EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Lifecycle Pharmacovigilance planning for public health: key to product development and safe and effective use of products

Tenth Stakeholder forum on the Pharmacovigilance legislation
21 September 2016

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EMA

Planning is key to product development and safe and effective use of products

Key messages

- Pharmacoepidemiology and pharmacovigilance play critical roles in medicines regulation: regulator as gate-keeper and enabler
- Planning data collection and integrating knowledge starts in early development and is life-long
- Embrace the evidence spectrum: different data and methods are best to address different questions
- Use of real world evidence holds great promise to support drug development and in the fulfilment of unmet needs
- Collaboration will be critical to realising that promise.

Planning is key to product development and safe and effective use of products

In this session: Explore the critical link between pharmacoepidemiology and risk management planning and the development of innovative medicines to fulfil the unmet needs of patients.

- Scientific Advice delivers planning during development - Spiros Vamvakas, EMA
- Epidemiology as an enabler for health - Alison Cave, EMA
- Actions from the Risk Minimisation Measures Workshop in 2015 - Jamie Wilkinson, PGEU
- Open panel discussion

Health Protection and Promotion – two sides of the same coin

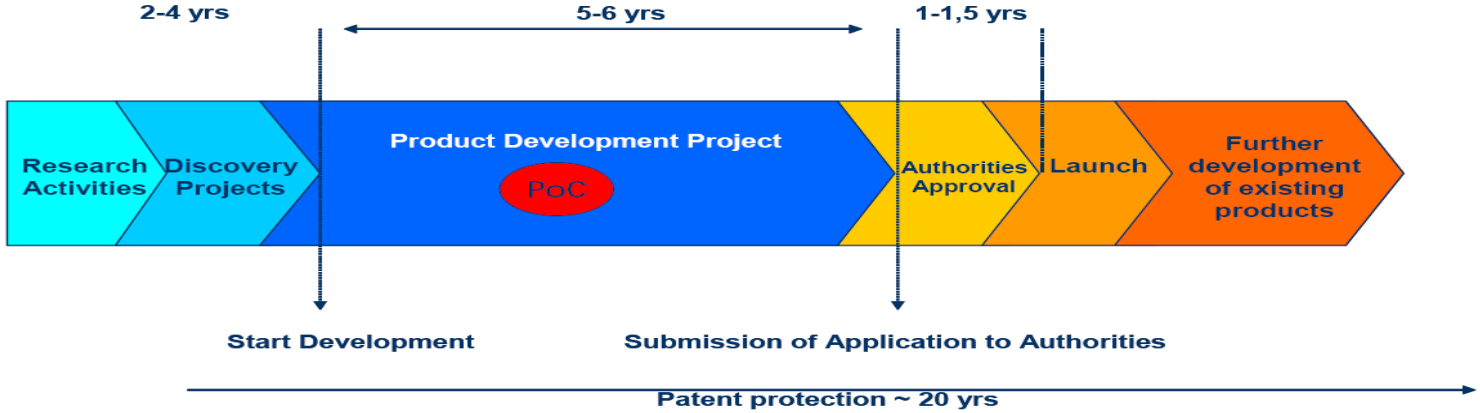
Protect
‘safety’
Through detection and management of side effects

Promote
‘efficacy’
Fulfil unmet medical needs

Better information throughout the product lifecycle and patient journey

How do pharmacovigilance and epidemiology support innovation?

- **Proactive enabler:** planning for data collection, management of risk monitoring of use
- **Reactive responder:** analysis and integration of various data streams – updated advice to optimise use **–** better patient outcomes and sustainable B/R management.
- Provides: assurance that data will be available once a product is on the market to allow actions for risk min and benefits optimisation
- **Development → Licensing → Utilisation → Monitoring.**



Experience with new EU PV legislation

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Associated links

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LINK TO ORIGINAL ARTICLE

Proactively managing the risk of marketed drugs: experience with the EMA Pharmacovigilance Risk Assessment Committee

Peter Arlett, Geraldine Portier, Roberto de Lisa, Kevin Blake, Noel Wathion, Jean-Michel Dogne, Almath Spooner, June Raine and Guido Rasi

challenges in the optimization of their safe and effective use.

In the first 18 months of its operation, the PRAC has considered risk management plans for 160 medicinal products. In this work the PRAC has focused on ensuring feasible, evidence-based and risk-proportionate planning[4].

The collection of individual reports of suspected adverse drug reactions (ADRs) is one of the foundations of drug surveillance, and the reporting rules have been strengthened. These now include the formal

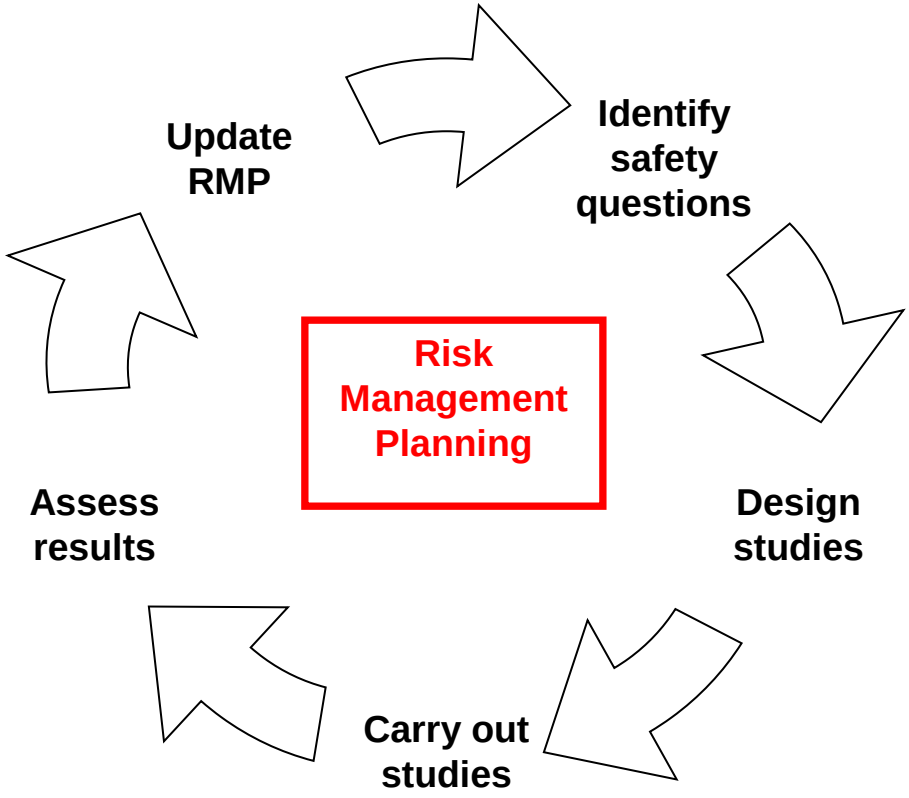
"After 18 months of operation of PRAC

We suggest more safe & effective drugs can be made available

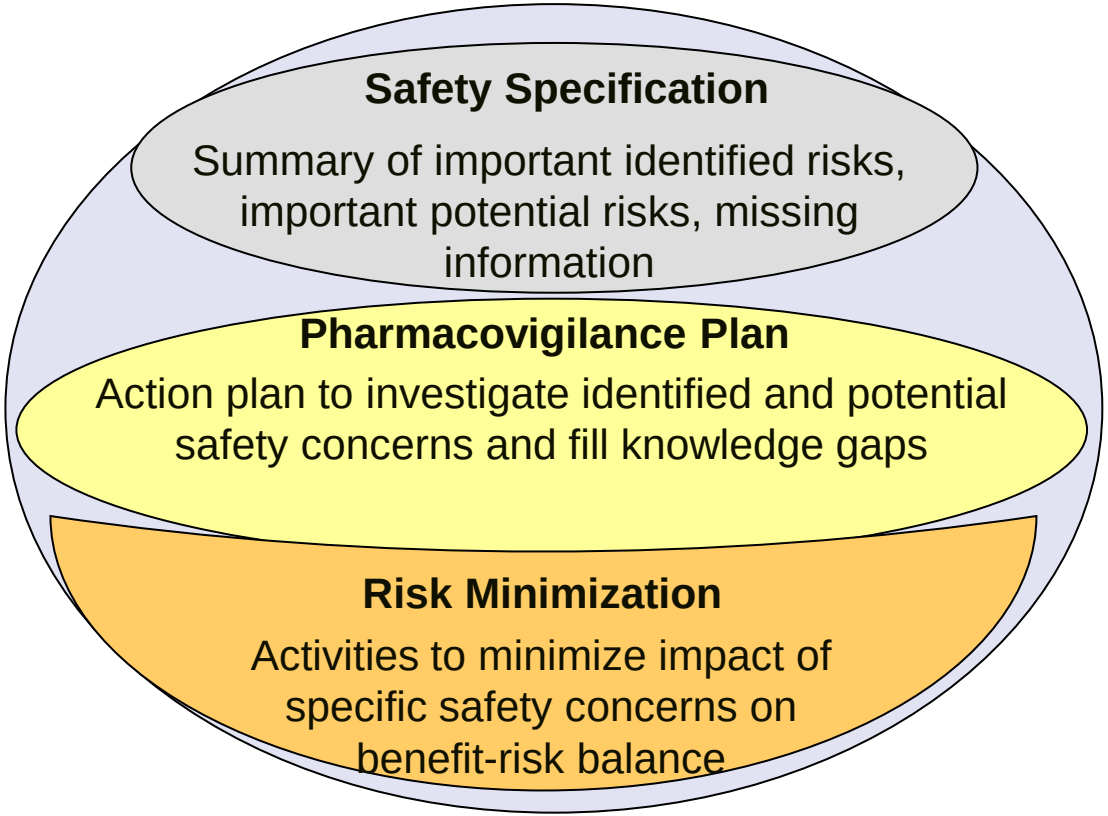
Through planning, engagement and transparency, as well as rapid assessment"

2014 Nat Rev Drug Disc

Proactive Risk Management Planning



EU Risk Management Plan



Advice on RMP at early stage

Scientific Advice Working Party includes PV expertise – PRAC members

Early discussion of risk management plans including design of studies

EC Report on 3 years of EU pharmacovigilance

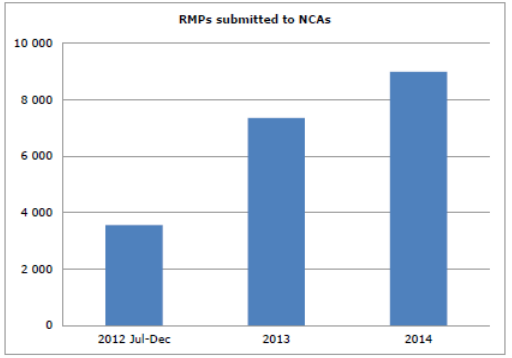
EUROPEAN COMMISSION

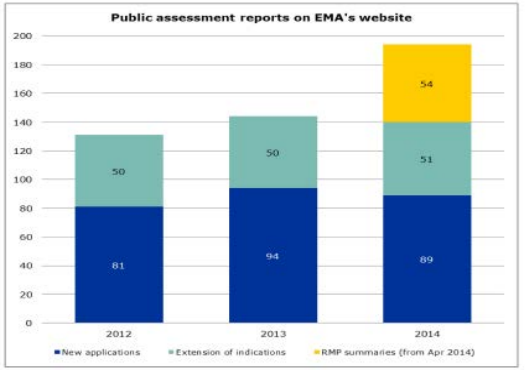
Brussels, 8.8.2016
SWD(2016) 284 final

COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

Commission Report

Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)





PRIME scheme - Goal & Scope

Medicines with major public health interest

Reinforce scientific and regulatory advice

- Foster and facilitate early interaction
- Raise awareness of requirements earlier in development

Optimise robust data generation

- Focus efficient development
- Promote generation of robust and high quality data

Enable accelerated assessment

- Facilitated by knowledge gained throughout development
- Building on existing regulatory framework

Eligibility for PRIME scheme

Based on EU Accelerated Assessment criteria

Medicinal products of major public health interest and in particular from the viewpoint of therapeutic innovation.

- Potential to address to a significant extent **an unmet medical need**
- **Scientific justification**, based on data and evidence available from nonclinical and clinical development

No satisfactory treatment or if method exists, brings a major therapeutic advantage

Introducing new methods- or improving existing ones

Meaningful improvement of efficacy - impact on onset, duration, improving morbidity, mortality

First 4 products granted eligibility

CCX-168
Treatment of patients with active ANCA-associated vasculitis (GPA and MPA)
Orphan

KTE-C19
Treatment of lymphomas (DLBCL, PMBCL, TFL)
Orphan

Emapalumab
Treatment of primary haemophagocytic lymphohistiocytosis (HLH)
Orphan

Aducanumab
Alzheimer's disease

Prime Web-page and supporting documents

Factsheet in lay language

Q&A, templates, application form for applicants

prime@ema.europa.eu

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Some dates for the diary

WebRADR workshop 19th October

EMA Registries workshop 28th October

EMA Big Data Workshop 14-15th November

ENCePP plenary
22nd November

EMA Pharmacovigilance Impact Workshop
5th - 6th December

Thank you for your attention

Further information

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