



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

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04/11/2019

EMA meeting on Sartans with N-nitrosamine impurities

[www.pgeu.eu](http://www.pgeu.eu)

# Pharmaceutical Group of European Union



## Members: Professional Bodies & Pharmacists' Associations



**2019: 32 Countries**

|   |           |   |                |
|---|-----------|---|----------------|
|    | Austria   |    | Luxembourg     |
|    | Belgium   |    | Malta          |
|    | Bulgaria  |    | Netherlands    |
|    | Croatia   |    | Poland         |
|    | Cyprus    |    | Portugal       |
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|    | Denmark   |    | Slovakia       |
|    | Estonia   |    | Slovenia       |
|    | Finland   |    | Spain          |
|    | France    |   | Sweden         |
|   | Germany   |  | United Kingdom |
|  | Greece    |  | FYR Macedonia  |
|  | Hungary   |  | Norway         |
|  | Ireland   |  | Serbia         |
|  | Italy     |  | Turkey         |
|  | Kosovo    |   |                |
|  | Latvia    |   |                |





01

## 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



## › Communication via

- › website
- › e-mail
- › bi-monthly magazine

## › Coverage 100 %

- › Community Pharmacists
- › Hospital Pharmacists
- › Wholesalers
- › Patient level if necessary (through Pharmacist)

## › Speed of publication

Où sommes-nous > L'Association Pharmaceutique Belge > Le fil de l'actualité > Liste des retraits

### Liste des retraits

« ‹ 1 2 3 4 5 ... › » 10 par page ▾

|                    |   |
|--------------------|---|
| 01<br>AOÛT<br>2018 | <b>Durex Real Feeling 01-08-2018</b><br>Date limite de retour au SCM 15-09-2018                     |
| 20<br>JUIL<br>2018 | <b>Diovine PI Pharma 20-07-2018</b><br>Date limite de retour au SCM 15-09-2018                      |
| 06<br>JUIL<br>2018 | <b>Valsartan Sandoz - Co-Valsartan Sandoz 06-07-2018</b><br>Date limite de retour au SCM 15-09-2018 |
| 06<br>JUIL<br>2018 | <b>Valsartan EG - Co-Valsartan EG 06-07-2018</b><br>Date limite de retour au SCM 15-09-2018         |

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### LISTE DE RETRAIT - INTREKKINGSLIJST

- › Retrait Valsartan EG - Co-Valsartan EG 06-07-2018
- › Intrekking Valsartan EG - Co-Valsartan EG 06-07-2018

Accès à l'application web Retraits

Toegang tot de webapplicatie Intrekkingen

N° 17 - 15 octobre 2019

www.apb.be

## NOUVELLES BRÈVES

Bureau de dépôt (DRP) Liège 5 - Dimensieul 15/10/2019 - 30/10/2019  
Numéro d'agrément: PD01094 - Expéditeur: APB, Rue Archimède 11, 1000 Bruxelles





# Belgian Pharmacy Recall System



- **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



The screenshot shows the APB web application interface. At the top, there is a navigation bar with the APB logo, a 'MES OUTILS' dropdown menu, and a user profile 'DIRK QUATACKER'. Below this is a secondary navigation bar with links for 'Retraits', 'Apotheek Petit Paris (351301)', 'Effectuer un nouvel envoi', 'Mes Envois', and 'Mes Remboursements'. The main content area features a large banner image of a pharmacy with a red and white pill in the foreground. Below the banner, there are four main service tiles: 1. 'Sélectionnez votre officine' (Select your pharmacy) with a home icon and a dropdown menu showing 'Apotheek Petit Paris (351301)'. 2. 'Effectuer un nouvel envoi' (Perform a new shipment) with a pencil icon and a button labeled 'Effectuer un nouvel envoi'. 3. 'Mes Envois' (My shipments) with a list icon and a button labeled 'Mes Envois'. 4. 'Mes Remboursements' (My reimbursements) with a Euro symbol icon and a button labeled 'Mes Remboursements'. Each tile includes a brief description of the service.



02

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

# Communication of recall sartans in Belgium

- › 04 & 05/07/18 Informed by first firms (EG – Sandoz)
- › 05/07/18 Publication website EMA
- › 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):
  - › EMA Publication 05/07/18 → 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.



U bent hier: [Home](#) > [Actueel](#) > [Nieuws](#) > [Nieuws 2018](#) > Recall valsartan (update 18)

## Recall valsartan (update 18)

5 juli 2018

Door een aantal handelsvergunninghouders is in overleg met de Inspectie Gezondheidszorg en Jeugd (IGJ) en het College ter Beoordeling van Geneesmiddelen (CBG) besloten over te gaan tot recalls van producten met valsartan. Het gaat om een terugroepactie op apothekerniveau in heel Europa.

### De laatste updates

- 18 september: Internationaal onderzoek naar de met N-nitrosodimethylamine (NDMA) vervuilde valsartan heeft aan het licht gebracht dat in de grondstof ook [N-nitrosodietilamine \(NDEA\)](#) kan worden aangetroffen.
- 27 augustus: [Het bestuur van de KNMP roept de Nederlandse apothekers wederom op](#) om patiënten te vragen vervuilde valsartan terug te brengen naar de apotheek.
- 27 augustus: Aurobindo roept twee nieuwe charges op apothekerniveau terug, [zie recallbrief Aurobindo van 24 augustus 2018](#).
- 16 augustus: IGJ bericht dat bij een tweede grondstoffabrikant ook vervuiling is geconstateerd. Het heeft nog geen gevolgen voor de producten op Nederlandse markt.
- 2 augustus: De [omzettebel is geüpdatet](#) en er is een [voorbeeldtekst beschikbaar voor voorschrijvers](#).
- 1 augustus: Het bestuur van de KNMP roept de Nederlandse apothekers op patiënten te vragen [vervuide valsartan terug te brengen naar de apotheek](#).
- 20 juli: [Equivalentietabel](#) toegevoegd.
- 19 juli: Het [actuele overzicht](#) van de bekende chargenummers is aangepast.
- 16 juli: Er zijn links opgenomen naar de [vijf recallbrieven](#). Aanwezige verpakkingen kunnen via de groothandel worden eëretourneerd.



QUI SOMMES NOUS NOS MISSIONS LE DOSSIER PHARMACEUTIQUE COMMUNICATIONS LES PHARMACIENS LES PATIENTS

• [Communications](#) • [Les actualités](#) • Rappel de certains médicaments à base de valsartan et de valsartan/hydrochlorothiazide

## Rappel de certains médicaments à base de valsartan et de valsartan/hydrochlorothiazide

12/07/2018

[Médicament](#) [Rappel](#) [Officine](#) [Distribution](#) [Etablissement de santé](#)



Les laboratoires pharmaceutiques, en accord avec l'ANSM, ont procédé au rappel de certaines spécialités à base de valsartan et valsartan hydrochlorothiazide le vendredi 6 juillet 2018 au niveau des pharmacies de ville, des grossistes-répartiteurs et des pharmacies hospitalières.

Ce rappel a été réalisé en concertation avec les Etats Membres de l'Union Européenne.

Ce retrait de lot fait suite à un défaut qualité affectant ces spécialités à base de valsartan et de valsartan/hydrochlorothiazide, utilisées dans l'insuffisance cardiaque, dans l'hypertension artérielle et en post-infarctus du myocarde. Il s'agit d'une impureté retrouvée dans la substance active fabriquée par la société chinoise Zhejiang Huahai Pharmaceuticals, et découverte par un laboratoire pharmaceutique commercialisant une des spécialités impactées. Cette impureté apparue au cours de la fabrication de la substance active, est la N-nitrosodiméthylamine (NDMA), substance considérée comme cancérigène probable chez l'Homme.

### LES ACTUALITÉS

#### Les actualités

- La lettre "L'actu"
- La revue "Tous Pharmaciens"
- Les vidéos et podcasts
- Les cahiers thématiques
- Communiqués de presse
- Prises de parole de la présidente
- Rapports d'activité
- Éléments démographiques
- Publications ordinales
- Prix de l'Ordre des pharmaciens
- Webcasts et webconférences
- Les archives de la lettre
- Les archives du Journal



03

## 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.



04

## 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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