

Action Plan for Implementation of the Strategy for Regulatory and Scientific Training within the European Regulatory Network

No	Action	Owner	Date	Status
	Work programme for the EU Office of Training			
1.	Maintain and publish updated Action Plan on HMA website	Steering Group	Ongoing	Up-to-date
2	Create the Virtual Office of Training	HMA		Complete
3	Prepare Pilot in the area of Quality of Medicines	Office		Complete
3.1	Identify and recruit panel of experts in the field of quality	Office	July-Dec 10	Complete
3.2	Act as secretariat to the panel(s) of experts in defining and documenting the competence and knowledge requirements for quality assessors	Office Experts	Jan-June 11	
3.4	Define quality criteria for supply of training in the area of quality to the regulatory network	Office		Office has decided not to perform a gap analysis but to publish the curriculum on the HMA website. It will then be up to NCAs and/or commercial providers to supply training to meet the needs identified.
3.5	Prepare a detailed inventory /electronic database / of training available to the network from EMA, NCAs and external suppliers /universities, not-for-profit organisations, learned societies and possibly at a later stage – for-profit organisations/. Make this inventory known and available through both HMA's and EMA's websites and keep its information updated.	Office NCAs EMA External providers	Dec 10 – Mar 11	
3.7	Work with external providers to fill gaps identified, particularly in terms of e-training aimed at regulatory training for new staff of agencies	Office External providers	From initiation	Assessment of quality and work to develop e-training or blended training materials will now await

3.8	Work with NCAs and external providers to provide blended learning solutions in the area of quality	Office NCAs EMA External providers	From initiation	expressions of interest from partner organisations with the resources to develop such tools.
4	Prepare annual report of operation of the office	Office	Currently each June HMA	1st report presented June 2011 2 nd report scheduled June 2012
5	Agree with HMA 3 priority topics for OTSG to seek topic leaders with which to work to develop competence frameworks As part of this process need to clarify status of OTSG with respect to training in new pharmacovigilance legislation	Office / Topic leaders	2012 - 2013	Awaiting confirmation from HMA
6	Maintain list of contact points in National Competent Authorities for training	Office in cooperation with HMA PS	Ongoing	
7	Establish and maintain a list/database of training carried out by NCAs/EMA	Office/NCA training contact points	Q3 2012	
8	Explore options for creation of dedicated OTSG training 'portals' on the EMA and/or HMA websites	EMA/Office	Q4 2012	Dependent on technical, financial and human resources made available
9	Explore cooperation with international partners establishing similar competence frameworks/training programmes to share resources and experience	Office	Q2 2013	Initial contact made with Health Canada
10	Establish cooperation with IMI to ensure that training of regulators is included as part of the 'Training Pillar'	Office	From initiation	Initial contacts made

14 May 2012