

Experiences from the Belgian & European Community
Pharmacists Associations on the communication of the sartans recall in 2018

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### **Pharmaceutical Group of European Union**



#### **Members:** Professional Bodies & Pharmacists' Associations



Latvia

At the heart of European communities





Belgian Pharmacy Recall system

# **Belgian Pharmacy Recall System**





- Unique, well-organized system in collaboration with national authorities and pharmaceutical companies.
- > Recall from the Belgian and/or Luxembourg market
- Recall of pharmaceutical products (medicinal products, food supplements, medical devices, raw materials, ...) from community pharmacies, hospital pharmacies, wholesalers
- Recalls requested by the company, the Belgian authorities or APB laboratory (no obligation to recall via APB)
- > Non-compliance, suspension or withdrawal of registration / authorization
- > GDP compliant
- > Average number of recalls: 1 per week



# Belgian Pharmacy Recall System Outsommes-nous > L'Association Pharmaceut





### > Communication via

- > website
- > e-mail
- > bi-monthly magazine
- > Coverage 100 %
  - Community Pharmacists
  - > Hospital Pharmacists
  - > Wholesalers
  - > Patient level if necessary (through Pharmacist)
- > Speed of publication







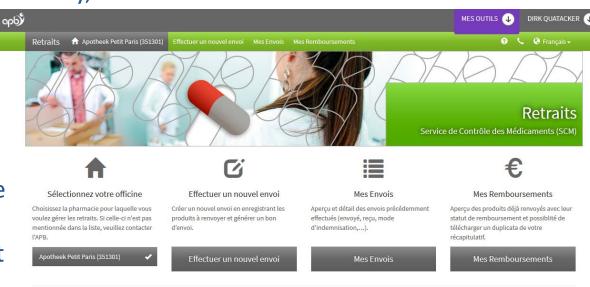
# **Belgian Pharmacy Recall System**





Intrekkingen

- Web Application developed and validated by APB
- Register new shipment + send via post or wholesaler
- Check-up of the incoming goods
- Follow-up (shipments and reimbursements)
- Status per batch number at all time available for the responsible company:
   number of samples on the way, received
- After closure
   detailed data
   are sent to the
   company
   for reconciliation
- Reimbursement by the company: no loss for pharmacist or patient









National and European perspective from community pharmacists on public communication on sartans

## Communication of recall sartans in Belgium



> 05/07/18	Publication	website EMA
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- > 06/07/18 Informed by Belgian authorities
- > 06/07/18 First recall publications (EG Sandoz)
- > 17/07/18 Publication website Belgian Authorities
- > 19/07/18 Additional explanatory information for the community pharmacists
- > 20/07/18 Other recall publication (PI Pharma)
- > 19/09/18 Publication of one more batch (EG)
- > 27/11/18 Other recall publication (Teva)
- No other sartans besides valsartan recalled by APB



### **Perspective on Communication**



#### > PGEU Survey (n=10):

- $\rightarrow$  EMA Publication 05/07/18  $\rightarrow$  Different NCA follow-up and satisfaction rates
- > Most occurring issues: late communication and incomplete information
- Lack of specific instructions from national authorities and/or any official guidelines on how to supply the population
- → pharmacists were not always able to answer patients whether their exact products were affected or not.
- > Follow-up communication: timely and comprehensive

#### > Belgium:

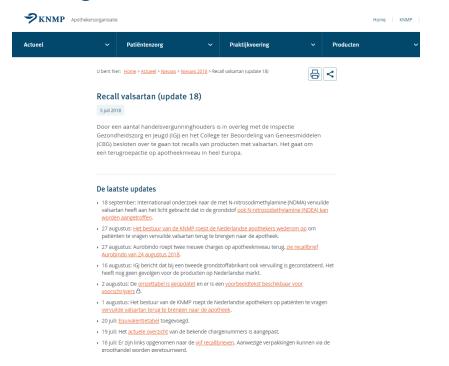
- > Recall information was duly published without specific instructions for the community pharmacist -> resulting in numerous questions from members
- → Additional APB communication 19/07/18
- → APB's recall communication is separate and not coordinated with other communication to our members

### Communication of recalls to community pharmacists



In addition to the NCA's, national pharmacy associations actively communicated the sartan recall information to community pharmacists.

Across Europe, different communication channels are used, such as direct e-mails to pharmacists, communication through the pharmacy software alert system, publication on the organisation's website, etc.









Collaboration between public authorities and healthcare professional organisations

### Collaboration with national authorities



> PGEU Survey (n=10)

In some countries: recall message to pharmacies by authorities sent out around the same time that the national press release was published

→ late information for pharmacists and prescribers.

The information on the exact products and batch numbers affected were not communicated to pharmacists at the time of the public communication

→ Pharmacists were not always able to answer patients whether their exact products were affected or not

### Collaboration with national authorities



#### > Belgium

Urged by the national authorities to publish due to the media pressure (06/07/18)

Publication of the sartans problem by national authorities on its website on 17/07/18 (quite late)

Press releases were available for the public as early as one week after the communication by EMA

The Belgian consumer organization had already contacted the national authorities before their official communication.

The same issues observed with the ongoing ranitidine recalls.





Recommendations for future improvements

### Recommendations for future



- > Authorities should provide clear hands-on communication
  - Including information on the therapeutic alternatives that can be provided, e.g. as a function of whether or not substitution is allowed
- > Health professionals should be alerted a full 24 48h in advance of going public, rather than panicking the public
- APB: This hands-on communication should be launched via our recall communication channel at the same time with the recall information
- Opportunity to better align at EU level on recall practices and communication strategies



### THANK YOU!



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