



Shortages of medicines

Presidency Conference on Options to Provide Better Medicines for All

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Call from the European Parliament

Report on access to medicines with recommendations on shortages of medicines:

- *formulate a better definition , to assess the impact of parallel trade and supply quotas, to establish and update together with the Member States, the EMA and relevant stakeholders a list of essential medicines, ...to monitor compliance with Article 81 of Directive 2001/83/EC on shortages of supply, to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons, and to take actions to remedy these shortages;*
- *establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis;*

...

Call from the Council

- SK Presidency made "shortages of medicines" a priority for its presidency.
- Working Party on Public Health at Senior level on 15 July 2016 and the informal Health Council on 3-4 October, all Member States agreed that the topic deserves action at EU level.
- Council of the EU (EPSCO) on 8 December 2017 held an exchange of views on the pharmaceutical policy and called on the Commission to perform a study on the impact of parallel exports on patients' access to treatment
- Bulgarian Presidency Conference on options to Provide Better Medicines for All

Shortages: Legal Tools (Dir. 2001/83/EC)

Member States' competence

- Article 81 obliges MAH and WD to ensure appropriate and continued supplies so that the needs of patients are covered (within the limits of their responsibilities)
- Article 23a obliges the MAH ceasing production to communicate all data relating to the volume of sales and prescriptions of the medicinal product to the competent authorities so to give advance notice of potential shortages.

Commission questionnaire to MS on the legal obligations

Questions on :

- the implementation of the continued supply obligation (Article 81 of Dir. 2001/83/EC), what are the responsibilities of the MAH, WD, limits of their responsibilities,
- Definition of shortages
- Measures for critical medicines
- Penalties,
- Export restrictions
- Notification of temporary or permanent interruption of supply,

23 MS replies so far

Goal: exchange of practice

Commission questionnaire to MS on the legal obligations - examples of measures

- MAH has to ensure continued supply to cover the needs of patients on the respective territory in adequate interval and time intervals,
- public service obligation on wholesalers to have a permanent stock to supply daily and the region he serves,
- mandatory reserve supply for critical medicines, list of essential/critical medicines for which export is not possible (e.g. vaccines)
- For monitoring the shortage situation, MS compare supply and consumption from the concerned MAH

Commission questionnaire to MS on the legal obligations - examples of measures

- Most of the MS didn't impose sanctions during the last 10 years. Some exceptions for non reporting of interruption of supply or for non-compliance to the public service obligation leading to warning letters, suspensions of authorisation or financial penalty.
- MAH to inform the authority from 2 months to one year before the cessation of the marketing of an essential medicines. No withdrawal until an alternative solution has been found
- Most MS publish info on shortages
- Purchasing policies also differ amongst health insurers possibilities to include items in contracts with the MAH (e.g. mandatory delivery, periodic report of supply, penalty, selection of another supplier as long as the shortage persists)

Commission questionnaire to MS on the legal obligations - examples of measures

- Export restrictions (sales outside the MS) necessary to achieve the objective of public health and to mitigate the risk of shortages of medicines:
 1. export bans of specified medicinal products if a number of conditions are fulfilled in particular when the volume of medicines does not meet current medical needs of the patients
 2. prior notification/authorisation procedures for export by wholesalers in a pre-defined list.

Export restrictions

- The Court recognised that in cases where parallel trade would effectively lead to a shortage of medicines on a given national market, national authorities may take action to resolve the situation, by taking **appropriate** and **proportionate** steps that are consistent with the obligations flowing from Article 81 of Directive 2001/83 and with the Treaty (TFEU) rules.

Appropriate and proportionate ?

- Scope: for medicines at risk of shortages or in shortages (should not cover all medicines)
- Should take into account the duration of the measures, definition of shortages and alternative treatments
- Restricted information should be requested from the distributors
- Negative decisions affecting requests for export are adopted on the basis of transparent, known-in-advance, and non-discriminatory criteria, which are open to being contested before the relevant national administrative or legal bodies.
- Negative lists of medicines whose export is forbidden operate for limited periods of time (are under periodic revision), and do not include non-justified, large amount of products.

Next steps

- Commission to collect the replies from all MS (6 missing)
- Outcome to be discussed in the Pharmaceutical Committee, expert group in May and in the HMA/EMA Task force on availability





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Thank You