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ENCePP Secretariat

ENCePP Work Plan 2011- 2012

(European Network for Centres of Pharmacoepidemiology and Pharmacovigilance)

Rev.2 adopted by the ENCePP SG on 13 April 2012

This Work Plan defines the objectives and milestones for the years 2011-12 in the context of the operation and future development of the ENCePP network, as well as the means of achieving these objectives in a timely manner. The Work Plan seeks to organise the work of the main active bodies of ENCePP, namely the ENCePP Secretariat, the ENCePP Steering Group and the ENCePP Working Groups against the background of the European Medicines Agency Work Programme for 2011.

1. Background and current status

In 2010 a number of milestones were achieved towards the further development and implementation of the ENCePP network.

Key Milestones

- Establishment of ENCePP Steering Group (SG) in January 2010.
- Launch of ENCePP e-database of research resources (centres and networks) on 31 January 2010 (http://www.encepp.eu/encepp/resourcesDatabase.jsp).
- Following public consultation, adoption of Checklist of Methodological Standards for ENCePP Study Protocols by ENCePP SG (March 2010).
- Launch of e-database of data sources in April 2010 (http://www.encepp.eu/encepp/resourcesDatabase.jsp).
- Launch of Members Forum on ENCePP Website in April 2010 (http://www.encepp.eu/jforum/forums/list.page).
- Following public consultation, adoption of ENCePP Code of Conduct by ENCePP Steering Group (May 2010).

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- Development and launch of ENCePP study concept, including the "ENCePP seal", on 8 June 2010 (development of a communication package consisting of leaflet, press release, publication on EMA public website). (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2010/06/news_detail_001034.jsp&murl=&mid=#)
- Adoption by the SG of 'access to data' policy and implementing rules in relation to ENCePP study data (12 September 2010).
- Release for public consultation of the Guide on Methodological Standards in Pharmacoepidemiology developed by Working Group 1. The public consultation started on 5 November 2010 and will be completed on 3 January 2011.
- Creation of a fully functional database of post-authorisation studies. The ENCePP e-register of studies was launched to the public during the ENCePP Plenary meeting on 18 November 2010 (http://www.encepp.eu/encepp/studiesDatabase.jsp).

Other Achievements

- Finalisation and adoption by SG of ENCePP Work Plan 2010. Publication of Work Plan on ENCePP website.
- Promotion of ENCePP at a number of international conferences and symposia.
- Organisation of the first "ENCePP Information day" in collaboration with DIA on 26 November 2010 targeted at pharmaceutical industry staff.

2. Main goal and objectives

Building on the initial phase of establishment, during 2011 and 2012 the priority will be to consolidate ENCePP as an important and internationally renowned resource in the field of pharmacovigilance and pharmacoepidemiology that delivers for health protection and promotion.

Additionally, during this work plan period, work will be initiated to broaden the scope of the network to further cover health outcome research.

Essential deliverables:

- Review of the Code of Conduct: as agreed by the Steering Group in May 2010 the Code of Conduct will be reviewed.
- Review of the Checklist of Methodological Standards for ENCePP Study Protocols.
- Publication and dissemination of the Guide on Methodological Standards in Pharmacoepidemiology.
- Exploration of the merits of developing an accreditation system and its features.
- Further development of the ENCePP Resources database and of the e-Register of Studies, including: overview of post-authorisation safety studies, interaction with HTA bodies and exploring collaboration with EnprEMA, the paediatric medicines network.
- To liaise with medical journals editors on the aims of ENCePP as regards independency and transparency in research and to increase the visibility of the network to the broader scientific community.

- To develop approaches to facilitate the conduct of multi-national studies in light of existing differences in data privacy laws across the EU, in collaboration with Working Group 3.
- Establish a strategy to be used in an ongoing impact analysis aimed at measuring the impact of ENCePP on current research practices and on regulatory activities.
- To further define the role of ENCePP as regards its interaction with regulatory decision-making and in light of the changes introduced by the new Pharmacovigilance legislation.
- To ensure that the ENCePP Studies database feeds in, as appropriate, to any international discussions on standardisation of data fields.
- To elaborate an ENCePP consensus statement on the definition/interpretation of the definition of non interventional study.
- Ensure visibility of the network through promotional events, including participation in international conferences, symposia

Other deliverables:

- 2 Plenary meetings in 2011 (30 June and 23 November) and plenary meetings in 2012 (to be confirmed),
- 1 workshop with medical journals to be organised at the EMA in 2011 and 1 follow-up meeting in 2012,
- Continue contact with international initiatives with complementary objectives to exchange information and consider complementarity with their respective initiatives

3. Resources and possible constraints

In order to achieve the objectives as described above, the active bodies of ENCePP will need to work together and exchange information and results as appropriate.

The ENCePP Secretariat will continue to ensure the timely flow of information, organising meetings and providing assistance to the Working Groups and the ENCePP Steering Group. Senior Agency staff and SG members will serve as Rapporteurs to the Working Groups and will, together with the respective working group chair and editors, ensure adequate progress. In order to guarantee that the deliverables as indicated in this Work Plan are achieved in due time, the Agency will need to make available sufficient resources.

The three currently active ENCePP Working Groups - consisting of ~ 10 volunteers from centres participating in ENCePP - will work according to their agreed mandates and prioritised activities assisted by the ENCePP Secretariat.

The ENCePP SG will meet on a regular basis (at least quarterly) to oversee the delivery of the outcome of the ENCePP Working Groups and provide advice to the European Medicines Agency.

The Agency has budgeted for a number of meetings including meetings of the Working Groups, Steering Group, and Plenary Meetings of ENCePP.

4. Strategy and action plan

See attached table of deliverables.

DELIVERABLE	EMA LEAD	WORKING GROUP	SG SPONSOR	MILESTONES	INITIAL DEADLINE(S)
Review of the Code of Conduct: as agreed by the Steering Group in May 2010 the Code of Conduct will need to be reviewed 1 year after its adoption or after 15 applications for ENCePP Study Seal, whatever comes first.	S. Prilla	WG2 Chair: H. Dolk	S. Blackburn C. de Vries	Convene a dedicated "task force" to further elaborate on the issue of access to data as regards ENCePP Studies	Q1 2011
				Convene WG2 to discuss need for amendments to the Code of Conduct and start drafting revision	July 2011
				Draft revised version of the Code of Conduct presented to SG for their adoption	Q3 2011
				Presentation to the plenary of the adopted revised version of the Code of Conduct	Q4 2011
Review of the Checklist of Methodological Standards for ENCePP Study Protocols.	X Kurz K. Blake	WG1 Chair: A. Arana	B. Leufkens	Preparation of a discussion paper on experience gained with ENCePP studies (possible breaches, problems encountered, etc)	Q2 2012
				Convene WG1 to discuss need for amendments to the Checklist and start drafting revision	Q2 2011
				Draft revised version of the Checklist presented to SG for their adoption	Q3 2011
				Presentation to the plenary of the adopted revised version of the Checklist	Q4 2011
Publication and dissemination of the Guide on Methodological Standards in Pharmacoepidemiology	X. Kurz K. Blake	WG1 Chair: A. Arana	B. Leufkens N. Moore Y. Moride	Publication on ENCePP Website	Q2 2011
				Agree on principle and method of periodic revision of Guide.	Q4 2011

DELIVERABLE	EMA LEAD	WORKING GROUP	SG SPONSOR	MILESTONES	INITIAL DEADLINE(S)
				Complete 1st revision of Guide	Q2 2012
Exploration of the merits of developing an accreditation system and its methodologies	X. Kurz	WG1	To be appointed	1st discussion at Steering Group.	Q1 2011
				SG to reach final decision.	Q4 2012
Maintenance of the ENCePP Resources database and of the e-Register of Studies. Possible further development including: overview of post-authorisation safety studies, interaction with EUNetHA and collaboration with EnprEMA as regards paediatric medicines	K. Blake L. Prieto J. Slattery I. Eichler	WG2 Chair: H. Dolk WG3 Chair: M. Sturkenboom Consultation of these WGs if required	S. Blackburn	First meeting with EUNetHTA	Q2 2011
				Preparation of separate concept papers on the possible applications of the ENCePP Resources database and the e-Register of Studies to health technology assessment and to paediatric medicines.	Q2 2011
				Explore the possibility of a registry for benefit risk and health outcome monitoring of medicines that will meet the needs of various stakeholders.	Q2 2012
To enhance public health prioritisation through ENCePP.	K.Blake	N/A	H. Fitt	A survey of diabetes research within ENCePP.	Q1 2012
				Consultation with PRAC to further prioritise public health needs.	Q4 2012
To liaise with medical journals editors on the aims of ENCePP as regards independency and transparency in research, to discuss the impact of sharing results with regulators before they are published and to increase the visibility of the network to the broader scientific community.	P. Arlett H. Fitt	N/A	C. de Vries N. Moore	Develop a strategic plan for interaction with journal editors.	Q1 2011
				Organise a workshop meeting with editors at EMA.	Q2 2011
				Organise a follow-up meeting with editors at EMA	Q1 2012

DELIVERABLE	EMA LEAD	WORKING GROUP	SG SPONSOR	MILESTONES	INITIAL DEADLINE(S)
Development of approaches to facilitate the conduct of multi-national studies in light of existing differences in data privacy laws across the EU, in collaboration with Working Group 3.	K. Blake S. Brosch A. Spina	WG 3 Chair: M. Sturkenboom	M. Sturkenboom	Agree on an ENCePP statement in response to the public consultation from the EC on a strategy to strengthen EU data protection rules.	Q1 2011
				Identify issues and current approaches.	Q4 2011
				Publication of best practice guidance for pharmacoepidemiology studies in light of data privacy legislation	Q4 2012
Establish a strategy to be used in ongoing impact analysis aimed at measuring the role of ENCePP on current research practices and on regulatory activities.	K. Blake	N/A	H. Fitt	Formal adoption of the concept paper on the proposed strategy for impact evaluation by the Steering Group	Q2 2011
				Preparation of summary quantitative outcome measures primarily relating to research capacity building	Q4 2011
				Publication of an article on the impact of ENCePP on research practices and regulatory activities	Q3 2012
To further define the role of ENCePP as regards its interaction with regulatory decision-making and in light of the changes introduced by the new Pharmacovigilance legislation.	K. Blake X. Kurz	WG 3 Chair: M. Sturkenboom	P. Arlett J. Raine B. Leufkens M. Sturkenboom Y. Moride	To deliver a paper outlining possible funding options to support pharmacovigilance studies*	Q1 2011
				Discussion paper on interface between medicines regulation and ENCePP*	Q2 2011
				Development of a detailed best practice on the interaction with Regulators to be followed in case researchers have findings of public health relevance (1. Submission of results in relation to time of publication, 2. Scrutiny of the analytical data set).*	Q4 2011
				*These milestones have been absorbed into the development of a 'Strategy for the European Medicines Agency to Support Informed Regulatory Decisions'	Q2 2011

DELIVERABLE	EMA LEAD	WORKING GROUP	SG SPONSOR	MILESTONES	INITIAL DEADLINE(S)
				Publication of best practice guide, i.e. the 'Strategy for the European Medicines Agency to Support Informed Regulatory Decisions'	Q2 2012
ENCePP consensus statement on the definition/interpretation of the definition of non interventional study	F. Sweeney P. Arlett	tbc	N. Moore S. Blackburn	Ad-hoc working group to meet with representatives of CTFG	Q3 2011
				Adoption of an ENCePP consensus statement on the definition/interpretation of the definition of non interventional study	Q1 2012
To ensure that the ENCePP Studies database feeds in as appropriate to any discussions on standardisation of data fields	N. Halsey	N/A	P. Arlett	Report to SG.	Q4 2011
Promotional events, including participation in international conferences, symposia	T. Goedecke	N/A	H. Fitt	Journal articles published on ENCePP. Minimum of 4 conferences/symposia	Ongoing