

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. | Prepare preliminary work programme for adoption by HMA/EMA including timetable and format for reporting activities and progress with the office to HMA and EMA | Steering Group | April 10 | Completed |
| 2 | Create the Virtual Office of Training | HMA | | |
| 2.1 | Assess responses of resources from HMA | Steering Group | April 10 | HMA agreed to proceed with pilot group so Office not created |
| 2.2 | First meeting of Office Project Team | Office | May 10 | N/A |
| 3 | Prepare Pilot in the area of Quality of Medicines | Office | | |
| 3.1 | Identify and recruit panel of experts in the field of quality | Office | July-Dec 10 | Completed |
| 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 | Completed |
| 3.3 | Act as secretariat to the panel(s) of experts in defining and documenting the training curricula required to meet the needs of quality assessors | Office Experts | | Planned |
| 3.4 | Define quality criteria for supply of training in the area of quality to the regulatory network | Office | | Planned |
| 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 | Completed |
| 3.6 | Conduct a gap analysis to identify un-met needs in terms of training for assessors and regulatory staff | Office | Mar 11 | Completed |
| 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 | |

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| 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 | |
| 4 | Explore with the European Commission the role of the Office in terms of training of experts for participation in ICH and VICH | Office EU Commission | From initiation | On Hold |
| 5 | Prepare report for review by HMA/EMA of the first annual report of the first year of operation of the office | HMA EMA | 1 year after start | Completed |
| 6 | Close cooperation with IMI to ensure that training of regulators is included as part of the 'Training Pillar' | Office | From initiation | Ongoing |

06/04/2011