fimea

Representation in international organisations

Updated 21.09.2023

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

Contents

1. European Union (EU)

European Commission

Pharmaceutical Committee

Anna Siira, Director, Marketing authorisations

Veterinary Pharmaceutical Committee

Irmeli Happonen, Head of Unit, Marketing authorisations

Standing Committee on Medicinal Products for human use

Juuso Haasto, Legal Advisor, Joint Services

Standing Committee on Veterinary Medicinal Products

Juuso Haasto, Legal Advisor, Joint Services

Drug Precursors Committee

Katja Pihlainen, Senior Inspector, Supervision and availability

Working Party on Notice to Applicants

Leena Pietilä, Head of Unit, Marketing authorisations

Ad hoc Expert Group on Good Clinical Practice and Clinical Trials

Pirjo Inki, Senior Medical Officer, Safety and effectiveness

Clinical Trials Advisory Group (CTAG)

Pirjo Inki, Senior Medical Officer, Safety and effectiveness

Working Group on Good Laboratory Practice

Mirka Laavola, Senior Inspector, Supervision and availability

Competent Authorities for Blood and Blood Components

Anu Puomila, Senior Inspector, Supervision and availability

Competent Authorities for Tissues and Cells

Anne Vaskunlahti, Head of Section, Supervision and availability

Sari Tähtiharju, Senior Inspector, Supervision and availability

Competent Authorities for Organ Donation and Transplantation

Anne Vaskunlahti, Head of Section, Supervision and availability

Competent Authorities for Medical Devices (CAMD)

Susanna Peltoniemi, Head of Unit, Supervision and availability

Jari Knuttila, Chief Specialist, Supervision and availability (alternate)

Nelli Karhu, Senior Inspector, Supervision and availability (alternate)

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

Anu Puomila, Senior Inspector, Supervision and availability

EUnet Health Technology Assessment Network

Tuomas Oravilahti, Pharmacoeconomist, Assessment of Pharmacotherapies Department

Expert Group on New Phychoactive Substances

Katja Pihlainen, Senior Inspector, Supervision and availability

Expert Group on the Delegated Act on Safety Features for Medicinal Products for Human use

Siv Jantunen, Senior Inspector, Supervision and availability

Committee on Medical Devices (Comitology Committee)

Susanna Peltoniemi, Head of Unit, Supervision and availability

Nelli Karhu, Senior Inspector, Supervision and availability (member in vitro diagnostic)

Medical Device Coordination Group (MDCG)

Jari Knuuttila, Chief Specialist, Supervision and availability (member MDR)

Nelli Karhu, Senior Inspector, Supervision and availability (member IVD)

Susanna Peltoniemi, Head of Unit, Supervision and availability (alternate member MDR/IVD)

MDCG Working Group on Notified Bodies Oversight (NBO)

Jari Knuuttila, Senior Inspector, Supervision and availability

Mika Erjanne, Senior Specialist, Supervision and availability (alternate member)

Nelli Karhu, Senior Inspector, Supervision and availability (alternate member)

MDCG Working Group on Standards

Risto Joro, Senior Engineer, Supervision and availability

Jari Knuuttila, Chief Specialist, Supervision and availability(alternate member)

MDCG Working Group on Borderline & Classification

Merja Hiltunen, Senior Medical Officer, Supervision and availability

Jari Knuuttila, Senior Inspector, Supervision and availability (alternate member)

Hanna-Maria Matinolli, Coordinator, Supervision and availability (alternate member)

MDCG Working Group on Clinical Investigations and Evaluation (CIE)

Minna Kymäläinen, Inspector, Supervision and availability

Hanna-Maria Matinolli, Coordinator, Supervision and availability (alternate member)

Sami Myllymaa, Senior Inspector, Supervision and availability (alternate member)

Hanna Valo, Senior Inspector, Supervision and availability (alternate member)

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

Markku Mård, Senior Inspector, Supervision and availability

Noora Ihala, Coordinator, Supervision and availability

MDCG Working Group on Market Surveillance (MS)

Jari Knuuttila, Senior Inspector, Supervision and availability

Nelli Karhu, Senior Inspector, Supervision and availability (alternate member)

Risto Joro, Senior Engineer, Supervision and availability (alternate member)

Jaana Eerola, Coordinator Supervision and availability (alternate member)

MDCG Working Group on New Technologies

Sami Myllymaa, Senior Inspector, Supervision and availability

Jari Knuuttila, Chief Specialist, Supervision and availability, (alternate member)

Sari Tuomaala, Coordinator, Supervision and availability (alternate member)

MDCG Working Group on EUDAMED

Päivi Nihtinen, Planning Officer, Supervision and availability

Jari Knuuttila, Chief Specialist, Supervision and availability (alternate member)

Sari Tuomaala, Coordinator, Supervision and availability (alternate member)

MDCG Working Group on Unique Device Identification (UDI)

Päivi Nihtinen, Planning Officer, Supervision and availability

Sari Tuomaala, Coordinator, Supervision and availability (alternate member)

MDCG Working Group on International Matters

Susanna Peltoniemi, Head of Unit, Supervision and availability

Jari Knuuttila, Chief Specialist, Supervision and availability (alternate member)

Markku Mård, Senior Inspector, Supervision and availability (alternate member)

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

Hanna Valo, Senior Inspector, Supervision and availability

Nelli Karhu, Senior Inspector, Supervision and availability (alternate member)

Edita Mulaku, Senior Inspector, Supervision and availability (alternate member)

MDCG Working Group on Nomenclature

Sari Tuomaala, Coordinator, Supervision and availability

Tuomo Aarnikka, Inspector, Supervision and availability (alternate member)

MDCG Working Group on "Annex XVI" products

Edita Mulaku, Senior Inspector, Supervision and availability

Merja Hiltunen, Senior Medical Officer, Supervision and availability (alternate member)

Joint assessments (JAT) of European medical device notified bodies – participating national experts

Jari Knuuttila, Chief Specialist, Supervision and availability (MDR)

Nelli Karhu, Senior Inspector, Supervision and availability (IVDR)

Hanna Valo, Senior Inspector, Supervision and availability (IVDR)

TF under MS WG Medical Device Inspectors Task Force (MDITF)

Jaana Eerola, Coordinator, Supervision and availability

Edita Mulaku, Senior Inspector, Supervision and availability

Joint temporary TF under MS WG and IVD WG: Distance sales

Nelli Karhu, Senior Inspector, Supervision and availability

Temporary TF under MDCG: Orphan Devices

Merja Hiltunen, Senior Medical Officer, Supervision and availability

Temporary Joint TF under IVD WG and NBO WG: Guidance on IVDR codes

Nelli Karhu, Senior Inspector, Head of Section, Supervision and availability

Temporary TF under NBO WG: requirements for NB personnel

Nelli Karhu, Senior Inspector, Head of Section, Supervision and availability

Temporary TF under IVD WG and CIE WG: Q&A performance studies

Hanna Valo, Senior inspector, Supervision and availability

TF under MS WG: Teleconference on market Surveillance issues (monthly market surveillance call)

Jaana Eerola, Coordinator, Supervision and availability

TF under PSMV WG: The Vigilance Coordination Group / CA's contact point (monthly vigilance call)

Markku Mård, Senior Inspector, Supervision and availability

SAMIRA (Strategic Agenda for Medical Ionising Radiation Applications) Steering Group on Quality and Safety

Risto Joro, Senior Engineer, Supervision and availability

EU TF BIA-ALCL: Update BIA-ALCL developments, updates breast implant illness

Minna Kymäläinen, Inspector, Supervision and availability

EU Quality and Safety of Medical Applications of Ionising Radiation -Committee

Risto Joro, Senior Engineer, Supervision and availability

Pharmaceutical Pricing and Reimbursement information network : The Subgroup on Medical Devices

Minna Kymäläinen, Inspector, Supervision and availability

The European Medicines Agency (EMA)

Management Board

Eija Pelkonen, Director General

Anna Siira, Director (alternate member)

Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

Eija Pelkonen, Director General

Executive Steering Group on Shortages of Medical Devices (MSSG)

Eija Pelkonen, Director General

IT Directors Group

Mirke Turunen, Head of IT, Joint services

Joonas Tuominen, IT Development Manager, Joint services

Working Group on European Sales and Use of Antimicropials for veterinary medicines (ESUvet)

Katariina Kivilahti-Mäntylä, Veterinary Officer, Marketing authorisations

European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)

Katariina Kivilahti-Mäntylä, Veterinary Officer, Marketing authorisations

Committee for Medicinal Products for Human Use (CHMP)

Outi Mäki-Ikola, Coordinating Senior Medical Officer, Marketing authorisations

Johanna Lähteenvuo, Senior Medical Officer, Marketing authorisations(alternate member)

Committee for Medicinal Products for Veterinary Use (CVMP)

Minna Leppänen, Veterinary Officer, Marketing authorisations

Tita-Maria Muhonen, Veterinary Officer, Marketing authorisationsDepartment (alternate member)

Committee for Orphan Medicinal Products (COMP)

Karri Penttilä, Senior Medical Officer, Marketing authorisations

Paediatric Committee (PDCO)

Pauliina Lehtolainen-Dalkilic, Senior Researcher, Marketing authorisations

Anne Paavola, Senior Researcher, Marketing authorisations(alternate member)

Committee for Herbal Medicinal Products (HMPC)

Maria Paile-Hyvärinen, Senior Medical Officer, Marketing authorisations

Sari Koski, Senior Researcher, Marketing authorisations(alternate member)

Committee for Advanced Therapies (CAT)

Heli Suila, Senior Researcher, Marketing authorisations

Maija Tarkkanen, Senior Medical Officer, Marketing authorisations(alternate member)

Pharmacovigilance Risk Assessment Committee (PRAC)

Kirsti Villikka, Senior Medical Officer, Safety and effectiveness

Kimmo Jaakkola, Senior Medical Officer, Safety and effectiveness (alternate member)

EMA Working Parties, Scientific Advice Groups and Ad Hoc Groups

CHMP Working Parties and other Groups

Biologics Working Party (BWP)

Niklas Ekman, Head of Section, Marketing authorisations

Biosimilar Medicinal Products Working Party

Niklas Ekman, Head of Section, Marketing authorisations (Vice Chair)

Biostatistics Operational Expert Group

Elina Asikanius, Biostatistician, Safety and effectiveness

John Aspegren, Biostatistician, Safety and effectiveness

Tommi Nurminen, Biostatistician, Safety and effectiveness

Hematology Working Party

Karri Penttilä, Senior Medical Officer, Marketing authorisations

Joint CHMP/CVMP Quality Working Party (QWP)

Karin Krogars, Senior Researcher, Marketing authorisations

Methodology Working Party

Elina Asikanius, Biostatistician, Safety and effectiveness

Non-Clinical Working Party

Pauliina Lehtolainen-Dalkilic, Senior Researcher, Marketing authorisations

Oncology Working Party

Olli Tenhunen, Senior Medical Officer, Marketing authorisations (vice chair)

Scientific Advice Working Party (SAWP)

Elina Asikanius, Biostatistician, Safety and effectiveness

Juha Kolehmainen, Senior Medical Officer, Marketing authorisations

Johanna Lähteenvuo, Senior Medical Officer, Marketing authorisations

Karri Penttilä, Senior Medical Officer, Marketing authorisations

Olli Tenhunen, Senior Medical Officer, Marketing authorisations

Working Group on Quality Review of Documents (QRD)

Nina Ruso, Research Coordinator, Marketing authorisations

Paula Kajaste, Coordinator for Marketing authorisations, Marketing authorisations

Modelling and Simulation Operational Expert Group

Juha Vakkilainen, Senior Medical Officer, Marketing authorisations

Pyry Välitalo, Senior Researcher, Marketing authorisations

CTIS Member State Group

Eija Mikkonen, Clinical Trials Coordinator, Safety and effectiveness

CAT Working Parties and other Groups

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

Heli Suila, Senior Researcher, Marketing authorisations

Maija Tarkkanen, Senior Medical Officer, Marketing authorisations

CVMP Working Parties and other Groups

Joint CHMP/CVMP Quality Working Party (QWP)

Karin Krogars, Senior Researcher, Marketing authorisations

Pharmacovigilance Working Party (PhVWP)

Jonna Kumpulainen, Veterinary Officer, Marketing authorisations

PRAC Working group

Signal Management Review Techical Working Group (SMART)

Terhi Lehtinen, Senior Medical Officer, Safety and effectiveness

Tiina Karonen, Senior Medical Officer, Safety and effectiveness

Groups of GMP, GCP, GVP and GLP Inspectors

GMP/GDP Inspectors Working Group

Mervi Saukkosaari, Head of Section, Senior Pharmaceutical Inspector, Supervision and availability

Mirka Laavola, Senior Inspector, Supervision and availability (alternate member)

Anne Junttonen, Head of Unit, Supervision and availability (alternate member)

GCP Inspectors Working Group

Sarianne Päivike, Senior Inspector, Safety and effectiveness

Anne Timonen, Senior Inspector, Safety and effectiveness (alternate member)

GVP Inspectors Working Group

Sarianne Päivike, Senior Inspector, Safety and effectiveness

Sami Paaskoski, Senior Pharmaceutical Inspector, Safety and effectiveness (alternate member)

Ad hoc group of GLP inspectors

Mirka Laavola, Senior Inspector, Supervision and availability

Working Groups

e-Submission Expert Group

Jyrki Makkonen, System Specialist, Joint services

Medicines Shortages (SPOC) Working Party

Julia Lehtinen, Senior Inspector, Supervision and availability

Johanna Linnolahti, Head of Section, Supervision and availability (alternate member)

Medical Device Shortages (SPOC) Working Party

Markku Mård, Senior Inspector, Supervision and availability

Noora Ihala, Coordinator, Supervision and availability

EMA Common Repository

Jyrki Makkonen, System Specialist, Joint services

UNICOM

Joonas Tuominen, Development Manager, Joint services

Markus Mäkelä, System Specialist, Joint services

Marko Kallio, Research Coordinator, Joint services

Anu Ollikainen, Research Coordinator, Marketing authorisations

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, Safety and effectiveness

HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary use

Johanna Linnolahti, Head of Section, Supervision and availability

Julia Lehtinen, Senior Inspector, Supervision and availability (alternate member)

Working Group of Quality Managers (WGQM)

Jaana Pohjonen, Senior Planning Officer, Joint services

Benchmarking of European Medicines Agencies

Jaana Pohjonen, Senior Planning Officer, Joint services

EMACOLEX

Irmeli Happonen, Head of Unit, Marketing authorisations

Common European Submission Platform Development Group (CESP)

Jyrki Makkonen, System Specialist, Joint services

eAF Maintenance Group

Jyrki Makkonen, System Specialist, Joint services

HMA Substancees Validation Group (SVG)

Anu Ollikainen, Research Coordinator, Marketing authorisations

EU Innovation Network (EU-IN)

Juha Kolehmainen, Senior Medical Officer, Marketing authorisations

HMA Veterinary Strategy Focus Group (HMA WGCP)

Irmeli Happonen, Head of Unit, Marketing authorisations

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, Safety and effectiveness

HMA Working Group of Biosimilars (HMA BSWG)

Esa Heinonen, consultant (chair)

Niklas Ekman, Head of Section, Marketing authorisations

Homeopathic Medicinal Products Working Group (HMPWG)

Sari Koski, Senior Researcher, Marketing authorisations

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

Tea Linhola, Coordinator for Marketing authorisations, Marketing authorisations

Pauliina Ikäheimo, Senior Medical Officer, Marketing authorisations(alternate member)

Variation Regulation Working Party (CMDh)

Pauliina Ikäheimo, Senior Medical Officer, Marketing authorisations

GCP Inspectors Working Group/CMDh Working Party

Sarianne Päivike, Senior Inspector, Safety and effectiveness

Non-prescription Working Party (CMDh)

Vesa Mustalammi, Senior Medical Officer, Marketing authorisations

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

Paula Kajaste, Coordinator for Marketing authorisations, Marketing authorisations

Kristina Lehmann, Veterinary Officer, Marketing authorisations(alternate member)

PharmacoVigilance Work Sharing Procedures Working Party (PhV WSP WP) (CMDh)

Rajaratnam Radhakrishnan, Senior Medical Officer, Safety and effectiveness

Petri Kaheinen, Research Coordinator, Safety and effectiveness (alternate member)

Ilpo Lundberg, Research Coordinator, Safety and effectiveness (alternate member)

HaRP: RMP peer review group (CMDh)

Kimmo Jaakkola, Senior Medical Officer, Safety and effectiveness

Radhakrishnan Rajaratnam , Senior Medical Officer, Safety and effectiveness

Heads of HTA agencies Group (HAG)

Heads of HTA agencies group (HAG)

Piia Vuorela, Director, Safety and effectiveness

HAG Working groups

Roles and responsibilities matrix working group (RRM)

Piia Vuorela, Director, Safety and effectiveness

Tuomas Oravilahti, Pharmacoeconomist, Safety and effectiveness

Member State Coordination Group on HTA (HTACG)

Member State coordination Group on HTA (HTACG)

Piia Vuorela, Director, Safety and effectiveness

Tuomas Oravilahti, Pharmacoeconomist, Safety and effectiveness (Alternate)

HTACG Subgroups

HTA subgroup for joint clinical assessments (JCA)

Tuomas Oravilahti, Pharmacoeconomist, Safety and effectiveness (Medicines)

Vesa Kiviniemi, Head of assessment, Safety and effectiveness (alternate medicines)

Merja Hiltunen, Senior Medical Officer, Supervision and availability (alternate medical devices)

HTA subgroup on joint scientific consultations (JSC)

Tuomas Oravilahti, Pharmacoeconomist, Safety and effectiveness (Medicines)

Vesa Kiviniemi, Head of assessment, Safety and effectiveness (alternate medicines)

Merja Hiltunen, Senior Medical Officer, Supervision and availability (alternate medical devices)

HTA subgroup on emerging health technologies (EHT)

Tuomas Oravilahti, Pharmacoeconomist, Safety and effectiveness

Vesa Kiviniemi, Head of assessment, Safety and effectiveness (alternate)

HTA subgroup for methodological guidance

Tuomas Oravilahti, Pharmacoeconomist, Safety and effectiveness

Vesa Kiviniemi, Head of assessment, Safety and effectiveness (alternate)

European Health Emergency Preparedness and Response Authority (HERA)

HERA Advisory board

Tuomas Oravilahti, Pharmacoeconomist, Safety and efectiveness

HERA Working groups

HERA MCM working group

Tuomas Oravilahti, Pharmacoeconomist, Safety and efectiveness

2. Council of Europe

European Directorate for the Quality of Medicines & HealthCare

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

Juha Sinnemäki, Senior Pharmaceutical Inspector, Supervision and availability

European Pharmacopoeia Commission

Piia Salo, Head of Section, Marketing authorisations

Marjo-Riitta Helle, Head of Unit, Marketing authorisations

Anniina Ritvanen, Research Coordinator, Marketing authorisations

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

Ari Lehtola, Senior Researcher, Supervision and availability

Expert Group No 17 (Medicinal products containing chemically defined active substances)

Jarkko Lipsonen, Senior Researcher, Supervision and availability

Working group CTP (Cell Therapy Products)

Hanna Kankkonen, Senior Researcher, Marketing authorisations

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

Jaana Vesterinen, Head of Section, Supervision and availability (Chair)

Working Party MAB (Monoclonial antibodies)

Jaana Vesterinen, Head of Section, Supervision and availability (Chair)

Secretary to the National Pharmacopoeia Authority

Piia Salo, Head of Section, Marketing authorisations

Anniina Ritvanen, Research Coordinator, Marketing authorisations

Certification of Suitability of the Monographs of the European Pharmacopoeia

Juha-Matti Juntunen, Senior Researcher, Marketing authorisations

European Network of Official Medicines Control Laboratories

Timo Mauriala, Head of Unit, Supervision and availability

Jaana Vesterinen, Head of Section, Supervision and availability

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

Juha Sinnemäki, Senior Pharmaceutical Inspector, Supervision and availability

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

Pekka Eränkö, Senior Medical Officer, Safety and effectiveness

3. The World Health Organisation (WHO)

WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations

Anne Paavola, Senior Researcher, Marketing authorisations

WHO Member State Mechanism for Substandard and Falsified Medical Products

Sami Paaskoski, Senior Pharmaceutical Inspector, Safety and effectiveness

Expert Committee on Drug Dependence, Member state Focal Point

Katja Pihlainen, Senior Inspector, Supervision and availability

4. United Nations (UN)

Commission on Narcotic Drugs (CND)

Katja Pihlainen, Senior Inspector, Supervision and availability

5. Inspection Convention (PIC), Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Committee of Officials

Anne Junttonen, Head of Unit, Supervision and availability

Subcommittee on Compliance

Anne Junttonen, Head of Unit, Supervision and availability

Subcommittee on Harmonization

Mervi Saukkosaari, Head of Section, Supervision and availability

6. Organisations for Economic Co-operation and Development (OECD)

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

Mirka Laavola, Senior Inspector, Supervision and availability