

## 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](#)  
[The European Medicines Agency \(EMA\)](#)  
[EMA Working Parties, Scientific Advice Groups and other Ad Hoc Groups](#)

[Heads of Medicines Agencies \(HMA\)](#)  
[HMA Committees and Working Groups](#)

### 2. [COUNCIL OF EUROPE](#)

### 3. [THE WORLD HEALTH ORGANISATION \(WHO\)](#)

### 4. [UNITED NATIONS \(UN\)](#)

### 5. [INSPECTION CONVENTION \(PIC\), PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME \(PIC/S\)](#)

### 6. [ORGANISATIONS FOR ECONOMIC CO-OPERATION AND DEVELOPMENT](#)

## 1. EUROPEAN UNION (EU)

### EUROPEAN COMMISSION

#### **Pharmaceutical Committee**

Anna Siira, Director, Assessment of Medicinal Products Department

#### **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

### **Competent Authorities for Medical Devices (CAMD)**

Susanna Peltoniemi, Head of Unit, Supervision and Licences Department  
 Jari Knuttila, Senior Inspector, Supervision and Licences Department  
 Nelli Karhu, Senior Inspector, Supervision and Licences Department  
 Minna Kymäläinen, Inspector, 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 Psychoactive Substances**

Katja Pihlainen, Senior Inspector, Supervision and Licences Department

### **Committee on Medical Devices (Comitology Committee)**

Susanna Peltoniemi, Head of Unit, Supervision and Licences Department  
 Nelli Karhu, Senior Inspector, Supervision and Licences Department (member in vitro diagnostic)

### **Medical Device Coordination Group (MDCG)**

Susanna Peltoniemi, Head of Unit, Supervision and Licences Department (alternate member in medical devices, alternate member in vitro diagnostic)

Jari Knuuttila, Senior Inspector, Supervision and Licences Department (member in medical devices)  
 Nelli Karhu, Senior Inspector, Supervision and Licences Department (member in vitro diagnostic)

**MDCG Working Group on Notified Bodies Oversight (NBO)**

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

**MDCG Working Group on Standards**

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

**MDCG Working Group on Borderline & Classification**

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

**MDCG 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)

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

Tarja Vainiola, Senior Inspector, Supervision and Licences Department  
 Risto Joro, Senior Engineer, Supervision and Licences Department (alternate member)  
 Sami Myllymaa, Senior Engineer, Supervision and Licences Department (alternate member)

**MDCG Working Group on Market Surveillance (MS)**

Tuomo Aarnikka, Inspector, Supervision and Licences Department  
 Jari Knuuttila, Senior Inspector, Supervision and Licences Department (alternate member)  
 Johanna Ekholm, Senior Engineer, Supervision and Licences Department (alternate member)  
 Sami Myllymaa, Senior Engineer, Supervision and Licences Department (alternate member)

**MDCG Working Group on New Technologies**

Susanna Peltoniemi, Head of Unit, Supervision and Licences Department  
 Jari Knuuttila, Senior Inspector, Supervision and Licences Department, (alternate member)  
 Sami Myllymaa, Senior Engineer, Supervision and Licences Department (alternate member)

**MDCG Working Group on EUDAMED**

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

**MDCG Working Group on Unique Device Identification (UDI)**

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

**MDCG Working Group on International Matters**

Susanna Peltoniemi, Head of Unit, Supervision and Licences Department  
 Jari Knuutila, Senior Inspector, Supervision and Licences Department (alternate member)

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

Nelli Karhu, Senior Inspector, Supervision and Licences Department  
 Hanna Valo, Senior Inspector, Supervision and Licences Department (alternate member)

**MDCG Working Group on Nomenclature**

Tarja Vainiola, Senior Inspector, Supervision and Licences Department  
 Hanna Valo, Senior Inspector, Supervision and Licences Department (alternate member)

**MDCG Working Group on “Annex XVI” products**

Johanna Ekholm, Senior Engineer, Supervision and Licences Department (alternate member)  
 Risto Joro, Senior Engineer, Supervision and Licences Department (alternate member)  
 Merja Hiltunen, Senior Medical Officer, Supervision and Licences Department (alternate member)

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

Jari Knuutila, Senior Inspector, Supervision and Licences Department (MDR)  
 Nelli Karhu, Nelli Karhu, Senior Inspector, Supervision and Licences Department (IVDR)  
 Hanna Valo, Senior Inspector, Supervision and Licences Department (IVDR)  
 Minna Kymäläinen, Inspector, Supervision and Licences Department (MDR)

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

Risto Joro, Senior Engineer, Supervision and Licences Department

**THE EUROPEAN MEDICINES AGENCY (EMA)**

**Management Board**

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

**EU Telematics Management Board**

t.b.n.

**Telematics Enterprise Architecture Board (TEAB)**

t.b.n.

**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 (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 Väliatalo, 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  
 Maija Tarkkanen, Senior Medical Officer, 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**

t.b.n.

#### **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)**

Jaana Pohjonen, Senior Planning Officer, Information Resources

### **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

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

Tea Linhola, 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)

Kristina Lehmann, Veterinary Officer, Assessment of Medicinal Products Department (alternate member)

**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 (Monoclonal 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