EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 4:
Looking towards the future: Brainstorming on funding mechanisms for PAS

Introduction

Presented by Xavier Kurz

An agency of the European Union

- Regulatory authorities need to continuously monitor, and investigate as necessary, the benefit/risk profile of medicines

- High quality information on clinical use of medicines is needed:
  - Population exposure
  - Utilisation patterns
  - Safety
  - Efficacy/effectiveness
  - Effectiveness of risk minimisation measures

  and their determinants.

Data sources that regulators/ EMA can use to obtain data on clinical use of medicines:

- Voluntary contributions: ENCePP network, other networks, registry holders, academics, patients and HCPs' associations,…

- Use of data sources owned or contracted
  - EMA: THIN & IMS, MHRA: CPRD, AEMPS: BIFAP, …

- Commissioned studies, e.g. EMA framework contract

- FP7 programme on drug safety (2007-2013) or other institutional programmes

- Studies requested to industry

Requests to ENCePP for data in the context of PRAC reviews and information received

Topic	Information received
Combined hormonal contraceptive and risk of venous thromboembolism + medicines containing cyproterone acetate 2 mg and ethinylestradiol 35 mcg and risk of venous and arterial thromboembolic events	Data from IMS on the dispensing of CHC in 5 EU countries
Flupirtine-containing medicines and concerns over liver problems associated with their use for short- and long-term pain relief	None
Strontium ranelate in the treatment of osteoporosis	* 1 centre provided a review of 51 publications and EU guidelines * 2 centres provided 1 published article * 1 centre provided a review of status of strontium ranelate in its country * 1 centre provided a paper and final report of a prescription event monitoring study and review of cardiovascular events identified * 1 centre provided information from HTA body in its country
Oral bromocriptine-containing medicines indicated in suppression of lactation post-partum	* 1 centre: review of spontaneous ADR reports * 1 centre: nb. of users and prescriptions in the country * 1 centre: research paper
Valproate and use in pregnant women	* 3 centres: set of publications related to previous studies
Oral methadone containing also povidone	None
Ambroxol- and bromhexine- containing medicines and allergic reactions	* 1 centre: review of spontaneous ADR reports * 1 centre: results of data analysis on mucolytics
Codeine-containing medicines < 18 years and risk of morphine toxicity	* 1 centre: review of spontaneous ADR reports * 1 centre: report on codeine use, misuse and dependence
Hydroxyzine-containing medicines and pro-arrythmogenic potential	* 1 centre: review of spontaneous ADR reports * 1 centre: review of cases series of 22 patients hospitalised in emergency department

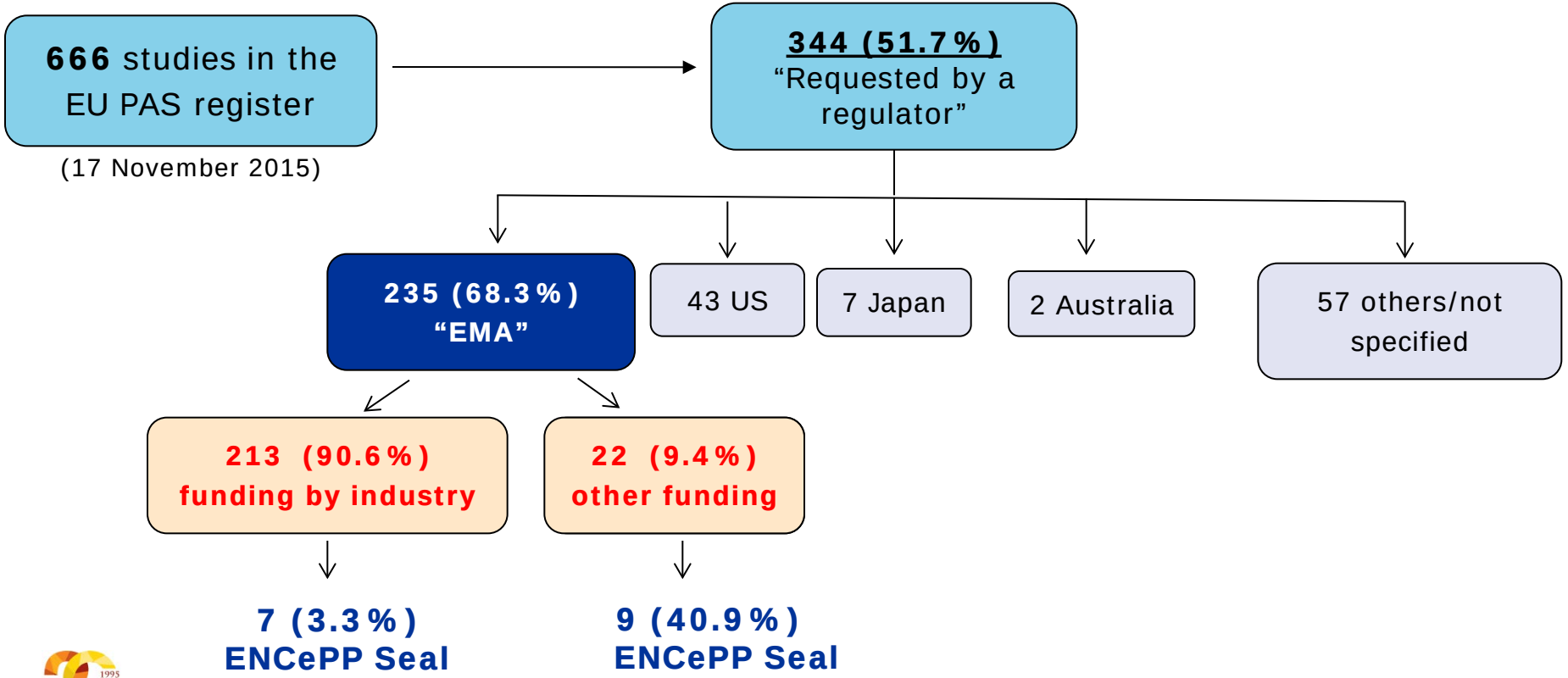
Studies funded by EMA via public procurement

Topic	Year	EU PAS Register ID
A/H1N1 pandemic vaccines and pregnancy outcomes	2010	5304
Impact of risk minimisation in patients treated with rosiglitazone-containing products	2010	2236
Isotretinoin and the effectiveness of the Pregnancy Prevention Programme in Europe	2011	4654
Patterns and determinants of use of oral contraceptives in the EU	2011	3520
Monitoring the effectiveness of risk minimisation in patients treated with pioglitazone-containing products	2011	3221
Risk of cardiac valve disorders associated with the use of biophosphonates	2011	7967
Association between anxiolytic or hypnotic drugs and total mortality	2012	1062
Metformin use in renal impairment	2013	7492

FP7-funded studies (2007 to 2013)

Year	Topics proposed	Topics published	Funded studies
2007-2008	5	1	SOS: Cardiovascular and gastrointestinal safety of NSAIDs
2009	6	1	ARITMO: Arrhythmogenic potential of drugs
2010	5	4	• ADDUCE: Chronic effects of Attention Deficit Hyperactivity Disorder Drugs • EUROmediCAT: Safety of Medication use in Pregnancy in Relation to Risk of Congenital Malformations • PHARMACHILD: Long-term Pharmacovigilance for Adverse effects in childhood arthritis • STOP: Suicidality: Treatment Occurring in Paediatrics
2011	5	4	• CARING: Cancer risk and insulin analogues • SAFEGUARD: Safety of anti-diabetes drugs (cardio/cerebrovascular and pancreatitis/pancreatic cancer) • Astro-Lab: Assessment of safety of LABAS in asthma in routine care by combining healthcare • EpoCan: Risk of thromboembolic events and tumour growth progression in cancer patients, and cardiovascular and cancer risk in chronic kidney disease
2012	3	0	
2013	3	1	PREDICTION-ADR: genetic factors predisposing patients to adverse drug reactions (ADRs) from cardiovascular disease (CVD) drugs

Studies requested to and funded by industry



Industry studies:

- Major source of funding for studies and data on clinical use of medicines
- Limited evidence as regards scientific independence and transparency
- Context of imposed studies : legal responsibility vs. investigators' independence

  e.g. A/H1N1 vaccines
- Barriers to collaborations with public institutions

Role of ENCePP?

Brainstorming on funding mechanisms for post-authorisation studies

Tom MacDonald: Central mechanisms for industry-funded studies

Helen Dolk: Medication safety in pregnancy

Xavier Kurz: Collaborative studies on vaccines