Table I List of meetings for Human Medicinal Products for Human use

GCP (Good Clinical Practice) Inspectors Working Group The GCP Inspectors Working Group provides expert advice and support, on GCP inspection and GCP interpretation, to the EMEA, its scientific committees, the European Commission, its own membership and other parties as required. It draws its membership from the GCP inspectorates of the EU/EEA states and observers from the EU accession countries and Switzerland.	24-25 Feb, 09-10 Jun, 08-09 Sep, 01-02 Dec 2010 01-03 Mar, 14-15 Jun, 13-15 Sep, 28-30 Nov, 05-07 Dec 2011
EU Good Clinical Practice Inspectors Working Group training course This is an annual, 3-day training course for EU GCP inspectors, organised by the CGP IWG in conjunction with one of the Member States GCP inspectorates. It takes place in a different Member State each year.	
Ad Hoc PhV (Pharmacovigilance) Inspectors Working Group The PhV IWG provides input and recommendations on all matters relating directly or indirectly to the preparation, conduct and follow up of PhV inspections in the context of post-authorisation processes and irrespective of the marketing authorisation procedure. Its main goals are to promote an effective management of PhV inspections in the Community, to establish proficient communication and information exchange and to provide input into PhV legislation preparation. The group meets 4 times/year, twice as Human Ad Hoc PhV IWG and twice as Joint Human and Veterinary Ad Hoc PhV IWG.	23 Feb 08 Jun 07 Sep 30 Nov 2010 24-25 Mar 16-17 Jun 29-30 Sep 01-02 Dec 08-09 Dec 2011
EU Pharmacovigilance Inspectors Working Group training course This training will take place in 2009 for EU PhV inspectors, organised by the PhV IWG in conjunctions with one of the Member States PhV inspectorate.	
GMP/GDP (Good Manufacturing Practice/Good Distribution Practice) Inspectors Working Group The GMP/GDP Inspectors Working Group consists of representatives of the GMP inspectorates of the EEA states, observers from EDQM, the inspectorates of the countries accessing to the EU and MRA partner countries. The meetings consider new and revised guidance on GMP, normally developed by drafting groups, work related to Mutual Recognition Agreements, how new legislation impacts GMP inspection activity and harmonization of GMP inspections. It is also where community-wide procedures relating to GMP inspections, known as the Compilation of Procedures are developed.	
QWP (Quality Working Party) The Joint CHMP/CVMP Quality Working Party (QWP) provides recommendations to the Committees on matters relating directly or indirectly to the quality of human or veterinary medicinal products. On request of the Committees, the QWP is involved in such areas as the preparation, review and update of quality guidelines, the provision of scientific advice on general and product-specific matters relating to quality, the resolution of national divergences regarding the assessment of quality issues, liaison with interested parties, international cooperation on quality-related matters, etc. All recommendations drawn up by the QWP are transmitted to the relevant Committee for adoption.	02-04 Feb, 01-03 Jun 07-09 Sep, 22-24 Nov 2010 (Joint QWP/GMDP IWG meting 24 November) 01-03 Feb, 30May-01 Jun, 05-07 Sep, 29 Sep-01 Oct 2011

HMPC (Committee on Herbal Medicinal Products) The HMPC's activities aim at assisting the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework.	13-14 Jan, 10-11 Mar, 05-06 May, 14-15 Jul,15-16 Sep, 24-25 Nov 2010 26-27 Jan, 30-31 Mar, 25-26 May, 13-14 Jul, 14-15 Sep, 23-24 Nov 2011
HMPC Assessors Workshop/Training	
NRG (Name Review Group) As part of the EMEA's role in evaluating the safety of medicinal products in the centralised marketing authorisation procedure, it is obliged to consider whether the invented name proposed for a medicinal product by its manufacturer could create a public-health concern or potential safety risk. The NRG performs reviews of invented names and updates the relevant guideline on the acceptability of invented names. *The representatives will not take part to the actual plenary, but can participate in the Interested Parties Workshop.*	
EMEA/CHMP Working Group with Healthcare Professionals The EMEA CHMP Working Group with Healthcare Professionals' Organisations' (HCP WG) is to set up a framework of interaction between EMEA, its Human Scientific Committees and HCPs, and prepare recommendations and proposals for actions in information on medicines addressed to HCPs, pharmacovigilance, involvement of HCPs in EMEA Scientific Committees related activities. (In addition, the HCP WG will contribute to contacts and exchange of information between the EMEA, the CHMP and Healthcare Professionals)	25 Feb 2010 28 Oct 2010
Joint meeting between the EMEA/Scientific Committees' WP with Patients' and Consumers' Org. (PCWP) and the EMEA/CHMP Working Group with Healthcare Professionals The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (more commonly known as the Patients' and Consumers' Working Party, or PCWP) has been established to provide recommendations to the EMEA and its human scientific committees on all matters of interest to patients in relation to medicinal products. The EMEA CHMP Working Group with Healthcare Professionals' Organisations' (HCP WG) is to set up a framework of interaction between EMEA, its Human Scientific Committees and HCPs, and prepare recommendations and proposals for actions in information on medicines addressed to HCPs, Pharmacovigilance, involvement of HCPs in EMEA Scientific Committees related activities. (In addition, the HCP WG will contribute to contacts and exchange of information between the EMEA, the CHMP and Healthcare Professionals)	16 Jun 2010
QRD (Quality Review of Documents) activities Templates, terminology, standard terms, review of product information and the general role of the QRD group. *The representatives will not take part to the actual plenary, these are special trainings organized for them.*	
EudraGMP database sub-working group	

In order to assist from a technical perspective, the EudraGMP TIG delegates some of its work to a subgroup (EudraGMP database sub-working group) composed of IT specialists from Member States with systems in place and of GMP inspectors. In particular the sub-working group is in charge of the definition of the technical requirements for the EudraGMP project	
EV TIG EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).	
EUTCT	09 Feb, 04 May, 27 Jul, 09 Nov 2010
RDM The aim of the RDM project is to develop a common understanding of information (semantic interoperability) within existing information systems, and allow the information exchange (syntactic interoperability) within the European Medicines Regulatory Network (EMRN) framework.	
ENCePP Academic Centres Annual Meetings This includes both the ENCePP General Assembly and scientific meetings. The General Assembly intends to inform all ENCePP partners about the current status and the recent developments of ENCePP and to discuss the next steps and key aspects of the network. The scientific meetings shall help to promote pan-EU partnerships and professional exchange of opinions and experience in order to strengthen EU excellence in the field of PhV and PEpi	
EudraPharm TIG EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA).	
EudraCT TIG / JOG and Paediatric subgroup	
EudraNet TIG EudraNet II is a managed virtual private IP network (IP VPN) based on encrypted tunnels over the public Internet. It is a star shaped network with the EMEA being the central site.	
TIGs The main objective of this IT strategy is the reinforcement of appropriate exchange of information between stakeholders (general public, industry, Member States, European Commission and EMEA) to support pharmaceutical regulatory activities for both human and veterinary medicines.	

Table II List of meetings for Veterinary Medicinal Products

Immunologicals Working Party (NK) The Immunologicals Working Party (IWP) is established to provide recommendations to the Committee of Medicinal Products for Veterinary Use (CVMP) on all matters relating directly or indirectly to immunological veterinary medicinal products (IVMPs) and to perform the following tasks: ➢ Preparation, review and update of guidelines ➢ Support to dossier evaluation ➢ At the request of the CVMP, provision of scientific advice on general and product specific matters related to IVMPs ➢ Liaison with interested parties (IFAH Europe, European Directorate for the Quality of Medicines) See VI. Rules of procedure point ➢ International cooperation on IVMP related matters ➢ Setting up of drafting groups (see VI. Rules of Procedure, point 4) ➢ Liaison with other Working parties on IVMP related matters ➢ Advice, through the CVMP, to European Commission on IVMP related issues ➢ On request, advice, through the CVMP, to CMD(v) on IVMP related matters ➢ Focus and catalyst for training for IVMP assessment ➢ Contribution to IVMP related workshops and training Liaison with the European Directorate for the Quality of Medicines to ensure consistency of approach in the development of European requirements for authorised IVMPs.	02-03 Feb, 09-10 Jun 05-06 Oct 2010 , 02-03 Feb, 31 May-1Jun , 05-06 Oct 2011
Ad Hoc PhV (Pharmacovigilance) Inspectors Working Group The PhV IWG provides input and recommendations on all matters relating directly or indirectly to the preparation, conduct and follow up of PhV inspections in the context of post-authorisation processes and irrespective of the marketing authorisation procedure. Its main goals are to promote an effective management of PhV inspections in the Community, to establish proficient communication and information exchange and to provide input into PhV legislation preparation. The group meets 4 times/year, twice as Human Ad Hoc PhV IWG and twice as Joint Human and Veterinary Ad Hoc PhV IWG.	23 Feb, 08 Jun, 07 Sep, 30 Nov 2010 24-25 Mar, 16-17 Jun, 29-30 Sep, 01-02 Dec, 08-09 Dec 2011 (not all meetings will be joint with Vet)
EU Pharmacovigilance Inspectors Working Group training course This training will take place in 2009 for EU PhV inspectors, organised by the PhV IWG in conjunctions with one of the Member States PhV inspectorate.	
Efficacy Working Party (BC) The Efficacy Working Party (EWP) provides recommendations on matters relating to efficacy and target animal safety of veterinary medicinal pharmaceutical products. Observers from Turkey and Croatia could provide useful input in relation to different geographical regions with possible different disease patterns / target animal species / animal husbandry systems in place. Possible problems further to those mentioned in the introduction would be the discussion of the EWP's internal data-collection, which is based on product related discussion. There is currently not much / no direct other product related discussion in EWP. If so, this could be scheduled e.g. for the first hour of the meeting only.	02-03 Mar, 06-07 Jul, 05-06 Oct, 14-15 Dec 2010 01-02 Mar, 21-22 Jun, 20-21 Sep, 13-14 Dec 2011
QWP (Quality Working Party)	

The Joint CHMP/CVMP Quality Working Party (QWP) provides recommendations to the Committees on matters relating directly or indirectly to the quality of human or veterinary medicinal products. On request of the Committees, the QWP is involved in such areas as the preparation, review and update of quality guidelines, the provision of scientific advice on general and product-specific matters relating to quality, the resolution of national divergences regarding the assessment of quality issues, liaison with interested parties, international cooperation on quality-related matters, etc. All recommendations drawn up by the QWP are transmitted to the relevant Committee for adoption.	02-04 Feb, 01-03 Jun, 07-09 Sep, 22-24 Nov 2010 (Joint QWP/GMDP IWG meting 24 November) 01-03 Feb, 30May-01 Jun, 05-07 Sep, 29 Sep-01 Oct 2011
Safety Working Party (NJ) The CVMP Safety Working Party (SWP-V) provides scientific expertise to the CVMP on all issues regarding the safety of veterinary medicinal products in the context of consumer and operator safety (excluding environmental-risk assessment and target-animal safety). This includes providing expertise on the establishment of maximum residue limits (MRLs) and on the preparation of guidelines relating to safety of veterinary medicinal products and to user safety.	
GMP/GDP (Good Manufacturing Practice/Good Distribution Practice) Inspectors Working Group The GMP/GDP Inspectors Working Group consists of representatives of the GMP inspectorates of the EEA states, observers from EDQM, the inspectorates of the countries accessing to the EU and MRA partner countries. The meetings consider new and revised guidance on GMP, normally developed by drafting groups, work related to Mutual Recognition Agreements, how new legislation impacts GMP inspection activity and harmonization of GMP inspections. It is also where community-wide procedures relating to GMP inspections, known as the Compilation of Procedures are developed.	
EudraGMP database sub-working group In order to assist from a technical perspective, the EudraGMP TIG delegates some of its work to a subgroup (EudraGMP database sub-working group) composed of IT specialists from Member States with systems in place and of GMP inspectors. In particular the sub-working group is in charge of the definition of the technical requirements for the EudraGMP project	
EV TIG EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).	
EUTCT	09 Feb, 04 May, 27 Jul, 09 Nov 2010
RDM The aim of the RDM project is to develop a common understanding of information (semantic interoperability) within existing information systems, and allow the information exchange (syntactic interoperability) within the European Medicines Regulatory Network (EMRN) framework.	
EudraPharm TIG	

EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA).	
EudraNet TIG EudraNet II is a managed virtual private IP network (IP VPN) based on encrypted tunnels over the public Internet. It is a star shaped network with the EMEA being the central site.	
TIGs The main objective of this IT strategy is the reinforcement of appropriate exchange of information between stakeholders (general public, industry, Member States, European Commission and EMEA) to support pharmaceutical regulatory activities for both human and veterinary medicines.	

Table III List of Trainings and Workshops

Event's Name	Location
3rd EMEA Workshop for SME's "Focus on Non-clinical Aspects" This workshop will include an overview of non-clinical data requirements, highlighting key success factors and practical advice from an EU assessors' perspective.	EMEA
First Workshop on Advanced Therapy Medicinal products (ATMP)	EMEA
DIA - Excellence in Pharmacovigilance: Clinical Trials and Post Marketing	Abroad
DIA - EudraVigilance Member States Training	EMEA
DIA - EVMPD (EudraVigilance Medicinal Products Dictionary)	EMEA
GCP Inspectors' Training Course	Abroad
PhV Inspectors' Training Course	Abroad