

# The French reporting system: classification and trends of reported causes of drug shortages from 2015 to 2018

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## Objective

The aim of this poster is to propose a classification and trends of the reported causes of drug shortages.

## Methods

Data from the national reporting system from the Agency of Medicine and Health Product Safety (ANSM) were analyzed. This database contains information regarding causes shortages of major therapeutic of interest (MTI) drugs (i.e. drugs whose shortage would be life-threatening or representing a loss of treatment opportunity for patients with a severe disease) which are mandatory reported by marketing authorization holders to the ANSM. Data are presented as numbers or percentages of pharmaceutical products (i.e. the product name and its formulation) reported on shortage between 2015 and 2018.

## Results

The classification work identified two major categories of causes of drug shortages : causes related to the manufacturing process and those related to the drug distribution system. Causes related to manufacturing dysfunction are divided into 5 subclasses: 83 types of causes have allowed building the systematic classification related to the manufacturing circuit. Materiel issues use ranked first (31%), followed by manufacturing issues, pharmaceutical market and regulatory issues and inventory and stockage practice (respectively 30.4%, 23.5% and 9.89%). The number of reported pharmaceutical market cause of shortages presented a 3.5-fold increase between 2015 and 2018. In 78% of reported shortage, only one dysfunction causes the shortage. The number of multiple causes of shortage increase by 2.4 during the period.

## Conclusion

Precise knowledge of the shortage rout causes can consider the identification of short-term solutions to reduce their severity and long-term solutions to reduce their numbers. In regard to the causes of shortages, the relocation of health industries in Europe should be a solution. Otherwise, including supply capacities in the market access assessment and making it a drug price criteria could represent a long-term solution to remedy the situation.

**Acknowledgements : The author thanks the French Health Products Safety Agency.**