# Briefing |ALDE Group and Medicines for Europe - “Patient access to medicines: how to prevent medicine shortages?”

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*Dods - Debate Summary*

**Source: ALDE Group and Medicines for Europe**

**Subject: "Patient access to medicines: how to prevent medicine shortages?"**

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*On December 6, the ALDE Group and Medicines for Europe organised a hearing on "Patient access to medicines: how to prevent medicine shortages?". Please find below a summary of the debate:*

**Welcome addresses**

**Marc-Alexander Mahl,** President, Medicines for Europe, opened the meeting by noting that in present times, Europeans are used of having immediate access to goods, when they want it and in an unrestricted fashion. Europeans are not used to an absence of goods, foods or medicines. In this context, it is even more disturbing if a medicine that we need is not available. For patients, the non-availability of a pharmaceutical product can have many implications. Even when an alternative treatment is available, this can lead to time lost for pharmacists. If there is not an alternative, it can have serious health implications.

Medicine shortage is an unspecific symptom, while root causes can relate to issues ranging from manufacturing or regulatory problems to economic factors. He warned that symptomatic short-term solutions, which do not solve the root cause in its local context, may not resolve the long-term problems.

He then noted that practically all member states have seen some form of medicine shortages and there are many beliefs that economic reasons play a key role. Unsuitable pricing and reimbursement mechanisms are a factor. The generics industry delivers substantial benefits to Europe. This only works if there is a free market with fair competition. He noted that a complex supply chain requires planning and predictably in tenders. Another question is regulatory efficiency to ensure that products can be moved quickly across borders to meet shortages. Generic manufacturers are faced with the high costs of new regulatory requirements such as the falsified medicines directive. In addition, tenders and stringent tender rules lead to further pressure on the industry. If tenders in a single country or large region are awarded to only a single winner, it increases the risk of shortages the number of competitors is decreased and another manufacturer cannot in short time jump in for another if the latter is not able to supply the medicine. This leads to unpredictability in manufacturing and supply, leading to high penalties as a consequence and discourages companies from competing for tenders. He then provided examples of a decreased number of competitors in Portugal, Romania, and the Netherlands.

**Keynote speech**

**Lieve Wierinck (ALDE, BE)** stressed that access to medicines is a crucial topic. Medicines shortages affect patients and their families, but also pharmacists in terms of time and budgets. She then cited her experience as a pharmacist and noted that shortages were a significant

burden to her work. For patients, the availability of a medicine at any point of their recovery is essential. High-value lifesaving medicines can cost less than a coffee. The environment must be favourable for generics since they can provide one of the solutions to this problem. The solution must be both national and European.

### Opening remarks

**Agnes Mathieu** , European Commission, agreed on the importance of the problem and noted that the Commission is aware of the growing nature of the issue. There are more and more incidents and this means that it's time for action. She also agreed that the problems are driven mainly by manufacturing problems and economic reasons. All types of products have been impacted. The Commission Representative noted that the recent Parliament report on access to medicines called on the Commission to come forward with a better definition of the shortage of medicines, called for a list of essential medicines and called for an annual report on shortages. The Council, under the Slovak Presidency, also raised this issue and organised a workshop on it. The European Medicines Agency EMA and Heads of Medicines Agencies HMA also have a taskforce on availability, which deals with the marketing of authorised medicines in smaller states and the supply chain question.

She then explained that the Commission has worked to ensure that once a product is placed on a market, in principle, there is an obligation to ensure that there is a continuous supply. This article has been transposed into legislation, but it appears difficult to enforce. Industry is also supposed to inform the authorities when they stop putting a product on the market. There are also possibilities to import from other member states.

She noted that in certain circumstances, some of the labelling requirements can be waived in order to deal with a shortage. Parallel export is clearly an issue for some member states. Whilst this is legal, there must be limits if there is a question of risks to public health. Some member states have introduced temporary blockage of parallel export for the purpose of protection of public health when the export would create a risk of shortages. Other member states may want to look at this type of legislation, she explained.

She explained that the Commission has no competence to advise the member states on pricing questions. In addition, the Commission cannot prevent the withdrawal of a product from a market. On what the Commission can do, she said that they can help the member states share best practices in relation for example to parallel trade. The Commission will continue to work closely with the HMA/EMA taskforce and will also work closely with member states. They are collecting information on shortages to the member states and will publish the results of this in 2018. On falsified medicines, she noted that whilst this may create costs for companies, the database could help in terms of coordination creating transparency in the supply chain. Finally, she concluded that off-patent competition can help diversify the medicines on the market and that it is important to keep competition alive.

**Marc-Alexander Mahl** , President, Medicines for Europe, asked about the obligation to supply and noted that if every company with a market authorisation must be prepared to supply at any time. When a company has not won a tender or when he is not the preferred supplier for a payer, you cannot expect that he has the medicine available at all time. Eventually products that are not sold will need to be destroyed when the date of expiry comes near. This has not only a cost implication but also an environmental aspect which and it could lead to the

withdrawal of market authorisations or even withdrawal of the company from that market. How would the Commission tackle this?

**Agnes Mathieu** accepted that this can be a problem. Having more manufacturers is thus important and she noted that generic producers can play a role in this respect. But of course when a manufacturer has won a tender, the manufacturers must take responsibility for providing the amounts of products that they have committed to.

**The Romanian Health Attaché** noted that parallel trade is a huge problem for them. However, the obligation to force the market authorisation holder to supply is not always respected. Regulators put in many efforts to approve new medicines to be available for patients and as such companies must be forced to comply with the law and it is the Community code that should be enforced.

**A representative of Medicines for Europe** called for the specificities of the industry to be taken into account in terms of the enforcement. There is a large difference between single source and multisource products. The implementation of obligation to supply clause and its enforcement should not have the opposite effect than expected. Instead of improving the availability, very high penalties system may lead to withdrawal of generic marketing authorisations and to discourage generic manufacturers to enter the market. Some Members States seem to go for a simple legal solution without taking into consideration the reality of business operation and capacity to compensate shortage gap by another generic producer in a very short time.

**Agnes Mathieu** clarified that in Romania, parallel trade is one of the problems. If the shortage is caused by the fact that a product is not available in the pharmacies, it would be possible for Romania to change its own legislation to block the export of products if there is evidence of a potential shortage. On penalties, she said that the Commission has no plans as of yet to change the legislation and introduce penalties. The Commission is instead looking to see how to share experience between the member states on how they enforce the obligation to provide continuous supply.

**Cristian-Silviu Buşoi (EPP, RO)** expressed his belief that the problem is important. He noted that at the European level, the sharing of best practices could provide a solution. He criticised the inequalities within the EU on access to treatments and health services. Indeed, some inequalities are widening. Access and affordability of medicines is a key interest and the role of generics in this respect must be stressed. Not only do they reduce prices, they also increase competition. In Romania one of the problems is also the clawback. Today, the price decreases of generic medicines are linked to the increase of spending on new innovative medicines. It would be better to differentiate the innovative budget from the off-patent budget and to differentiate the clawback to balance both budgets. Whilst he is a supporter of generics, there must be a balance that protects the capacity to innovate. Looking outside of Romania, it is clear that some member states do not use enough generics

**Panel**

**Ortwin Schulte** , Head of Health Policy Unit, German Permanent Representation, noted that there will be a political orientation debate in the Health Council on Friday and there will also be a debate on access to life saving medicines. Patent protection is essential for pharmaceutical innovation. However, Germany has a specific system for health administration. This will be a factor when the Commission produces the HTA proposal as the competence of the EU and

the member states must be respected. He then claimed that there needs to be solutions for all member states whilst taking into account that certain developments like personalised medicines will have budgetary implications for all member states.

**Marc-Alexander Mahl** asked if shortages are also seen as a German topic.

**Ortwin Schulte** explained that there is a global problem in terms of access to supplies. On parallel trade, there is under German legislation a minimum quota for parallel import. There is also a debate on whether price negotiation or parallel trade is the solution. It would seem to be difficult to combat parallel trade in a single market.

**Eddy Gilissen** , VP Supplier Alliances, IQVIA, spoke about the medicine shortages and the correlation with economic factors. Shortages can have different causes, including manufacturing issues, shortages of raw materials or lack of production. However, the tendering systems can lead to a downward pricing impact that leads to manufacturers leaving the market. He noted that the lack of competition can make markets more susceptible to shortages and can have a negative impact on prices. If tendering systems are driven in such a way that it leads to companies leaving the market, this can create an effective monopoly. He also noted that it can lead to time losses for pharmacists as they are forced to look for alternatives. He then warned that significant price drops increase the risk of shortages, before explaining that the dependence of manufacturers on imports of intermediates and APIs can lead to supply shortages. When there is a problem in the production line, their common reliance on the same producer can lead to problems across the market.

There are many underlying causes of shortages in Europe. He stressed that the impact on the patient must not be forgotten.

**Vlad Voiculescu** , Member of Romanian Health Observatory, Romania, accepted that shortages happen for many reasons, but in Romania, it is mostly due to economic reasons. Romania has the lowest prices and a no exception clawback tax system, although the country is looking at potential exemptions to this for essential medicines. He argued that the introduction of the WHO list of essential drugs has helped. He agreed that having single suppliers due to the fierce pricing policies, this can create huge problems in terms of shortages especially if the supplier in question decides to leave the market. He noted that there needs to be sufficient data to ensure that the obligation to supply can be enforced. In Romania, there is an online reporting mechanism to ensure that shortages are reported. This enables the authorities to act on shortages.

**Lieve Wierinck** noted that's shortages lead to deaths. It is essential to ensure the availability of life-saving medicines. As former cancer patient, she witnessed that if she would have lived in Romania, she probably would not have had access to the therapy she received in Belgium.

**Elfi de Weerdt** , PhD medicine shortages, KU Leuven, Belgium, focused on the impact of the legal framework on drug shortages. There is often a combination of factors that lead to shortages. On legal causes, she raised the issue of tendering. A one winner takes all tender system can lead to the creation of a vulnerable market with too few manufacturers on a single market. Price cutting is also a problem that can prevent generic manufactures from entering the market. Manufacturers clearly must deliver high quality goods, but audits under the GMP directive can lead to delays. Quality requirements on the labelling could lead to shortages, but

she noted that if there is just a small error on a leaflet, pragmatism from member states could perhaps avoid a shortage.

The withdrawal of market authorisation is also an issue that can lead to an instable market. Any factors that cause manufacturers to withdraw from the market can be seen as contributing to drug shortages.

Concluding, she noted that pricing procedures and quality requirements seem to strengthen each other in causing shortages. She explained that there is a need to balance the question of pricing and access. If prices are too low, there will be reduced access.

**Marc-Alexander Mahl** , President, Medicines for Europe, noted that there is no one size fits all solution. If policy makers work on solutions, they should talk to the industry. The manufacturers also suffer from shortages as they make their money from supplying a product.

**A member of the audience** noted that the increasing regulatory burden on one side and cost cutting measures from payers and the other side are leading to shortages. How can the dialogue between payers and regulators be improved to stop the downward spiral?

**Elfi de Weerdt** called for all member states to set up taskforces to work on drug shortages and how to prevent and deal with them.

**Eddy Gilissen** argued that many member states see their spending in silos. As such, there is a budget for medicines and the lower that this is, the better. He called for more horizontal thinking that accepts that if medicines are always available on the market, this may reduce the cost of the healthcare system overall.

**A representative of Medicines of Europe** ensured that there is no call to lower regulatory standards, but rather a call to make the regulatory system more efficient.

### Closing remarks

**Marc-Alexander Mahl** concluded by saying that it must be made as efficient as possible for the industry to stay in the market. Maintaining the number of market authorised companies in the market is essential. Market predictability is also essential. Having a large market with a small number of suppliers can create large problems in terms of supply. Companies need predictability on what they will need to produce. The negative impact of parallel trading also needs to be combatted. He then said that the falsified medicines directive will provide much more information. He then called for it to be made far easier to address shortages in one member state by shifting excess products from another.

He then stressed that:

- A multi-source market is clearly a way to prevent medicine shortages.
- Single winner tenders increase the risk of shortages.
- The increased cost of the falsified medicines directive must be considered.
- Penalties for failure to supply discourage companies from entering a market.
- Communication between regulatory authorities and the industry is key.