



Pharmacovigilance in the next 5 years

The Community Pharmacist's vision



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Pharmaceutical Group of European Union



Members: Professional Bodies & Pharmacists' Associations



2018: 32 Countries

	Austria		Netherlands
	Belgium		Poland
	Bulgaria		Portugal
	Cyprus		Romania
	Czech Rep		Slovakia
	Denmark		Slovenia
	Estonia		Spain
	Finland		Sweden
	France		United Kingdom
	Germany		Croatia
	Greece		FYR Macedonia
	Hungary		Norway
	Ireland		Serbia
	Italy		Switzerland
	Luxembourg		Turkey
	Malta		





Pharmaceutical Group
of European Union

PGEU Best Practice Paper:
**Pharmacovigilance and
Risk Minimisation**

Ref 17.08.26E 003

1. Personalised safeguarding of medicines through wider integration of data in pharmacovigilance

- Wider integration of **clinical patient data** (drugs, allergies, contra-indications, lab measurements) through access to **shared electronic health records**;
- Indications** should be communicated to pharmacists (e.g. on the prescription) to ensure the most effective and appropriate therapy is provided, as well as to ensure the correct reporting of suspected adverse events from the use of medicines off-label;
- Integration of **real-world data on Adverse Drug Reactions (ADRs) and Medication Errors (MEs)** at point of dispensing;
- Future prospects: inclusion of pharmacogenomics testing data

Key conditions: Data privacy and security

2. Maximise use of eHealth and ICT tools to report, prevent, resolve and communicate safety risks

Report

Improve **reporting of adverse drug events** by HCPs by reducing the barrier of administrative reporting procedures through **integrated eHealth solutions**

Prevent

Point of care ICT support in detection of **interactions, drug-related problems (DRPs), duplications** and **vulnerable patient groups**

Resolve

Further integration of **electronic evidence-based decision support systems** in pharmacy software

Integrated **electronic alerting systems** for **recalls** and **withdrawals**

Communicate

Use of several **digital media tools** to inform targeted audiences on **risk-minimisation measures**

Patient-friendly information available on the **outside of the package**, as a pictogram, summary, or prompt/removable card to facilitate our dialogue with patients

Employing ICT at the point of care

Functions Utilities Reports Find Goods In CDR Drug Price - Ctrl+R Repeat Management ID EPharmacy NMS DMR MAS Intranet Favourites Stock PMR

F1 Patient Details F2 Create Owing F3 Product Choice F4 Change Dose F5 Change Quantity F6 Next Item F7 Edit MDS F8 Last Item F9 Label Options F11 Start Again Esc

Not Dispensed Alt+R - Edit Record Move Up Alt+D - Delete Item Alt+V - View RX

Item No. 2 HS21 Dr C Mathews

28 Moxonidine 200mcg tabs
Use As Directed By The Prescriber.

MAKE YOU FEEL SLEEPY. IF
VE OR USE TOOLS OR
ES.

est

DT Part 1 Category M drug.
POCKET EXPENSES are NOT

Showing 27 months. Alt+S to show all
 Show excluded su

Qty	Dispensed Product Choice
28.00	Moxonidine 200mcg tabs (2

Now May Jun Jul Aug Se

Max Day

Mnth Total

Forms

Suggested Lvl.

Product

Alt+B - Basket Alt+O - Order Pad Alt+I Interventions

Alt+F6 - No Label Ctrl+F8 - Repeat this Script Alt+A - Add Endorsements Alt+W - Alter Warnings

MUR Alt+U Counselling

Proscript Interaction

There is a possible serious interaction between Moxonidine 200mcg tabs and Amitriptyline 25mg tabs :antagonism of hypotensive effect Manufacturer advises avoid concomitant use.(Not taken together) This is regarded as a POSSIBLE MAJOR OR SERIOUS INTERACTION

F10 - Continue F2 - Print Interaction

Example: Clinical decision rules integrated in pharmacy software in the Netherlands

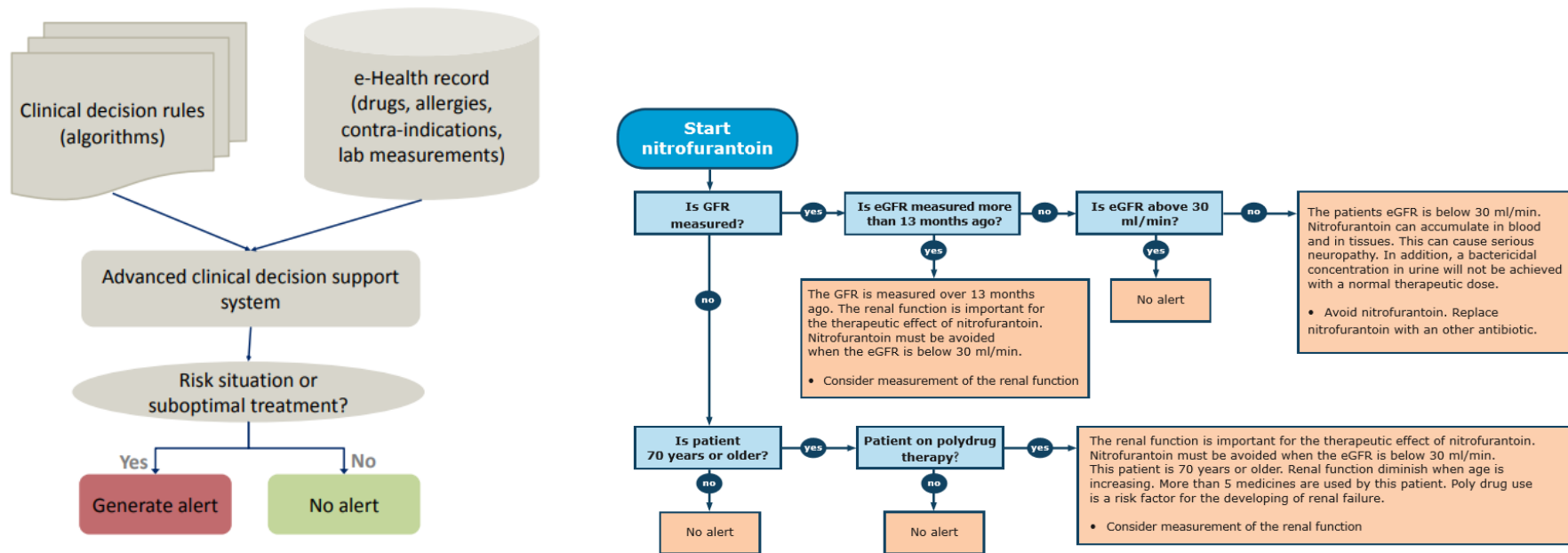
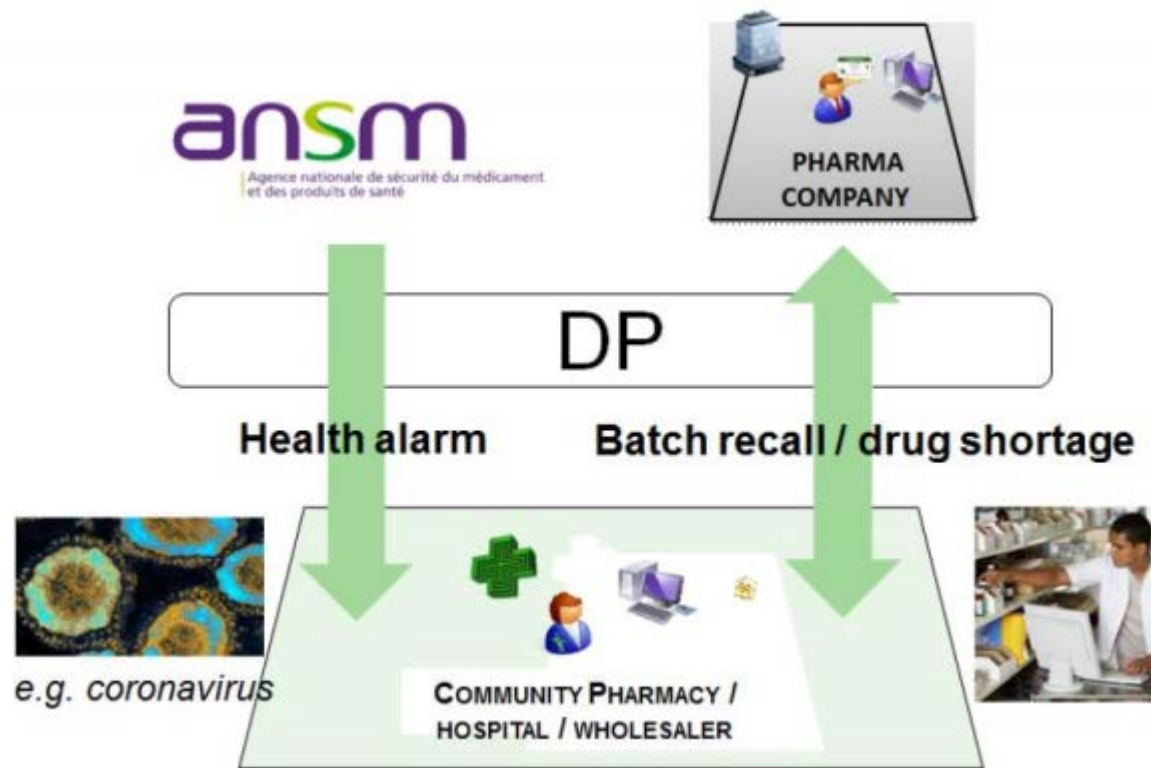


Fig.1 Advanced clinical decision support systems uses all patient characteristics from the e-Health record to detect risk situations

Example: French Shared Medication Record with integrated electronic medication recall system



3. Expanding pharmacy services supporting the safe, effective and rational use of medicines

Medication review (MR) is a structured evaluation of a patient's medicines with the aim of optimising medication use and improving health outcomes. This entails detecting drug related problems and recommending interventions. Type 1 MRs are performed in all European pharmacies, type 2 in 13 European countries and type 3 in three European countries to date

Characterisation		Information available		
Type	Level	Medication history	Patient interview	Clinical data
Type 1	Simple	+	-	-
Type 2(a)	Intermediate	+	+	-
Type 2(b)		+	-	+
Type 3	Advanced	+	+	+

New medicines services for patients starting a new medicine which provide tailored support during the first few months of treatment. Patients are recruited at the point of dispensing, counselled on relevant points about the medication and provide consent for the service. Within several weeks, a consultation between the pharmacist and patient takes place where the pharmacist conducts a semi-structured interview to identify any problems, ADRs, concerns or nonadherence to the new medication.

4. Further multi-professional collaboration to maximise the benefits for patient safety



- More effective problem solving and prevention of adverse drug events in partnership
- Ensuring **continuity of care**: collaboration both within primary and secondary/tertiary care
- Importance of **integrated eHealth solutions** to facilitate communication, reduce costs and administrative burden
- Continued collaboration between **national pharmacy associations and national medicines agencies** and the **PGEU and the European Medicines Agency** to further strengthen the role and contribution pharmacists can make to patient and medication safety;

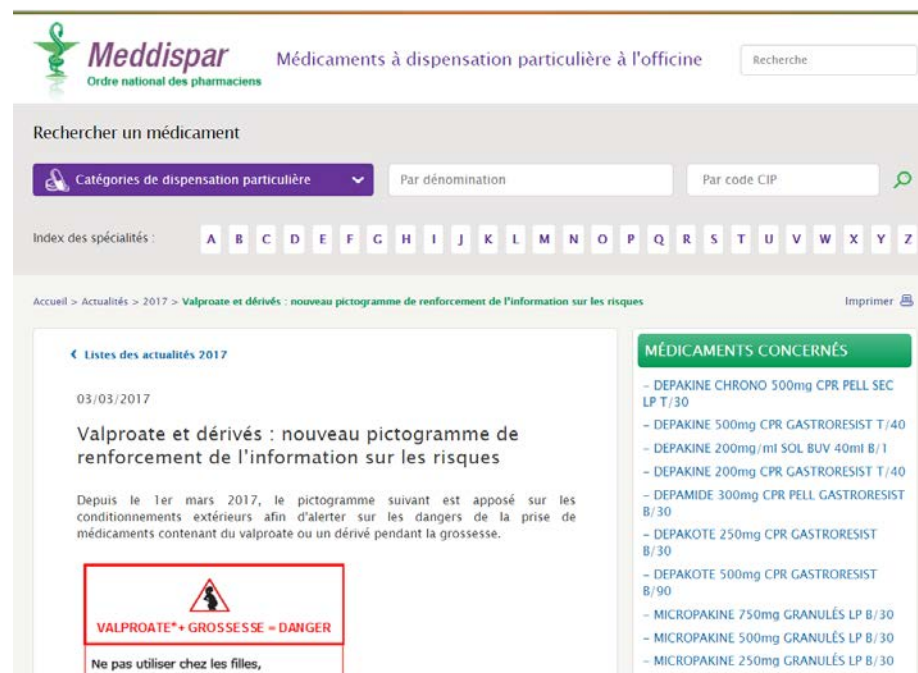


5. Stronger integration of training and education on pharmacovigilance and RMMs

- Incorporating good pharmacovigilance practices, risk minimisation measures and medication safety activities into **Good Pharmacy Practices, standard operating procedures, institutional protocols, continuous education, continuous professional development** and pharmacy education and training.

- Early involvement of community pharmacists in the development process of additional and routine risk minimisation measures

- Close collaboration between authorities and healthcare professional associations



Meddispar Médicaments à dispensation particulière à l'officine
Ordre national des pharmaciens

Rechercher

Rechercher un médicament

Catégories de dispensation particulière Par dénomination Par code CIP

Index des spécialités : A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Accueil > Actualités > 2017 > Valproate et dérivés : nouveau pictogramme de renforcement de l'information sur les risques

Imprimer

← Listes des actualités 2017

03/03/2017

Valproate et dérivés : nouveau pictogramme de renforcement de l'information sur les risques

Depuis le 1er mars 2017, le pictogramme suivant est apposé sur les conditionnements extérieurs afin d'alerter sur les dangers de la prise de médicaments contenant du valproate ou un dérivé pendant la grossesse.



VALPROATE*+ GROSSESSE = DANGER

Ne pas utiliser chez les filles,

MÉDICAMENTS CONCERNÉS

- DEPAKINE CHRONO 500mg CPR PELL SEC LP T/30
- DEPAKINE 500mg CPR GASTRORESIST T/40
- DEPAKINE 200mg/ml SOL BUV 40ml B/1
- DEPAKINE 200mg CPR GASTRORESIST T/40
- DEPAMIDE 300mg CPR PELL GASTRORESIST B/30
- DEPAKOTE 250mg CPR GASTRORESIST B/30
- DEPAKOTE 500mg CPR GASTRORESIST B/90
- MICROPAKINE 750mg GRANULÉS LP B/30
- MICROPAKINE 500mg GRANULÉS LP B/30
- MICROPAKINE 250mg GRANULÉS LP B/30

Community pharmacist's vision on pharmacovigilance



Community pharmacists are committed to continue developing their contribution to pharmacovigilance and risk minimisation through:

1. Personalised safeguarding of medicines at point of dispensing through **wider integration of data** in pharmacovigilance
2. Maximise use of **eHealth and ICT tools** to report, prevent, resolve and communicate safety risks
3. Expanding **pharmacy services** supporting the safe, effective and rational use of medicines
4. Further **multi-professional collaboration** to maximise the benefits for patient safety
5. Stronger integration of **training and education** on pharmacovigilance and RMMs






THANK YOU!



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