

Supply shortages of medicines



François Houyez

Director of Treatment Information and Access

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Room for improvement

■ Transparency:

– MAH/MAA to inform EMA as soon as shortage becomes possible

- in particular when shortage can lead to severe damage to public health

– Patients' organisations and clinicians should be involved from the beginning, when EMA is notified a possible shortage

- Patients/HCP to be part of the decision-making, not only the communication

– When shortage, we must know precisely how much product is left

– Transparency of distribution of the remaining supply should be total

- the rules for distribution of the product among EEA/EU Member States and beyond should be decided at the European level, publicly explained, and should be binding, with the objective of ensuring equity, with equal chance for all eligible patients to access what remains of the supply

■ Supply management measures

– When even biomedical criteria are not enough to select patients who can receive treatment, how do we do?

- Waiting list? First come first served? Random allocation? Other?

INDUSTRY

PO, HCP

**EMA, EC
MS**

ALL



Information we need

- Context and causes of supply shortage
- Location of the manufacturing sites, suppliers' name when applicable
- Dispensation (community pharmacy and/or hospital pharmacy)
- Available stock when supply shortage reported
- Sales volumes when supply shortage reported
- Countries where product is marketed and availability in these countries
- Estimated date of supply shortage (start)
- Estimated supply shortage duration
- Estimated date of supply resumption
- Proposed corrective measures (quota system, use of other formulations, stock management between hospitals, wholesale distributors and importers, stock exchange between countries, use of another product available in other countries, etc.)
- Communication strategy
- Alternative treatments



In the report, proposals on:

- Prioritise patients' needs
- Confidentiality
- Disclosure of information
- Fair distribution
- Shortages and parallel import
- Decision-making in a timely manner
- Involvement
- Communication strategy
- GMP, inspections and transparency
- Management of shortage in situations of extreme shortage
- Management of shortage when product in R&D or commercial use
- End of shortage
- Industry corporate responsibilities