

# DRUGSHORTAGES PROJECT OF LAW IN FRANCE

## EMA (LONDON)

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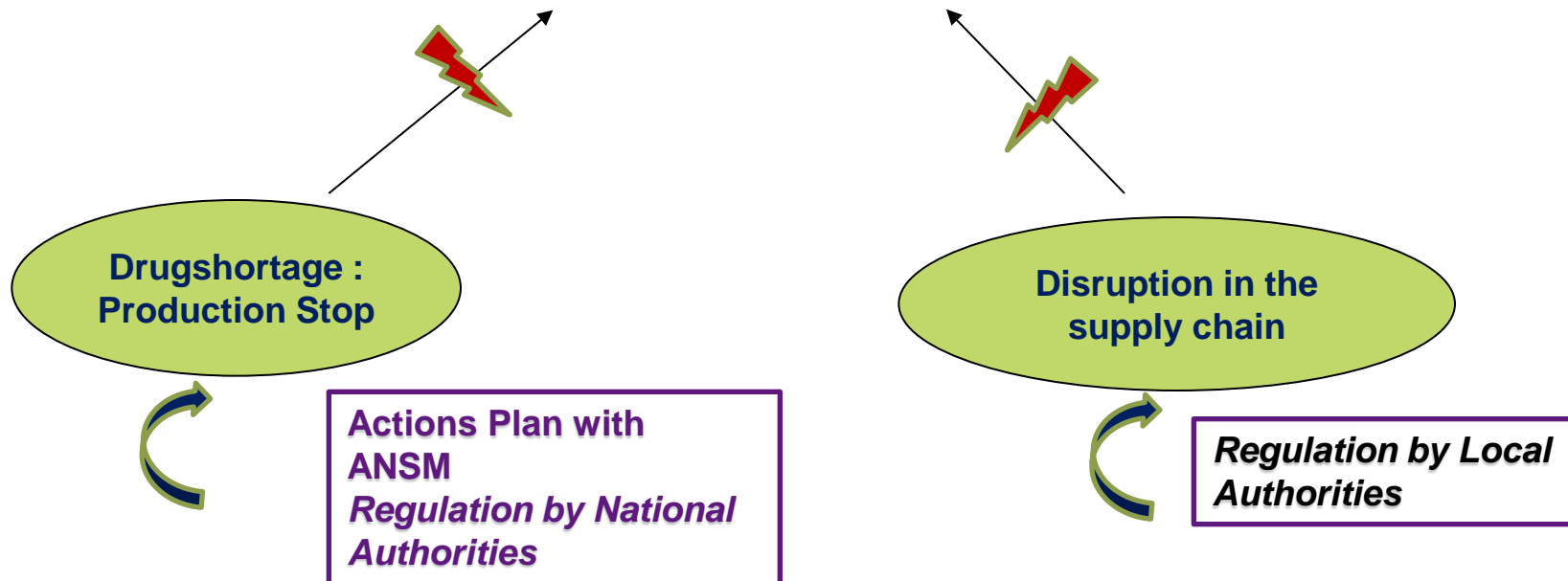
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# SOMES DEFINITIONS : Supply disruption, Drugshortage...What are the differences ?



**Supply disruption**

Incapacity for a pharmacy/hospital to dispense a medicinal product to a patient within 72 h



**Manufacturing sites of Medicinal products**  
i.e ... for examples

1. Production Stop or insufficient Capabilities
2. Increase of forecasts – Long Lifecycle
3. Manufacturing difficulties (MAH transfert site)
4. Non conformance or significant deviations – Recall

**Wholesale dealer sites of Medicinal products**  
i.e ... for examples

1. Distributor failure
2. Restriction of supplies
3. Global or local disruption

## DRUGSHORTAGE OF CRITICAL MEDECINES

- ◆ Critical medicines or therapeutic class of critical medicines are defined as medicines for which disruption of treatment is life-threatening or irreversibly progressive, or without which the patient could be severely harmed (short or mid-term) considering the potential evolution of the disease.
- ◆ A list of therapeutic class containing critical medicines will be published



### ***MAH will issue a list of critical medicines marketed in France taking in account :***

- ❖ The absence of available alternatives in sufficient quantity on the French territory: e.g. medicine containing the same active substance or belonging to the same therapeutic class, taking into account, if necessary, the specificities with regard to the use of the product, the conditions of administration, the target population and the pathology ;
- ❖ The market share of the medicinal product in France and the market shares of the identified alternatives ;
- ❖ The weaknesses in the manufacturing process of the product, e.g. the absence of alternate sites of manufacturing and/or packaging for raw materials, finished products, packaging articles; the complexity of these processes or those relative to the storage or to the transport of the product

# HOW TO PREVENT DRUGSHORTAGE ... ? Or DRUGSHORTAGE PREVENTION

*Based on a **risk analysis** of production and distribution cycle of the critical medicines identified*



- ◆ the MAH should develop and implement prevention/mitigation plans to prevent any drugshortage;
- ◆ These plans should anticipate measures to be implemented according to the weaknesses identified and the market shares of the related product : e.g. security stocks of products, alternate production sites and also identification of alternatives
- ◆ The MAH should update the prevention/mitigation plans whenever necessary
- ◆ The list of critical medicines for which prevention /mitigation plans are set up, should be mentioned in the Site Master File.



These documents should be available on demand by ANSM

# HOW TO MANAGE DRUGSHORTAGE ... ? DRUGSHORTAGE MANAGEMENT

.....What will the Law foresee ?



## 1. For Critical Medicines

- ◆ When a MAH anticipates, notices, or is informed about a situation of drugshortage of a critical medicine, it should inform immediately the ANSM and specify the leadtime for shortage, the available stocks, the deadline for the end of shortage and (if necessary) the identification of alternatives. In case of critical medicines, the measures described in the shortage prevention/mitigation plan should also be provided.
- ◆ The firm should implement, with the agreement of ANSM, alternative solutions to face with the situation
- ◆ The firm should inform, with the agreement of ANSM, healthcare professionals and patients
- ◆ The list of critical medicines mentionned in the article L. 5121-31, for which shortage/risk of shortage is identified or declared to ANSM in the conditions mentioned in the article R.5121-32 is published on the ANSM website
- ◆ The wholesalers should not sell outside France critical medicines in case of risk of shortages

# HOW TO MANAGE DRUGSHORTAGE ... ? DRUGSHORTAGE MANAGEMENT

.....What will the Law foresee ?



## 2. For all products

- ◆ MAH should implement permanent emergency call centers (or equivalent system) to allow direct contact with pharmacies and wholesalers.
- ◆ The emergency call centers are organized in order to allow the effective dispensation of the missing medicinal product (in case of disruption within the supply chain)

### **Avertissement**

- Lien d'intérêt : personnel salarié de l'ANSM (opérateur de l'Etat).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis-à-vis des autres intervenants.
- Toute utilisation du matériel présenté, doit être soumise à l'approbation préalable de l'ANSM.

### **Warning**

- Link of interest: employee of ANSM (State operator).
- This speech is made under strict compliance with the independence and impartiality of ANSM as regards other speakers.
- Any further use of this material must be submitted to ANSM prior approval.

## Description of Supply disruption

