Stakeholders meeting

observations of three years of operation and opportunities for the future

Perspectives for the future
A Members States Perspective

London September 2015
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Medicines Evaluation Board

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Questions & Answers

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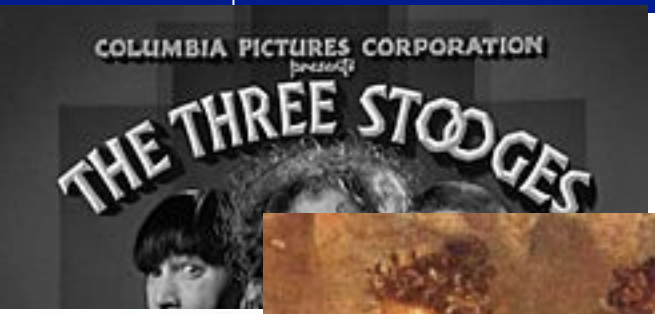
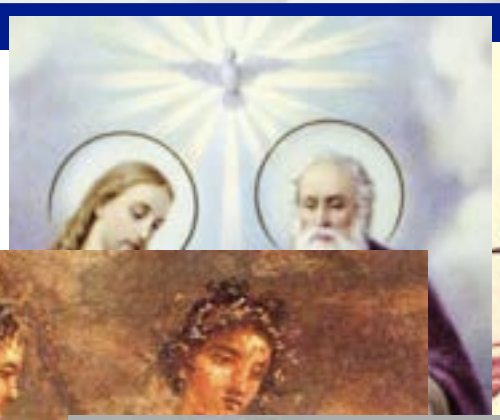
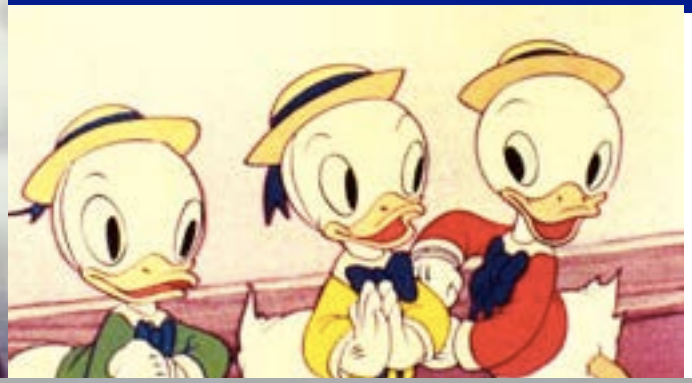
What? - Scope of Changes

- Strengthened coordination
- Authorisation requirements
- Risk Management Plans
- Post-Authorisation Studies
- Measure effectiveness of risk minimisation
- Adverse Drug Reactions reporting
- Signal detection
- Periodic Safety Update Reports
- Pharmacovigilance Risk Assessment Committee
- Decision-making legally binding –
- Transparency /communication
- Coordination of inspections
- Audits
- Better funding - Fees

Rule of 3*





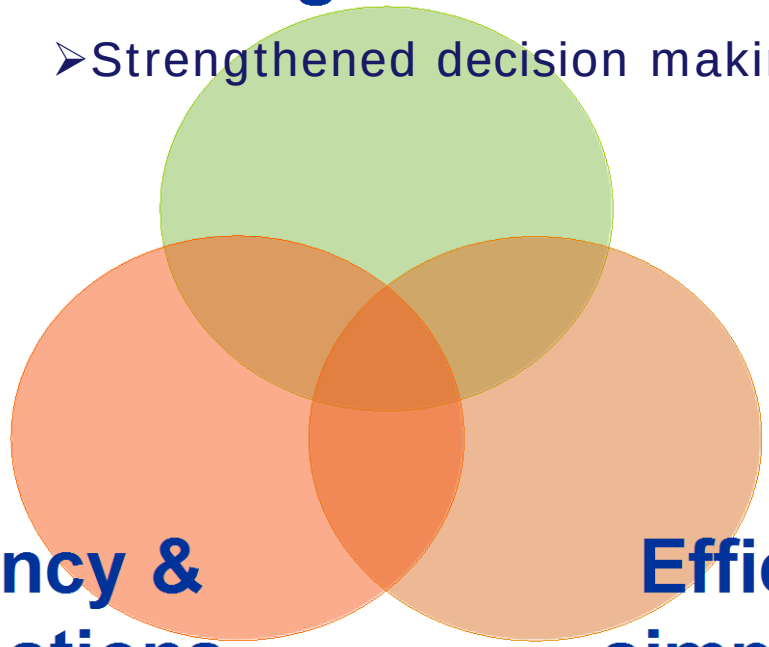


THE
GOOD BAD UGLY

main pillars of the new legislation to realise benefits

Strengthened Vigilance

- Strengthened decision making



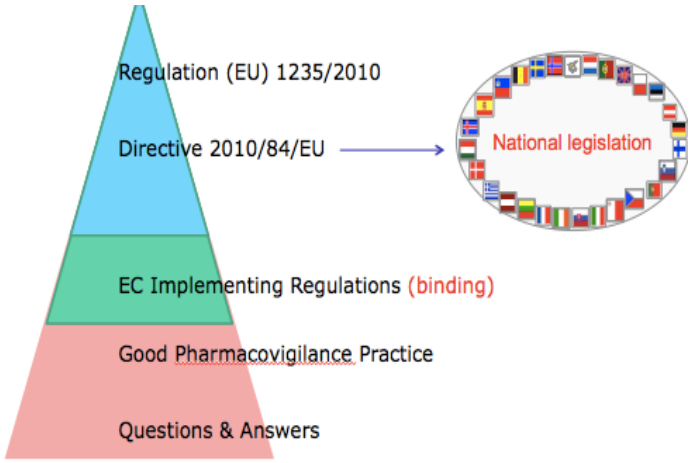
Transparency & communications

- Greater transparency

Efficiency & simplification

- Streamlined processes

- Key achievements from a NCA perspective
- Areas for improvements from a NCA perspective
- Priorities Future work from a NCA perspective



Observations

Real-time signal detection and signal prioritisation every month

Rapid action to manage risk with binding outcome

Benefit risk monitoring throughout a medicine's life cycle in clinical use

New era of transparency and openness in place

Coordinated **communication**

Engagement of **patients and HCP**

Signal recommendations from PRAC

Table 2 PRAC final recommendations regarding signals

Recommendation	*N*	Time until recommendation (days)		
		Mean	Median	Range
SmPC update	51	81	57	0–243
Routine pharmacovigilance	33	60	0	0–273
Referral started	9	54	27	0–186
DHPC	7	51	0	0–153
RMP update	7	132	144	0–234

the majority of PRAC recommendations affect products marketed by multiple MAHs

A.C.Pacurariu et al 2014

Consequent

1. Innovator submits PI update
2. Once Competent Authority approves safety VAR for Innovator, generics are asked to submit in line with the innovator

Concurrent

- All MAHs (Innovator and generics) for products containing the concerned substance are asked to submit at the same time

Consequences

- **Duplication** of efforts: all MAHs have to translate individually from English
- Wording **not harmonised**
- Divergent **quality** of translations
- Some translations accepted by one Member State, but considered not sufficient by another Member State
- **Workload** for network in assessing submissions
- If consecutive submissions (innovator 1st, generics follow) divergency and time gap)

- EMA publishes translations (in 22* EU languages) of PRAC recommendations for PI update first publication in Feb 15

Benefits

- Recommended translations of PI wording provided centrally by the EMA
- **Harmonisation** of PI wording in all EU languages
- Decrease of **workload** for MAHs
- **Simplification** of assessment of variations to update PI, with decrease in workload for network
- Enhanced **quality**
- **Concurrent** submissions

* Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Lithuania, Latvia, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden

- ✓ For the future
- ✓ clarity in definitions
- ✓ risk proportionality /frequency of monitoring ……

access to EV for all stakeholders and mandatory monitoring ……

Single assessment of PSURs

- PSUR assessment procedures
  - well defined procedures
  - Clear binding timetables
  - Clear recommendations

  integration of benefit and risk and direct application of new labelling (faster impact)

- Efficiency gain for MS in assessments

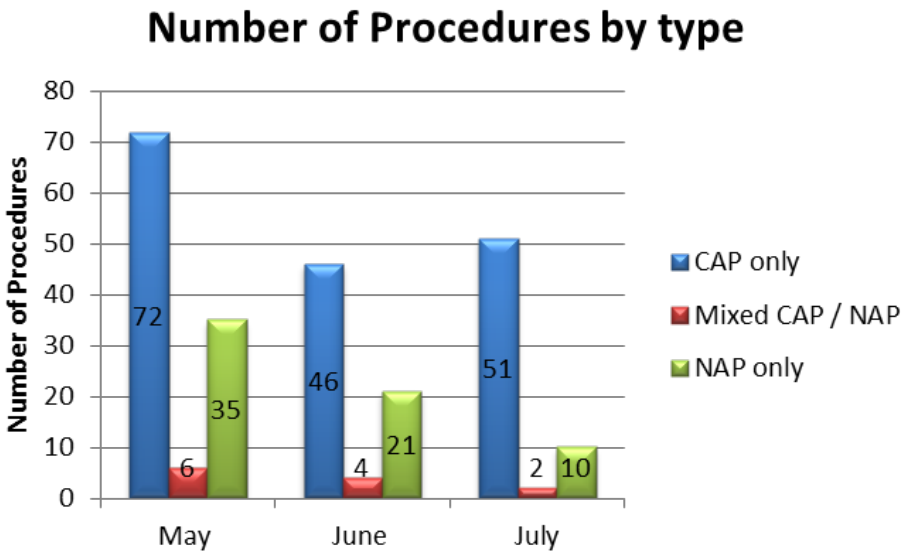
PSUR procedures: May – July 2015

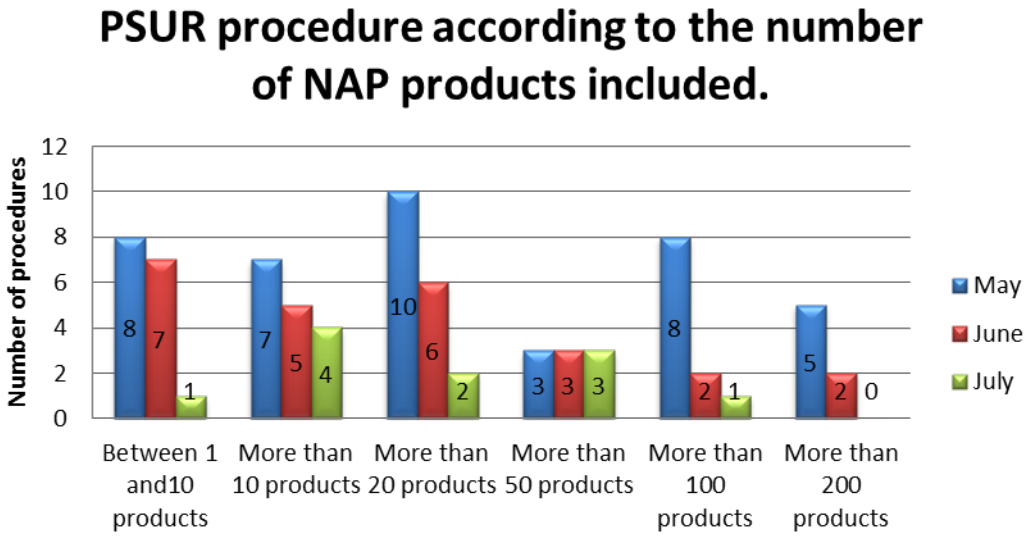
Total Number of Procedures under Assessment:

May - 113

June - 71

July - 63





PSUSAs for NAPs only

- Complex assessment
- No consistent SmPC in the EU
- No “ CSP”
- EURD list mono /FDC

Risk Management Plans

- Different applicants submit different RMPs for same active substance
- Different RMSs (CMSs) assess the RMPs for the same active substances in a different way
- Same (generics) active substance → different RMPs

- efficiency,
- process improvement,
- simplification

This presentation reflects my personal points of view

My perception of the world might be distorted/biased