



Association Pharmaceutique Belge
Algemene Pharmaceutische Bond



Patient Protection in Belgian Pharmacies A Real Life Experience

Association of the Pharmacists of Belgium

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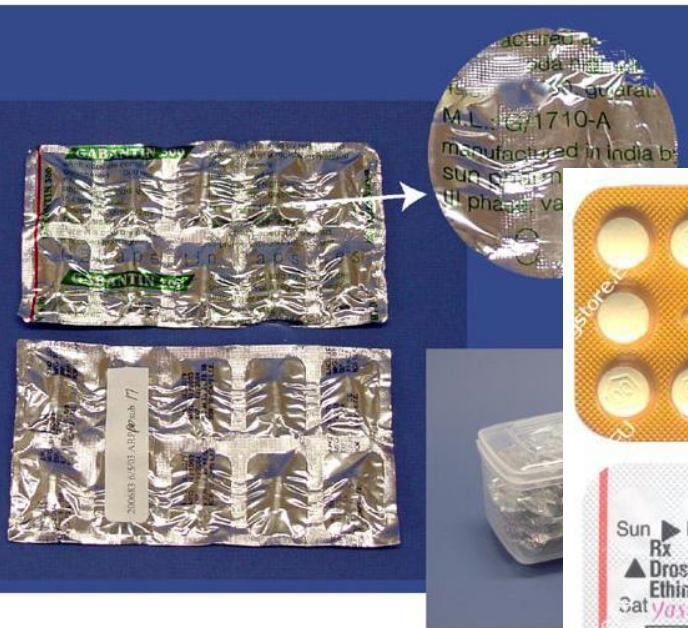


CAN YOU TELL THE DIFFERENCE?

Counterfeit Aricept Approved Aricept



fake.



Genuine



Belgian pharmacies have an anti-counterfeiting system in operation

Our **rationale** for implementing an online authentication system in **4Q2006** :

- 1. PATIENT SAFETY IS PARAMOUNT*
- 2. INTEGRITY AS HEALTH CARE PROVIDER IS AT STAKE*
- 3. COUNTERFEITING MEDICINES IS ON THE RISE*
- 4. EUROPE AND BELGIUM ARE NOT IMMUNE*
- 5. MANUFACTURERS' INITIATIVES LACKING OR UNSUITABLE*
- 6. HEALTHCARE AUTHORITIES ARE LATE AND SLOW*
- 7. TIME FOR ACTION !!!*

Belgium : a unique country

1885

- The Pharmaceutical Practice Law introduces the principle of « NO FAULT responsibility »
- The pharmacist has the final responsibility for every product (s)he delivers

Belgium : a unique country

- **1885** The Pharmaceutical Practice Law introduces the principle of « NO FAULT responsibility »
- **1952** Start-up by APB of the Medicines Control Laboratory (MCL – DGO – SCM) to combat post-war fraud of penicillin-containing pharmaceuticals. In the meantime MCL has become instrumental in guaranteeing the quality of all medicines delivered in Belgian pharmacies



- Financed by all Belgian pharmacies (fee per pack)
- Unique model of auto-control
- Staff : +/-60 (pharmacists & lab technicians)
- Co-management with DRA and Ophaco
- Operates centralised recall procedure

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2004

- Healthcare Authorities introduce Unique Barcode per package
- Mass serialisation of reimbursed pharmaceuticals to combat healthcare insurance fraud

Unique Barcode permits to identify each single pack



Simple but effective tools

Packs with Unique Barcode



Social Identity Card
(chip card with

patients'

Prescription with
Doctors' unique
bar-coded ID-number



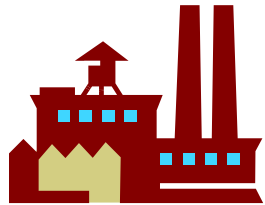
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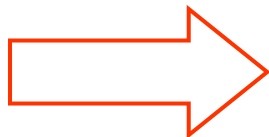
2006

- APB and Aegate start collaboration
- Use existing mass serialisation to combat counterfeiting of medicines
- Prepare first launch worldwide of an authentication system

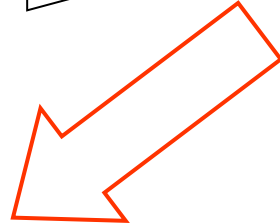
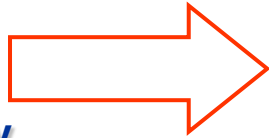
Authentication in the pharmacy : how does it work ?



Unique Barcodes
Batch numbers
Expiry dates



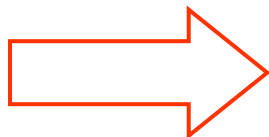
Product dictionary



Validated & dispensed

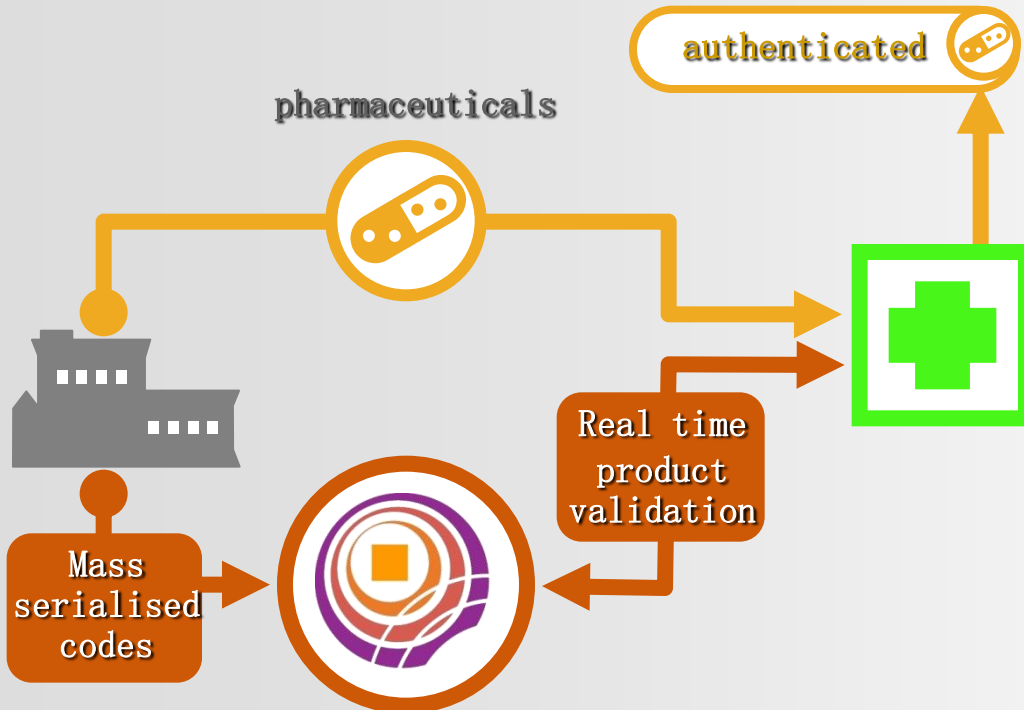


Not validated & withdrawn

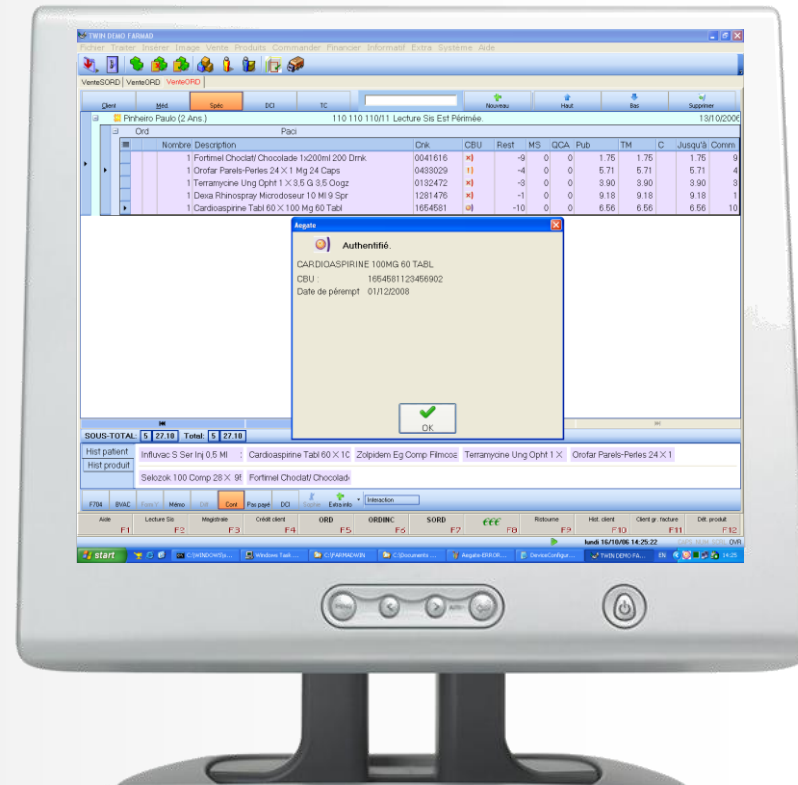


Recalls


Authentication in the pharmacy : in real time



Authenticated



Authentication in the pharmacy: rapid alerts

 **Art. a été retiré.**

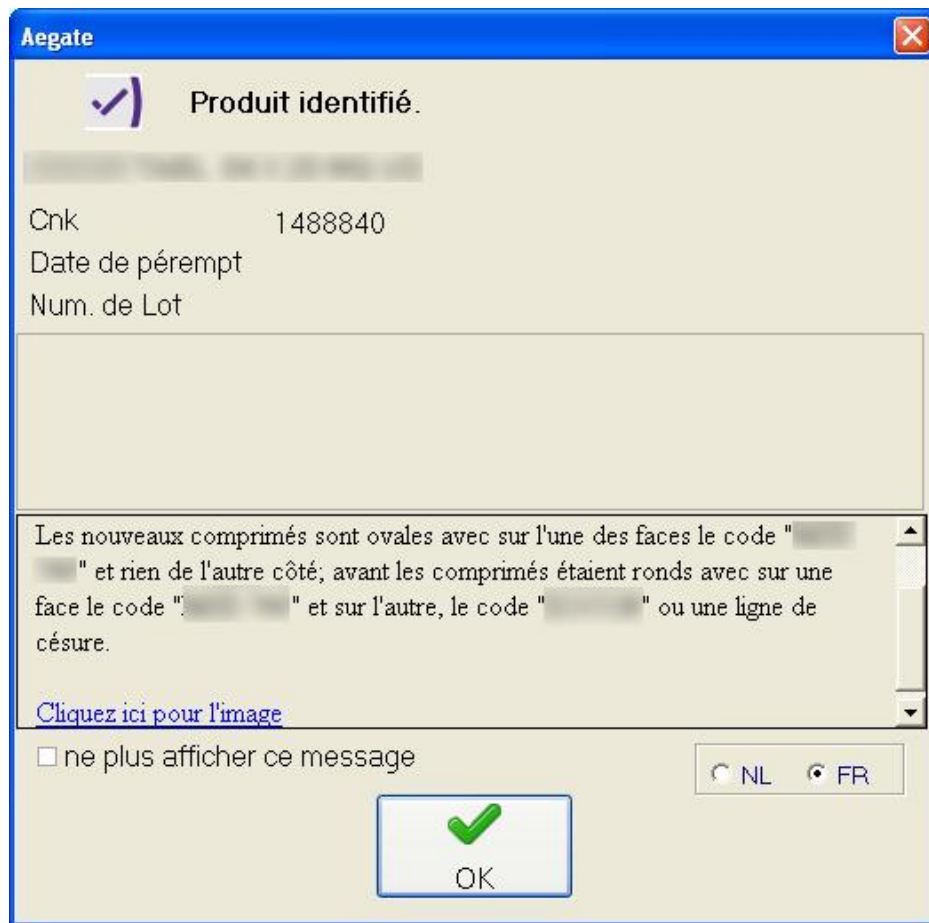
Nom du produit **Reductil Caps 28 x 10 mg**
Numéro de lot Tous les lots

Tous les lots non périmés. Raison: NON-CONFORMITÉ - Recommandation de l'Agence Européenne des Médicaments (EMA) de suspendre l'autorisation de mise sur le marché après une réévaluation du rapport bénéfice/risque. A retourner au SCM avant le 31/03/2010. Réf: 2010-2.

aegate

OK

Authentication in the pharmacy : practical information

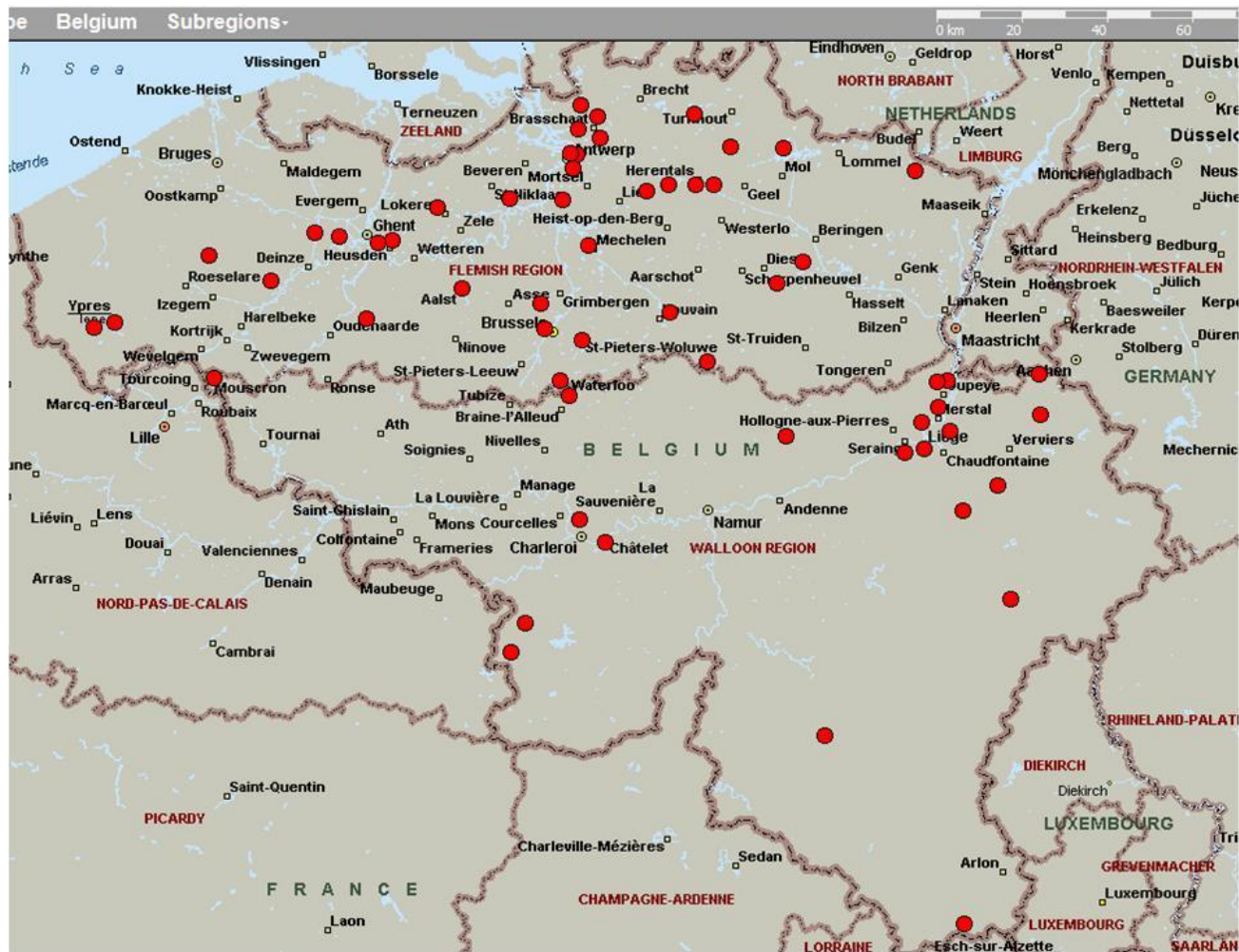


From authentication to info tool

- **Originally :**
 - Authentication system
 - Internet based
 - At point of dispensing
 - To combat counterfeiting
- **Additionally:**
 - Uploading expiry dates
 - Recall info (rapid alert)
 - Product- & therapy- related messages benefiting patient management
 - Value adding tool for pharmacy
- **Not:**
 - Data collection system

- **Response time : 0.269 sec**
- N° products that can be authenticated : 902
- N° UBC in database : 101.9 mio
- N° recalled products currently in database : 28
- N° product messages added : 688
- **N° pharmacies scanning : 2184**
- N° items authenticated : 14.077.172
- Notification expired : 1177
- Notification soon to expire : 3960
- **Notification has been recalled : 1954**
- **Already dispensed elsewhere : 502**

“The June 2009 case”



Summary points

- Last check at time of delivery provides ultimate patient safety
- Effective, simple, user-friendly and flexible system
 - Based on existing pharmacy practice and tools
 - No interference with workflow (time !)
 - Low infrastructure needs (costs !)
 - Authentication + expiry date + recall check + product messages, but NO data collection
- Helps protecting patients (but pharmacists, wholesalers and manufacturers as well)
- Operational in daily practice in 2000+ pharmacies
- Reliability and relevance is function of rapid and full roll-out (manufacturers, software providers, pharmacists)

Recommendations

- **Authentication in the pharmacy just prior to dispensation provides patient safety**
- **Full track & trace (e-pedigree) is of less value to patient & pharmacist**
- **Authentication system should be open to all (medicines, pharmacies, wholesalers...)**
- **Over-sophistication is a burden to**
 - utilisation by the end-user
 - costs (drugbill !)
- **Dispensing data are the property of the pharmacy and need to be**
 - handled by Trusted Third Party
 - restricted to authentication purposes only
- **Ensure optimal use of extremely valuable communication tool/moment**
- **Operational Belgian system is compliant with upcoming EU-legislation**
- **Migrate from UBC to GS1 DataMatrix (harmonisation & multipurpose)**



Thank you !

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