence, this does not in itself contribute to shortages. Parallel export is not a legal concept. Export is done by wholesalers and can be done just as well for exports requested by the manufacturer (e.g. for multimarket packs), exports outside the EU (not to be conflated with parallel trade as is done in the recommendation with regards to "demand from non-EEA-based companies") as well as for exports intended for unlicensed imports.

Secondly, we would like to question what the second part of the notion on parallel trade being dependent "on several factors such as arbitrage and, more recently, demand from non-EEA-based companies" mean? To which non-EEA-based companies does it refer? Does this mean non-EU exports, which should normally not be conflated with the notion "parallel" in relation to the EU's internal market? Also, we are unaware of such a new trend, and wonder what data this statement builds on?

As mentioned in the introduction, we have to strongly caution, that in many instances a stop to exports to other EU markets may lead to a shortage in the import market. Hence, this has to be considered just as carefully in relation to equitable distribution as mentioned in recommendation 9. Therefore such consideration should be taken into account in the guide.

Furthermore, we object that in the context of this recommendation another definition of shortage than the commonly agreed HMA/EMA definition be used. Hence, we suggest inserting that definition as the appropriate wording.

We must also strongly object to the definition that "Parallel trade is the activity of supplying medicines intended for patients in the country to another country". In essence, parallel trade builds on the concept of establishing (typically over time) larger supply quantities via different routes in the exporting country, in order to be able to export the excess quantities not needed to supply patients in the export country to other countries. We ask the definition to reflect this.

Finally, we remind the HMA/EMA, that recommendations for companies to take active stances to limit parallel trade can be against as well competition law as the common principles adopted by the European Commission and Member States in May 2018[6], relating to Article 34-36 TFEU. Hence, the reference to such

[6] *European Commission, Paper on the obligation of continuous supply to tackle the problem of shortages of medicines of 25 May 2018, https://health.ec.europa.eu/system/files/2018-10/ev_20180525_rd01_en_0.pdf.*

measures must be extremely clear and be taken by Member States, not competitors. We cannot stress strongly enough therefore, that MAHs must be removed from the recommendation.

Based on this, we would suggest the following rewording of recommendation 10:

*"~~**Take appropriate steps to m**~~ **Minimise the risk of ~~**parallel trade or**~~ export exacerbating shortages*

*Parallel trade is the activity of supplying medicines **placed on the market** ~~intended for patients~~ in ~~the~~ **one** country to another country. The free movement of medicines is a legitimate business practice. It depends on several factors, including arbitrage and **competition**~~, more recently, demand from non-EEA based companies. When a shortage of medicine occurs, the medicine supply is insufficient to meet patients' needs~~ **When a shortage of a medicinal product occurs, the supply does not meet demand at a national level**. Although the supply of medicines outside of the ~~State~~ **country** is unlikely to cause a shortage, it can contribute to worsening the extent of a shortage. Where the shortage of a medicinal product significantly affects patients and health systems, it is vital to ensure that the supply of that medicine to patients in the State is maintained for as long as possible to minimise the clinical impact on patients**, while taking into consideration the effect this may have on other countries**. Companies~~, such as MAHs and wholesale distributors,~~ involved in ~~parallel trade and~~ export should establish effective procedures whereby they do not engage in ~~parallel trade or~~ export activities relating to medicines ~~subject to potential or actual~~ **published on** shortages**/ban/restriction lists** ~~(e.g. first checking available information, such as shortages webpage, to establish if there is a possible supply issue with the product or clinical alternatives)~~, in strict accordance with the principles established by the European Commission and Member States in May 2018."*

A new recommendation 11

Considering that Recommendation 10 specifically focuses on the impact of parallel export on shortages we would like to recommend the insertion of a new Recommendation 11 describing as well the role that parallel import and unlicensed import can play in alleviating shortages.

For this new Recommendation 11, we would suggest the following wording:

"NCAs should together with the relevant import stakeholders establish a national process for fast-track parallel imports (fast-track licensing process) or unlicensed imports. Such a process should be triggered when a shortage is expected or actually occurring. The process should foresee the possibility for direct dialogue with relevant importers and a responsibility on MAHs to assist NCAs in the process where necessary."

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Affordable Medicines Europe represents Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition for patented medicines and a supplementary layer of product safety. We represent 125 companies in 23 EU/EEA Member States. These members account for approximately 85% of the total parallel import market volume in the EU/EEA. Membership in Affordable Medicines Europe is exclusive to companies holding a wholesale (GDP) license (export and import). All importing members furthermore are GMP licensed.

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