Updated 1.3.2021

REPRESENTATION IN INTERNATIONAL ORGANISATIONS

The Finnish Medicines Agency is represented in the following organisations in the field of medical devices, medicinal, blood and tissue products and safety.

1. EUROPEAN UNION (EU)

EUROPEAN COMMISSION

Pharmaceutical Committee

Risto Salmi, Consulting Legal Advisor, Internal Services

Veterinary Pharmaceutical Committee

Irmeli Happonen, Head of Unit, Assessment of Medicinal Products Department

Standing Committee on Medicinal Products for human use

Risto Salmi, Consulting Legal Advisor, Internal Services

Standing Committee on Veterinary Medicinal Products

Risto Salmi, Consulting Legal Advisor, Internal Services

Drug Precursors Committee

Katja Pihlainen, Senior Inspector, Supervision and Licences Department

Working Party on Notice to Applicants

Leena Pietilä, Head of Unit, Assessment of Medicinal Products Department
Paula Kajaste, Coordinator for Marketing Authorisations, Assessment of Medicinal Products Department

Ad hoc Expert Group on Good Clinical Practice and Clinical Trials

Pirjo Inki, Head of Section, Assessment of Medicinal Products Department

Working Group on Good Laboratory Practice

Mirka Laavola, Senior Inspector, Supervision and Licences Department

Competent Authorities for Blood and Blood Components

Anu Puomila, Senior Inspector, Supervision and Licences Department

Competent Authorities for Tissues and Cells

Anne Vaskunlahti, Head of Section, Supervision and Licences Department
Sari Tähtiharju, Senior Inspector, Supervision and Licences Department

Competent Authorities for Organ Donation and Transplantation

Anne Vaskunlahti, Head of Section, Supervision and Licences Department

Regulatory Committee on the Quality and Safety of Blood (C19800)

Anu Puomila, Senior Inspector, Supervision and Licences Department

EUnet Health Technology Assessment Network

Tuomas Oravilahti, Pharmacoeconomist, Assessment of Pharmacotherapies Department

Expert Group on New Phychoactive Substances

Katja Pihlainen, Senior Inspector, Supervision and Licences Department

Committee on Medical Devices (Comitology Committee)

Heikki Mattlar, Head of Unit, Supervision and Licences Department
Jukka Räisänen, Legal Advisor, Internal Services

Medical Device Coordination Group (MDCG)

Heikki Mattlar, Head of Unit, Supervision and Licences Department (medical devices, in vitro diagnostic)
Jari Knuuttila, Senior Inspector, Supervision and Licences Department (alternate member, medical devices)
Nelli Karhu, Senior Inspector, Supervision and Licences Department (alternate member, in vitro diagnostic)

Notified Bodies Oversight (NBO)

Jari Knuuttila, Senior Inspector, Supervision and Licences Department
Nelli Karhu, Senior Inspector, Supervision and Licences Department (alternate member)

Working Group on Standards

Jari Knuuttila, Senior Inspector, Supervision and Licences Department
Tuomo Aarnikka, Inspector, Supervision and Licences Department (alternate member)

Working Group on Borderline & Classification

Merja Hiltunen, Senior Medical Officer, Supervision and Licences Department
Jari Knuuttila, Senior Inspector, Supervision and Licences Department (alternate member)

Working Group on Clinical Investigations and Evaluation (CIE)

Minna Kymäläinen, Inspector, Supervision and Licences Department
Merja Hiltunen, Senior Medical Officer, Supervision and Licences Department (alternate member)

Working Group on Post-market Surveillance and Vigilance (PMSV)

Tarja Vainiola, Senior Inspector, Supervision and Licences Department
Elli Ekholm, Senior Technical Officer, Supervision and Licences Department (alternate member)

Working Group on Market Surveillance

Tuomo Aarnikka, Inspector, Supervision and Licences Department
Elli Ekholm, Senior Technical Officer, Supervision and Licences Department (alternate member)

Working Group on New Technologies

Jari Knuuttila, Senior Inspector, Supervision and Licences Department
Elli Ekholm, Senior Technical Officer, Supervision and Licences Department (alternate member)
Nelli Karhu, Senior Inspector, Supervision and Licences Department (alternate member)

Working Group on EUDAMED

Päivi Nihtinen, Planning Officer, Supervision and Licences Department
Jari Knuuttila, Senior Inspector, Supervision and Licences Department (alternate member)

Working Group on Unique Device Identification (UDI) and Device Traceability

Päivi Nihtinen, Planning Officer, Supervision and Licences Department
Tarja Vainiola, Senior Inspector, Supervision and Licences Department (alternate member)
Jari Knuuttila, Senior Inspector, Supervision and Licences Department (alternate member)

Working Group on International Matters

Heikki Mattlar, Head of Unit, Supervision and Licences Department
Merja Hiltunen, Senior Medical Officer, Supervision and Licences Department (alternate member)

Working Group on In-Vitro Diagnostic Medical Devices (IVD)

Nelli Karhu, Senior Inspector, Supervision and Licences Department
Merja Hiltunen, Senior Medical Officer, Supervision and Licences Department (alternate member)

THE EUROPEAN MEDICINES AGENCY (EMA)

Management Board

Eija Pelkonen, Director General
Johanna Nystedt, Director (alternate member)

EU Telematics Management Board

Jaakko Hartikka, ICT-Manager, Information Resources

Telematics Enterprise Architecture Board (TEAB)

Mika Kuivamäki, IT Development Manager, Information Resources

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

Katariina Kivilahti-Mäntylä, Veterinary Officer, Assessment of Medicinal Products Department

Committee for Medicinal Products for Human Use (CHMP)

Outi Mäki-Ikola, Coordinating Senior Medical Officer, Assessment of Medicinal Products Department
Johanna Lähteenvuo, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)

Committee for Medicinal Products for Veterinary Use (CVMP)

Minna Leppänen, Veterinary Officer, Assessment of Medicinal Products Department
Tita-Maria Muhonen, Veterinary Officer, Assessment of Medicinal Products Department Department (alternate member)

Committee for Orphan Medicinal Products (COMP)

Karri Penttilä, Senior Medical Officer, Assessment of Medicinal Products Department

Paediatric Committee (PDCO)

Pauliina Lehtolainen-Dalkilic, Senior Researcher, Assessment of Medicinal Products Department
Anne Paavola, Senior Researcher, Assessment of Medicinal Products Department (alternate member)

Committee for Herbal Medicinal Products (HMPC)

Maria Paile-Hyvärinen, Senior Medical Officer, Assessment of Medicinal Products Department
Sari Koski, Senior Researcher, Assessment of Medicinal Products Department (alternate member)

Committee for Advanced Therapies (CAT)

Heli Suila, Senior Researcher, Assessment of Medicinal Products Department
Olli Tenhunen, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)

Pharmacovigilance Risk Assessment Committee (PRAC)

Kirsti Villikka, Senior Medical Officer, Assessment of Medicinal Products Department
Kimmo Jaakkola, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)

EMA WORKING PARTIES, SCIENTIFIC ADVICE GROUPS AND AD HOC GROUPS

CHMP Working Parties and other Groups

Biologics Working Party (BWP)

Jaana Vesterinen, Head of Section, Supervision and Licences Department
Niklas Ekman, Head of Section, Assessment of Medicinal Products Department (alternate member)

Biosimilar Medicinal Products Working Party

Niklas Ekman, Head of Section, Assessment of Medicinal Products Department (Vice Chair)

Biostatistics Working Party

Tiina Asikanius, Biostatistician, Assessment of Medicinal Products Department (observer)

Blood Products Working Party (BPWP)

Karri Penttilä, Senior Medical Officer, Assessment of Medicinal Products Department (Vice Chair)

Cardiovascular Working Party

t.b.n.

Central Nervous System Working Party (CNSWP)

t.b.n.

Joint CHMP/CVMP Quality Working Party (QWP)

Karin Krogars, Senior Researcher, Assessment of Medicinal Products Department

Oncology Working Party

Olli Tenhunen, Senior Medical Officer, Assessment of Medicinal Products Department

Pharmacogenomics Working Party (PgWP)

Juha Kolehmainen, Senior Medical Officer, Assessment of Medicinal Products Department

Pharmacokinetics Working Party

Saila Antila, Senior Researcher, Assessment of Medicinal Products Department, (standing observer)

Rheumatology Immunology Working Party

t.b.n.

Safety Working Party (SWP)

Markku Pasanen
Tiina Palomäki, Senior Researcher, Assessment of Medicinal Products Department (alternate member)

Scientific Advice Working Party (SAWP)

Markku Pasanen
Olli Tenhunen, Senior Medical Officer, Assessment of Medicinal Products Department
Juha Kolehmainen, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)
Johanna Lähteenvuo, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)
Karri Penttilä, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)

Working Group on Quality Review of Documents (QRD)

Nina Ruso, Research Coordinator, Assessment of Medicinal Products Department
Paula Kajaste, Coordinator for Marketing Authorisations, Assessment of Medicinal Products Department

Modelling and Simulation Working Group

Pyry Välitalo, Senior Researcher, Assessment of Medicinal Products Department
Juha Vakkilainen, Senior Medical Officer, Assessment of Medicinal Products Department (standing observer)

EU Clinical Trials Information System Group

Eija Mikkonen, Clinical Trials Coordinator, Assessment of Medicinal Products Department

CAT Working Parties and other Groups

EMA/CAT-and Medical Devices Notifies Body (EMA/CAT-NB) Collaboration Group

Heli Suila, Senior Researcher, Assessment of Medicinal Products Department

CVMP Working Parties and other Groups

Joint CHMP/CVMP Quality Working Party (QWP)

Karin Krogars, Senior Researcher, Assessment of Medicinal Products Department

Pharmacovigilance Working Party (PhVWP)

Jonna Kumpulainen, Veterinary Officer, Assessment of Medicinal Products Department

Groups of GMP, GCP, GVP and GLP Inspectors

GMP/GDP Inspectors Working Group

Mervi Saukkosaari, Head of Section, Senior Pharmaceutical Inspector, Supervision and Licences Department
Mirka Laavola, Senior Inspector, Supervision and Licences Department (alternate member)
Anne Junttonen, Head of Unit, Supervision and Licences Department (alternate member)

GCP Inspectors Working Group

Sarianne Päivike, Senior Inspector, Supervision and Licences Department
Tiina Holmberg, Senior Inspector, Supervision and Licences Department (alternate member)
Pirjo Hänninen, Senior Inspector, Supervision and Licences Department (alternate member)

GVP Inspectors Working Group

Sarianne Päivike, Senior Inspector, Supervision and Licences Department
Sami Paaskoski, Senior Pharmaceutical Inspector, Supervision and Licences Department (alternate member)

Ad hoc group of GLP inspectors

Mirka Laavola, Senior Inspector, Supervision and Licences Department

Working Groups

IT Directors Group

Jaakko Hartikka, ICT Manager, Information Resources
Mika Kuivamäki, ICT Development Manager, Information Resources (alternate)

EMA Common Repository

Jyrki Makkonen, System Specialist, Information Resources

HEADS OF MEDICINES AGENCIES (HMA)

Heads of Medicines Agencies HMA, human and veterinary medicines

Eija Pelkonen, Director General

HMA COMMITTEES AND WORKING GROUPS

Clinical Trials Facilitation and Coordination Group (CTFG)

Marita Kailajärvi, Senior Medical Officer, Assessment of Medicinal Products Department

HMA/EMA Task Force on Availability of Authorised Medicines

Johanna Linnolahti, Head of Section, Supervision and Licences Department

Working Group of Quality Managers (WGQM)

t.b.n.

Benchmarking of European Medicines Agencies

Jaana Pohjonen, Senior Planning Officer, Information Resources

EMACOLEX

Risto Salmi, Consulting Legal Advisor, Internal Services

Common European Submission Platform Development Group (CESP)

Jyrki Makkonen, System Specialist, Information Resources

HMA Working Group of Communication Professionals (HMA WGCP)

Minna Takaloeskola, Communications Director, Communications
Katja Lindgren-Äimänen, Communications Manager, Communications (alternate member)

HMA Working Group of Enforcement Officers (HMA WGEO)

Sami Paaskoski, Senior Pharmaceutical Inspector, Supervision and Licences Department

Homeopathic Medicinal Products Working Group (HMPWG)

Sari Koski, Senior Researcher, Assessment of Medicinal Products Department
Tea Linhola, Coordinator for Marketing Authorisations (alternate member)

Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)

Päivi Jutila, Coordinator for Marketing Authorisations, Assessment of Medicinal Products Department
Pauliina Ikäheimo, Senior Medical Officer, Assessment of Medicinal Products Department (alternate member)

Variation Regulation Working Party (CMDh)

Pauliina Ikäheimo, Senior Medical Officer, Assessment of Medicinal Products Department

GCP Inspectors Working Group/CMDh Working Party

Sarianne Päivike, Senior Inspector, Supervision and Licences Department

Non-prescription Working Party (CMDh)

Vesa Mustalammi, Senior Medical Officer, Assessment of Medicinal Products Department

Co-ordination Group for Mutual Recognition and Decentralised Procedure -Veterinary, (CMDv)

Paula Kajaste, Coordinator for Marketing Authorisations, Assessment of Medicinal Products Department (Vice Chair)

2. COUNCIL OF EUROPE

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH)

Anna von Bonsdorff-Nikander, Senior Pharmaceutical Inspector, Supervision and Licences Department

European Pharmacopoeia Commission

Piia Salo, Head of Section, Assessment of Medicinal Products Department
Marjo-Riitta Helle, Head of Unit, Assessment of Medicinal Products Department
Anniina Ritvanen, Research Coordinator, Assessment of Medicinal Products Department (alternate member)

BWP representative in the EDQM Biological Standardisation Programme (BSP) steering committee

Jaana Vesterinen, Head of Section, Supervision and Licences Department

Expert Group No 10B (Organic chemistry - Synthetic products)

Ari Lehtola, Senior Researcher, Supervision and Licences Department

Working group CTP (Cell Therapy Products)

Hanna Kankkonen, Senior Researcher, Assessment of Medicinal Products Department

Working group GTP (Gene Therapy Products)

Mari Martikainen, Senior Researcher, Assessment of Medicinal Products Department

Working group MG (General Methods)

t.b.n.

Working Group RCG (Raw Materials for the Production of Cellular and Gene Transfer Products)

Jaana Vesterinen, Head of Section, Supervision and Licences Department (Chair)

Working Party MAB (Monoclonial antibodies)

Jaana Vesterinen, Head of Section, Supervision and Licences Department (Chair)

Secretary to the National Pharmacopoeia Authority

Piia Salo, Head of Section, Assessment of Medicinal Products Department

Certification of Suitability of the Monographs of the European Pharmacopoeia

Veikko Ulvi, Senior Researcher, Assessment of Medicinal Products Department
Juha-Matti Juntunen, Senior Researcher, Assessment of Medicinal Products Department

European Network of Official Medicines Control Laboratories

Paula Korhola, Senior Researcher, Supervision and Licences Department
Timo Mauriala, Head of Unit, Supervision and Licences Department
Jaana Vesterinen, Head of Section, Supervision and Licences Department

Advisory Group CAP

Jaana Vesterinen, Head of Section, Supervision and Licences Department

Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC)

Anna von Bonsdorff-Nikander, Senior Pharmaceutical Inspector, Supervision and Licences Department

Committee of Experts on the Legal Classification of Medicines as Regards their Supply (CD-P-PH/PHO)

Pekka Eränkö, Senior Medical Officer, Assessment of Medicinal Products Department

3. THE WORLD HEALTH ORGANISATION

WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations

Anne Paavola, Senior Researcher, Assessment of Medicinal Products Department

WHO Member State Mechanism for Substandard and Falsified Medical Products

Sami Paaskoski, Senior Pharmaceutical Inspector, Supervision and Licences Department

Expert Committee on Drug Dependence, Member state Focal Point,

Katja Pihlainen, Senior Inspector, Supervision and Licences Department

4. UNITED NATIONS

Commission on Narcotic Drugs (CND)

Katja Pihlainen, Senior Inspector, Supervision and Licences Department

5. INSPECTION CONVENTION (PIC), PHARMACEUTICAL INSPECTION COOPERATION SCHEME (PIC/S)

Committee of Officials

Anne Junttonen, Head of Unit, Supervision and Licences Department

Subcommittee on Compliance

Anne Junttonen, Head of Unit, Supervision and Licences Department

Subcommittee on Training

Mervi Saukkosaari, Head of Section, Supervision and Licences Department

Subcommittee on Harmonization

Mervi Saukkosaari, Head of Section, Supervision and Licences Department

6. ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

OECD's Working Group on Good Laboratory Practice (GLP)

Mirka Laavola, Senior Inspector, Supervision and Licences Department