



Supply shortages of medicines in Europe

A common position proposed to patients', consumers' and healthcare professionals' organisations involved in the activities of the EMA: click [here](#)

Policies should first and foremost aim to ensure timely and adequate supply of medicines to patients

We strongly urge the creation of a robust early warning system that put patients at first

EMA with NCAs should:

Create an unit to facilitate prevention, coordination of resolution and of communication on shortages

Create a public catalogue on supply shortages

Conduct market research to improve the understanding of the causes and the scale of shortages

Work more closely with industry to prevent shortages and to better organise the end of a shortage (no aggressive competition)

Reinforce of Good Manufacturing Practices (GMP) inspections and more resources to this activity

Involve patients and HCPs in decision making and communication

e.g. Netherlands:
<http://farmanco.knmp.nl/>

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Farmanco

Special reports

Type	Active substance	Brand	Form of administration	Revision Date	Impact
	Typhoid Vaccine, parenteral and oral	Typherix, Typhim Vi, Vivotif	injection, gastro-resistant capsule	15-07-2013	Alternatives are not available
	Varicella Vaccine	VARIVAX	Powder for suspension for injection	17-06-2013	Alternatives are not available
	Cefotaxime	Cefotaxime	powder injection	14-06-2013	Import possible
	Vinblastine	Vinblastine	Liquid Injection	08-07-2013	Import possible
	Vincristine	Vincristine	Liquid Injection	08-07-2013	Import possible
	Bleomycin	Bleomycin	powder for solution for injection	10/06/2013	Import possible

Latest Reports

Type	Active substance	Brand	Form of administration	Revision Date	Impact
	Typhoid Vaccine, parenteral and oral	Typherix, Typhim Vi, Vivotif	injection, gastro-resistant capsule	15-07-2013	Alternatives are not available
	Corifollitropin alfa	Elonva	Liquid Injection	08-07-2013	Substitution is possible
	Levothyroxine (sodium)	Euthyrox 75 mcg	tablet	08-07-2013	Solved
	Epirubicin	Epirubicin PCH	infusion, injection	09-07-2013	Substitution is possible
	Lactulose	Lactulose PCH, RP	syrup, powder for oral use	09-07-2013	Substitution is possible
	Enalapril	Enalapril PCH, Apotex, CF	tablet	09-07-2013	Substitution is possible

Public authorities should

Explore the establishment of buffer stocks to be held by wholesalers for more flexibility to the supply chain

Ensure fair distribution of the remaining supply

When a MS stockpiles some supply, this should not pre-empt stocks to the detriment of others

Establish a mechanism for stakeholders to report evidence of a product shortage to the authorities

Examine the causes of shortages, including economic ones and to formulate recommendations to prevent or alleviate them

Industry: preventing shortages

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Supply Shortage Risk Assessment Plan with MA submission (SSRAP)

Consider multiple manufacturing sites

When possible shortage: confidentiality because of business sensitive information not accepted

When communicating on CT results, anticipate potential consequences on compassionate use

In the EU, medicines shortages might also stimulate an increase in cross-border treatments

Adapt production capacity to the planned dates of marketing authorisation

Supply Shortage Risk Assessment Plan

- where the applicant would explain how the production capacity is planned in order to satisfy the demand (both for pre-marketing authorisation i.e. compassionate use and after marketing authorisation),
- and which measures the company could take if there is an issue (higher demand than expected, manufacturing defect...
- This plan should be agreed upon with EMA/national authority before MA.
- Although small starting companies cannot be obliged to have different manufacturing sites, EMA should think of basic requirements to minimise a risk for shortage, including regular inspections and realistic calculations based upon assessment of population, production capacity etc.

Industry: managing shortages

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Inform the EMA and relevant HCP and patients' organisations when a shortage is possible (even if false alerts)

Involve POS and HCPs in all aspects of the shortage management: guidelines, programmes, communication

Communicate the exact figures (production capacity, remaining stocks...)

Treat all countries equally, and within countries, each hospital / wholesaler equally

Other recommendations

Alternative unlicensed treatments should be made available through compassionate use programs if considered sufficiently safe

General guidelines might be helpful, developed with support of ethicists and legal advisors, how to distribute a small supply of a medicine when prioritisation is impossible (randomisation?)

The scope of pharmacy practice should be extended when medicines are in short supply. Where a medicine is not available, to establish the right to substitute with another one



Proposals which require

Changes to the framework

Legal obligations

Legislation should require companies to notify the EMA of shortages even when the shortage is only possible

To strengthen the provisions of Article 81 of the EU Directive on Medicines for Human Use

GMP inspections should be more frequent for all medicines on the EU market

For medicines that are life-saving, or to treat severe conditions, with no substitution product: SSRAP

Review of the operation of the pricing system in Europe including its impact on medicines shortages

In situations of extreme shortage: as a last resort, consider legislate on random allocation of remaining supply

Legally binding coordination at European level (by the EMA) to ensure fair distribution of the remaining supply

Other points to discuss (later)

Prohibition on the parallel exporting of medicines ?

- EU free movement of goods seems to matter more to those responsible for the medicines supply chain than the best interests of EU patients
 - a. Parallel exporting is highlighted frequently as being the major underlying cause of the medicines shortages currently being experienced
 - b. Although legal under EU law, the practice could be prohibited if it posed a threat to public health

Legal separation between wholesaling and dispensing pharmacies ?

- There should be a legal of separation between wholesaling and dispensing activities. Such an approach would allow manufacturers to prioritise supply to pharmacies that serve patients directly, and would also provide clear evidence of transactions for regulators.

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Parallel import

- Nothing in the recommendations on supply shortages prevents a Member State from authorising the export of medicines to other Member States to the detriment of patients living on its territory, for instance by siphoning the drug supply available for treatment of its patients.
- Export of drug supply may create a shortage in a Member State for a given treatment. In such exceptional cases, the Member State should retain the right to remedy the situation on the grounds of public health, in accordance with Articles 52 and 62 TFEU.
- However, this limitation should be without prejudice to Member States' obligations under Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems