EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP supporting EMA Committees

Experience so far

ENCePP Plenary meeting 18 June 2013

Presented by K Blake

ENCePP reflected in GVP

- Cited in GVP Module VIII PASS:
  - Code of Conduct
  - Guide on Methodological Standards in Pharmacoepidemiology
  - Checklist for Study Protocols

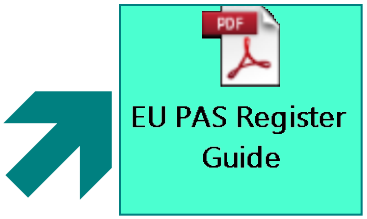
- ENCePP E-Register acting as ‘EU PAS Register’

ENCePP e-Register of studies (EU PAS Register)

→ **ENCePP E-Register acts temporarily as 'EU PAS Register'** for all PhEpi and PhV studies

- initiated, managed or financed by a MAH
- conducted by a (ENCePP) research centre within the EU

Further guidance: **EU PAS Register Guide** published on ENCePP Website



ENCePP Secretariat notifies PRAC of studies requested by a Regulator and funded by an MAH

- 119 studies registered as of 14 June 2013
  - 15 display 'ENCePP Study Seals'
  - 5 of these 15 are MAH funded and conducted by ENCePP centre

Promote/facilitate uptake of ENCePP study seal

- Engagement with Committees is bearing fruits i.e. request for PASS on bladder cancer and pioglitazone to be ENCePP study
- Further engage with industry ➢ Industry workshop with ENCePP SG members on 22 May 2013

ENCePP supporting Committees: referrals

- Provision of (pharmaco)epidemiology expertise for Ad-hoc expert groups. *NB: individuals subject to full EMA conflicts of interest procedure*[#]
- Provision of data in response to an invitation from EMA e.g. tetrazepam Art 107i, CHC Art 31, Diane Art 107i, strontium ranelate Art 20
- Final studies feeding into referrals e.g. SOS consortium NSAIDs study and NSAIDs Art 5.3 + Art 31

[#] *http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&mid=WC0b01ac0580028c78*

ENCePP supporting Committees: safety issues

- Provision of information/data in response to a request from EMA
- Discussion of scope of existing/ongoing studies regarding further endpoints/exposures and/or confounders as new issues arise
- EMA Call for Expressions of Interest for Drug Safety Studies
  - ✓ *Requirement in each call for tender that an ENCePP Study Seal is applied for*
  - ✓ *7 studies complete/on-going*

EMA funded ENCePP studies

Name of study	Timeframe
Isotretinoin and the effectiveness of the Pregnancy Prevention Programme in Europe *http://www.encepp.eu/encepp/viewResource.htm?id=2706	19/12/2011 - 19/06/2013
Impact of risk minimisation in patients treated with rosiglitazone-containing products http://www.encepp.eu/encepp/viewResource.htm?id=2236	15/10/2010-17/10/2011
A/H1N1 pandemic vaccines and pregnancy outcomes http://www.encepp.eu/encepp/viewResource.htm?id=2758	18/10/2010-30/06/2013
Patterns and determinants of use of oral contraceptives in the EU http://www.encepp.eu/encepp/viewResource.htm?id=2914	02/12/2011-22/03/2013
Monitoring the effectiveness of risk minimisation in patients treated with pioglitazone-containing products http://www.encepp.eu/encepp/viewResource.htm?id=2918	20/01/2012-20/03/2013
Risk of cardiac valve disorders associated with the use of biphosphonates http://www.encepp.eu/encepp/viewResource.htm?id=2772	02/12/2011-02/10/2013
Association between anxiolytic or hypnotic drugs and total mortality http://www.encepp.eu/encepp/viewResource.htm?id=3786	17/09/2012-17/09/2013

* *Entry in ENCePP Register*

Current call for expression of interest EMA/2012/08/CN

- Any interested person or company can submit an application up to last 3 months of period of validity i.e. **02 January 2015**
- Candidates meeting published selection and exclusion criteria added to list
- May be invited to submit tenders in response to possible future restricted invitations to tender
- Contracts with an estimated value › €60,000 but ‹ €130,000*

- *http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000320.jsp&mid=WC0b01ac05800a3991*

**(threshold for Public Procurement Directive for services and supplies)*

European Commission Framework Programme

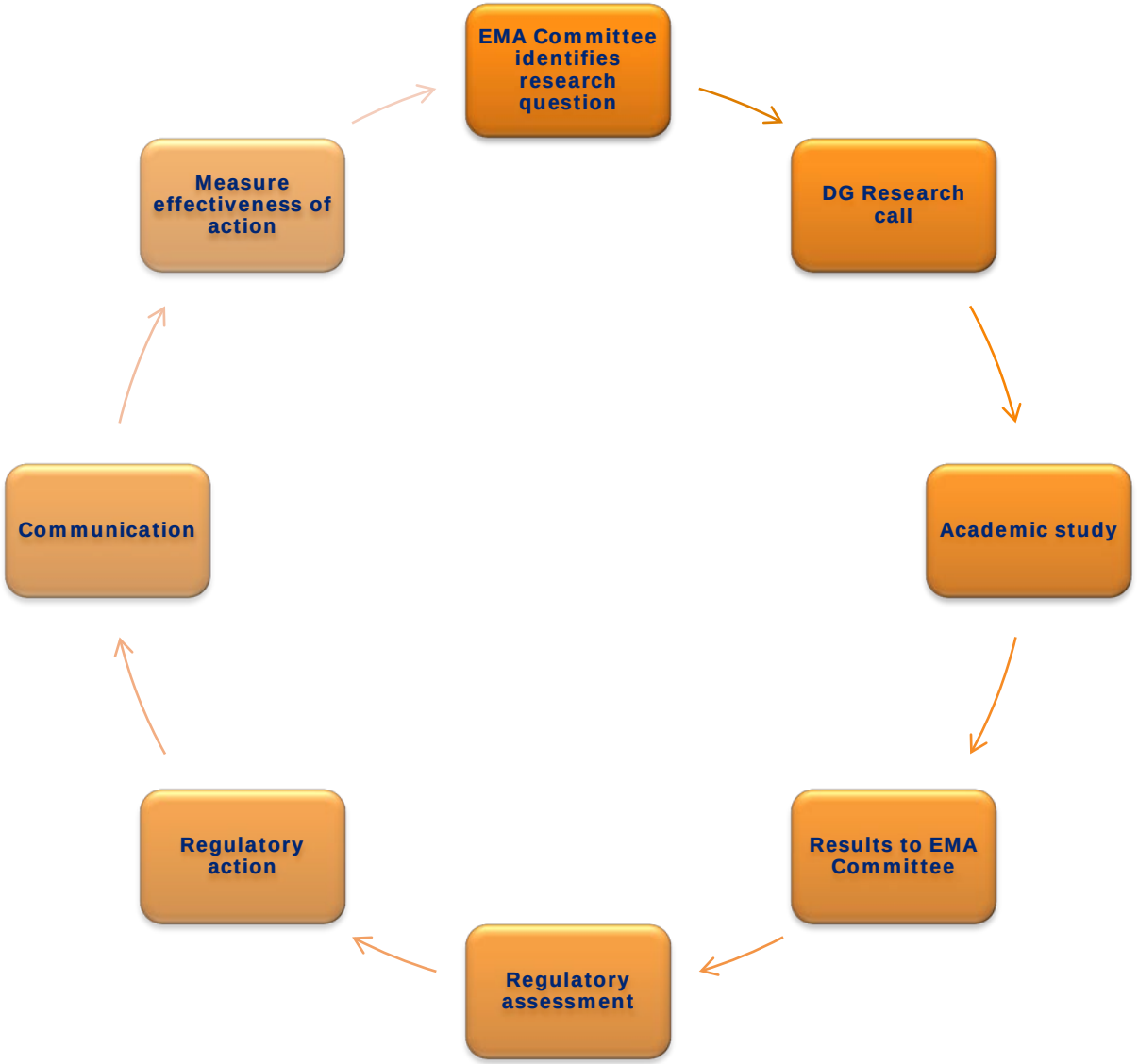
- Run by DG RTD (Research), it is the largest public funder of research in EU http://cordis.europa.eu/fp7/health/
- For the past 6 years EMA has been sending Priority Drug Safety Research topics adopted by our CHMP/PRAC for consideration in the annual list of FP Calls.
- To date, 10 research projects are being/have been funded, totalling a ~26-30 M Euro investment.
- All but one these projects is led by an ENCePP centre#
- FP7 will end 2013 and next Work Programme 2014 Horizon 2020

exception is EpoCAN which is coordinated by a non-EU centre

EC FP7-funded consortia

Name	*Classes of drugs*	*Timelines*
SOS	NSAIDs.	2008-2011
ARITMO	Antipsychotics (ATC N05A); anti-infectives (antibacterials (J01); antimicotics (J02); antivirals (J05); H1-antihistamines.	2010-2012
ADDUCE	Methylphenidate.	2010-2015
EUROmediCAT	New anti-epileptics; insulin analogues; anti-asthmatics; SSRIs.	2011-2015
PHARMACHILD	Immune modulatory drugs	2011-2014
STOP	Risperidone in conduct disorder; fluoxetine in depression; montelukast in bronchial asthma.	2010-2014
CARING	Insulin; insulin analogues.	2011-2015
SAFEGUARD	Non-insulin blood glucose lowering drugs.	2011-2014
Astro-Lab	Long acting ß-agonists (LABAs).	2011-2015
EpoCan	Epoetins.	2011-2014

Regulatory Decision Making e.g. SOS



Challenges

- Sustainability of research infrastructure platforms beyond timeframe of a specific project
- Funding for additional activities arising from new/emerging safety issues

Thank You!