Pharmacovigilance in the next 5 years

The Community Pharmacist's vision

Jan De Belie MPharm

Professional Affairs Advisor

j.de-belie@pgeu.eu

@PGEU

24/09/2018

Pharmaceutical Group of European Union

PGEU GPUE

Members: Professional Bodies & Pharmacists' Associations

2018: 32 Countries

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


PGEU GPUE
Pharmaceutical Group
of European Union
PGEU Best Practice Paper:
Pharmacovigilance and
Risk Minimisation
Ref 17.09.26E 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

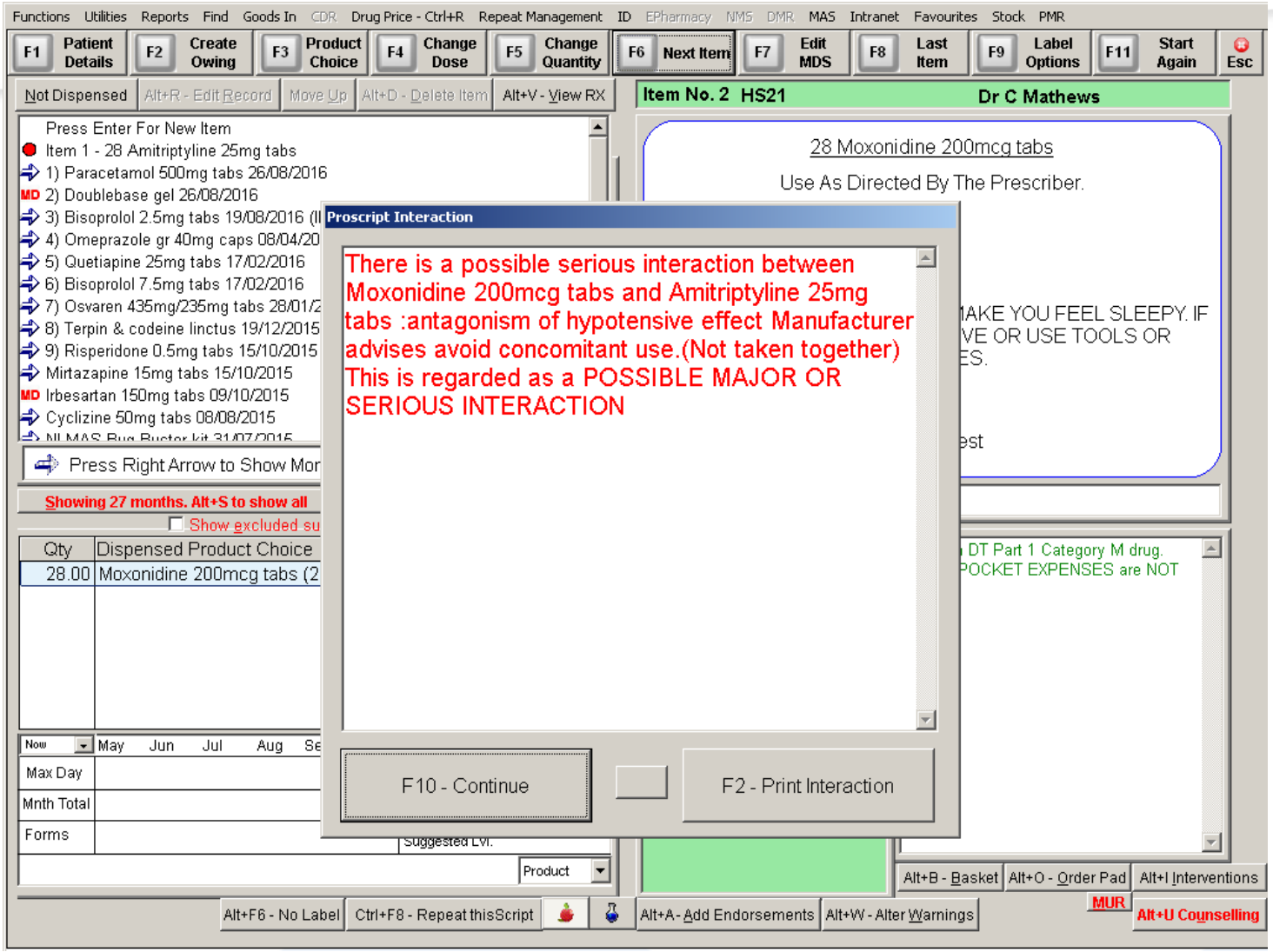
Integrated **electronic alerting systems** for **recalls** and **withdrawals**

Communicate

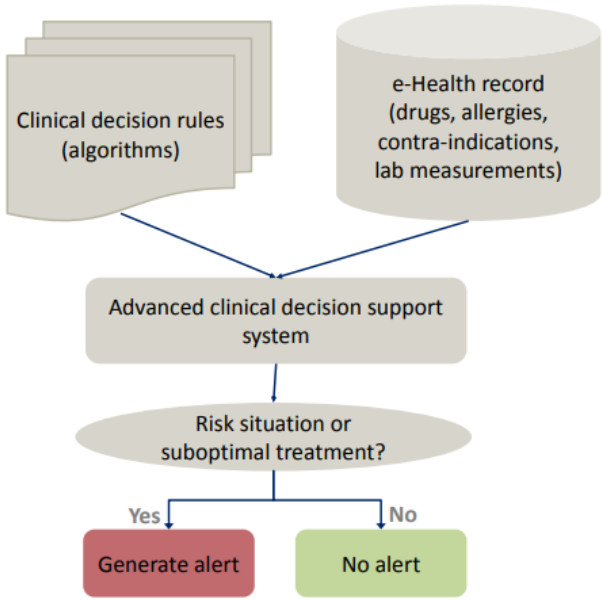
Use of several **digital media tools** to inform targeted audiences on **risk-minimisation measures**

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



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



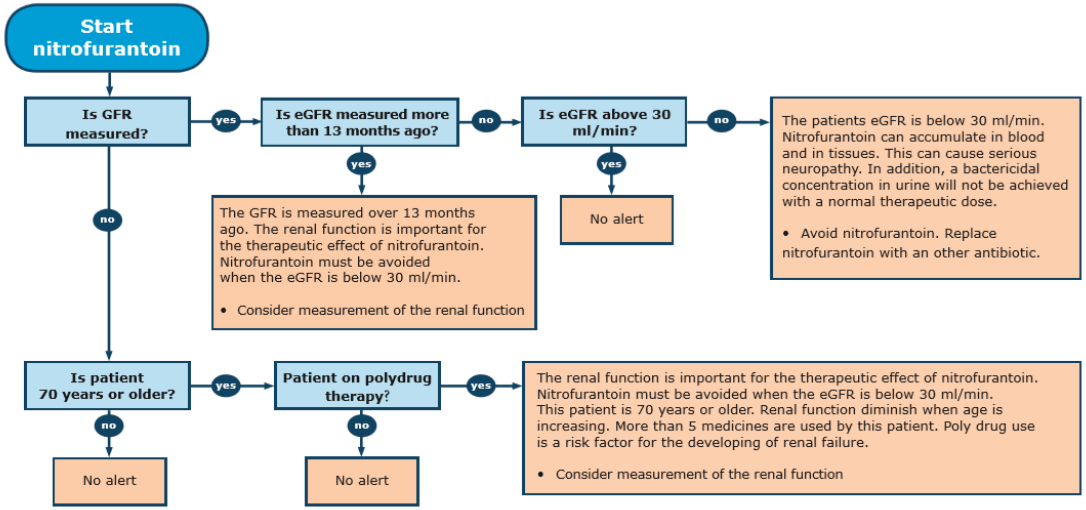
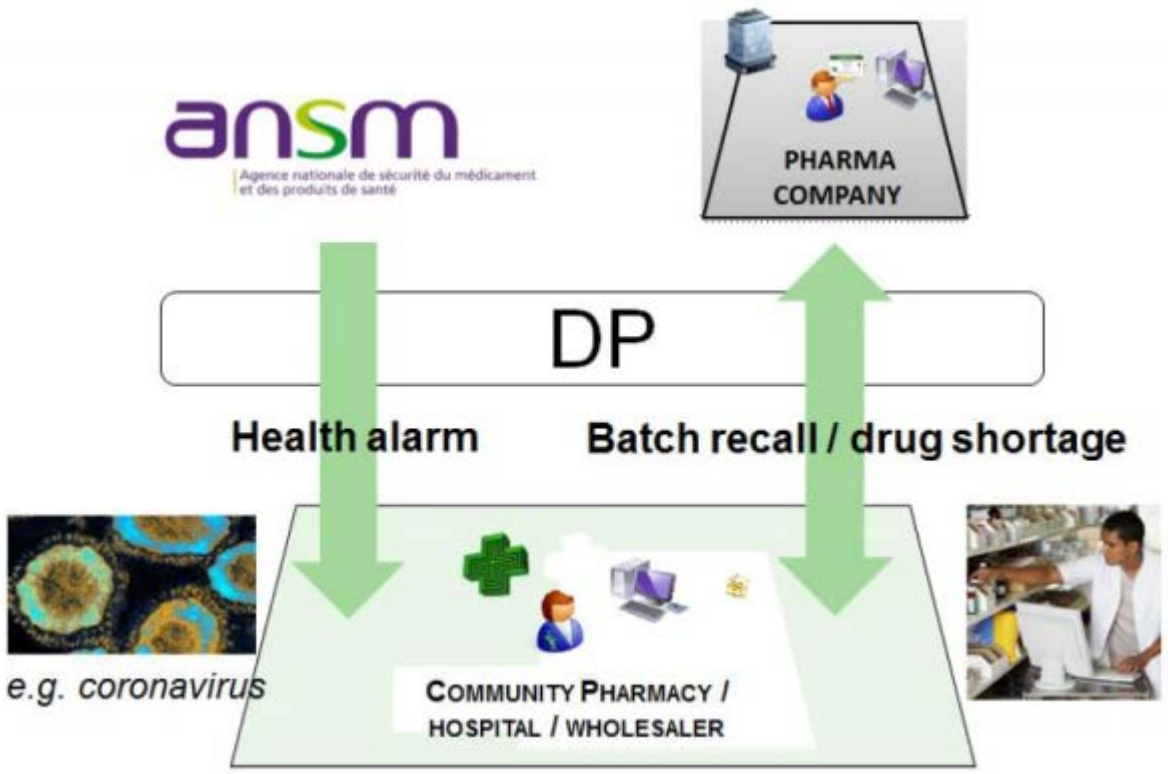


Fig.1 Advanced clinical decision support systems uses all patient characteristics from the e-Health record to detect risk situations

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

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!

Pharmaceutical Group of the European Union (PGEU)

Rue du Luxembourg 19, 1000 Brussels, Belgium

+32 (0)2 238 08 18

pharmacy@pgeu.eu

www.pgeu.eu