22 October 2014

ENCePP Working Groups: Report from the Chair[1]

Date of last report: February 2014

Working Group:	**HEALTH TECHNOLOGY ASSESSMENT**
Chairperson:	Marlene Sinclair

1. Key deliverables from current ENCePP Work Plan:

KEY DELIVERABLE	MILESTONES	STATUS
Provide a forum of academics and service providers for consultation as appropriate to support the development of guidance by ENCePP, EMA and EUnetHTA, including on post-authorisation efficacy studies, on post-authorisation safety studies and health technology assessment.	Consolidate the scope of the ENCePP HTA Working Group established Q4 2012.	**Completed**
	Ad hoc comment on specific consultations.	Ongoing
Capacity building on the conduct of studies that bridge to meet the requirements of medicines regulators and health technology assessment bodies.	Detailed survey on the: 1. experience the members of the WG / ENCePP have in conducting research activities for HTA; 2. resources their centres can provide; 3. specific training needs for HTA	**Completed**
	Explore how the ENCePP Resources Database can be adapted to reflect the resources available for HTA.	Initial deadline: Q2 2014 – postponed for consideration in the context of the ENCePP 2015 – 2016 Work-Plan

[1] This report is to be completed twice a year in advance of each biannual ENCePP SG face-to-face meeting, and presented to the SG by the relevant working group Chair. Following endorsement of the report, it shall be published on the ENCePP website.

KEY DELIVERABLE	MILESTONES	STATUS
Lead on the development of a considerations paper on practice in conducting post authorisation studies (PAS) that might meet the needs of regulators and HTA with a view to development of good practice guidance.	Draft concept paper.	Initial deadline: Q2 2014 – postponed for consideration in the context of the ENCePP 2015 – 2016 Work-Plan

2. Summary of activities:

- **Number of meetings & dates:** 24/03/2014 (f2f); 22/09/2014 (TC)
- **Progress Update:**
    - The survey results were analysed at the WG's meeting on 22nd September 2014. A survey of the 139 centres in ENCePP was launched on 17 June 2014 to identify indicators of experience in conducting research with HTA outcomes. Responses were received from 35 of the 139 centres that then formed the network. The apparently low response rate needs to be seen in the context of the network being focussed on pharmacovigilance and pharmacoepidemiology. The results, however have confirmed that a proportion of centres within ENCePP are conducting research with HTA outcomes. The centres who responded are likely to be those with interest and experience. While this picture may not be representative of all ENCePP centres (primarily focusing on safety), the results are an index of current European capacity and will be helpful in defining approaches to building capacity, including through training. The detail of the responses may serve to assess how the ENCePP Research Resources Database might be used to reflect the competencies in HTA outcomes of individual centres. The results also indicate that there is a level of experience that can form the basis for the development by the WG of a considerations paper on practice in conducting studies that include HTA and drug safety outcomes with a view to either developing stand-alone good practice guidance or integrating into existing guidance.
    - Abstracts (poster) were accepted for ICPE 2014 and ISPOR 2014 titled 'ENCePP-HTA Working Group 2014 survey of capacity to conduct research to support HTA'.

3. Next steps / Milestones:

- To be determined in the context of the ENCePP 2015 – 2016 Work Plan taking account of the results of the survey having shown that an important proportion of ENCePP centres have experience in conducting studies with endpoints relevant to HTA, and given the increasing interest in individual studies responding to both regulatory and HTA questions, ENCePP may be a useful platform to develop European capacity to deliver such studies.