Risks related to drug recalls: a case report

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PS-051

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Background

In case of anomaly or incident concerning batches of medicine, the ANSM (French Agency for the safety of health products) proceeds to the recall of the affected batches. The recalls are needed for various reasons: error of packaging, defect affecting the quality of the product, statutory motive… Hospitals are then obliged to implement the recall but it can sometimes lead to drug shortage when the only held batches are concerned.

Purpose The aim of this work is to describe risks related to drug recalls when all the batches held in stock are recalled and when the drug quality is not affected. This paper focuses on the recall of one batch of an injectable local anesthetic due to the presence of a leaflet mentioning wrong indications.

Materials and Methods A risk analysis was carried out : the risks of implementing the recall were compared to the risks of keeping using this medicine

Results

		Propability		
		Low	Medium	High
Impact	Minor			
	Moderate	**(3)**		**(1)**
	Significant		**(2)**	

Legend:

- Low risk
- Medium risk
- High risk

(1) Drug shortage **(2) Dosage errors** **(3) Prescription errors**

(2) Other dosages of this anesthesic were available but the substitution could cause **dosage errors** in operating theatres.

(3) Prescription errors: our hospital practitioners use a medical prescription writing software including a medical database so they do not consult the medication leaflet to prescribe. Nurses generally use the leaflet as an aid for administering this intravenous drug but all informations written on the leaflet, except indications were valid so the probability for nurses to make mistakes was very low.

We decided, in agreement with the Committee of Medicines and Sterile Medical devices, not to remove the concerned batch in our hospital. The erroneous leaflets were removed from packagings and an information note including a new leaflet was sent to users.

Discussion/ Conclusion

This example illustrates difficulties and risks related to drug recalls. As sometimes drug recalls can lead to consequences for patients, a risk analysis must be carried out and a multidisciplinary decision is needed. Since this event, a risk analysis has been included in our internal drug recall management procedure. However, if an incident happens in our hospital with a recalled medicine, the pharmacist is legally responsible.