

19 February 2014

ENCePP Working Groups: Report from the Chair¹

Inaugural report to the new ENCePP Steering Group – 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	Ongoing
	Explore how the ENCePP Resources Database can be adapted to reflect the resources available for HTA.	Initial deadline: Q2 2014
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: Q4 2014

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.

2. Summary of activities:

- **Number of meetings & dates:** N/A

- **Progress Update:**

As detailed in table above.

3. Next steps / Milestones:

In a teleconference on 21 January 2014 the group agreed the way forward in terms of progressing the survey. The following steps were agreed:

- i. First draft to be circulated within a 2 week timeframe taking account of what we have following the face-to-face (f2f) meeting last November. This was circulated on 06 February 2014.
- ii. Second step will be for comments for the group on this and volunteers to lead on different domains of the survey
- iii. These comments would be compiled into a more mature draft which would again be re-circulated for comments in writing.
- iv. This draft based on 2 rounds of comments in writing would form the basis for discussion at the full-day f2f meeting of the group which is scheduled for 24 March 2014 at the EMA. The goals of the f2f meeting will be to finalise a draft survey and to agree next steps including in terms of piloting the survey, the target audience, possibility of focus groups, and how results will be analysed.