Multistakeholder workshop on shortages of Glucagon-Like Peptide-1 (GLP-1) receptor agonists

1 July 2024, 11.45-18.30

Hybrid meeting / EMA, Amsterdam

A shortage of medicines containing Glucagon-Like Peptide-1 (GLP-1) receptor agonists has been affecting EU Member States since 2022 and is expected to continue throughout 2024. The shortage is due to an increased demand for these medicines in conjunction with other causes, such as manufacturing capacity constraints. The medicines are authorised for the treatment of diabetes or for weight management under certain conditions or both.

The off-label use for cosmetic weight loss and the emergence of falsified products further complicates the situation, particularly given the competing indications of these medicines.

EMA and the European Network are committed to tackling these shortages, and several actions have been taken at national and EU level; while these actions are helping to manage the situation, it is clear

that they are not enough and that further action is needed to successfully mitigate or end these shortages.

New EU legislation[1] has given EMA additional responsibilities for managing shortages at EU level. As a result, EMA has established an Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to play a central role in coordinating, preventing and mitigating medicine shortages in the EU.

The MSSG acknowledges the complexity of this shortage situation and the fact that it involves many parties and stakeholders, each with varying interests and facing different challenges. Given the limited impact of current measures, the MSSG has organised this multi-stakeholder workshop to bring together all relevant parties to facilitate a common understanding and to jointly discuss and identify possible additional solutions.

Therefore, the objectives of this workshop are as follows:

- Clarify the needs and challenges of the different stakeholder groups in the context of shortages of GLP-1 receptor agonists.
- Share experiences of ongoing activities to mitigate and prevent shortages of GLP-1 receptor agonists.
- Identify novel solutions to mitigate and prevent the shortages of these medicines.
- Strengthen cooperation amongst all stakeholders and improve coordination of activities.
- Discuss and agree on key messages for communication and how to best reach target audiences.

The following mailbox has been set up to **collect** feedback **from stakeholders** in the context of the workshop on shortages of GLP-1 receptor agonists: GLP1_workshop@ema.europa.eu

Feedback could be questions you would like to see addressed during the discussions of the workshop; expectations for specific stakeholders and suggestions for actions.

Although EMA will not individually acknowledge or respond to the contributions made, they will be used to inform EMA's future actions.

[1] Regulation (EU) 2022/123

Multistakeholder workshop on shortages of Glucagon-Like Peptide-1 (GLP-1) receptor agonists

Chaired by Emer Cooke (EMA) and Karl Broich (HMA)

12:15 Technical checks

12:30 Welcome and opening speech

Welcome and introduction **10'**
Emer Cooke (EMA) and Karl Broich (HMA)

Outline of the day and objectives **5'**
Monica Dias (EMA)

12:45 Session 1: Setting the scene

Chair: Karl Broich (HMA)

Overview of the supply situation of GLP-1 receptor agonists **10'**
Klaus Kruttwig (EMA)

Clinical impact of shortages **15'**
Francesco Giorgino (EASD)
Euan Woodward (EASO)

Round table discussion with concerned stakeholders and partners **30'**
Elisabeth Dupont (IDF Europe)
Jaqueline Bowman (PA-AP)
Ancel.la Santos (BEUC)
Stefano del Prato (EUDF)
Mary McCarthy (UEMO)
Jorge Batista (PGEU)
Elspeth Kay (TGA)

Questions and Answers **20'**

14:10 Session 2: Mitigation measures

Chair: Hugues Malonne (HMA)

Mitigation measures recommended by EMA/MSSG **5'**
Klaus Kruttwig (EMA)

Sharing of good practice – examples from EU/EEA countries **20'**
Sybille Schotte (FAGG-AMPS, BE)
Jakub Velik (SUKL, CZ)
Domenico di Giorgio (AIFA, IT)
Guri Wilhelmsen (NoMA, NO)

	Sharing of good practice – examples from a non-EU regulator *Robert Kosko (FDA)*	**5'**
	Prevention and mitigation measures taken by companies *Emily Pegg (Eli Lilly)* *Emel Mashaki Ceyhan (Novo Nordisk)* *Jukka Westerbacka (Sanofi)*	**20'**
	Questions and Answers	**40'**
15:50	**Coffee break**	**30'**
16:20	**Session 3: Communication and engagement**	
	Chair: Björn Eriksson (HMA)	
	Communication activities by EMA/MSSG on shortages of GLP-1 receptor agonists *Juan Garcia Burgos (EMA)*	**10'**
	Role of Patients and Consumers'/Healthcare Professional organisations in supporting communication activities *Elisabeth Dupont (IDF Europe)* *Jaqueline Bowman (PA-AP)* *Francesco Giorgino (EASD)* *Euan Woodward (EASO)*	**15'**
	Sharing of good practice – examples on communication from Member States *Diego Pernas Cabo (AEMPS, ES)* *Yngvil Knudsen (NoMA, NO)*	**15'**
	Sharing of good practice – examples on communication from a non-EU regulator *Anthony Lostracco (Health Canada)*	**10'**
	The role of social media in shortages of GLP-1 receptor agonists *Ancel.la Santos (BEUC)*	**10'**
	Questions and Answers	**30'**
18:00	**Final discussion and conclusion**	
	Chair: María Lamas (HMA) and Monica Dias (EMA)	**25'**
18:25	**Closing remarks**	
	Wrap up *Emer Cooke (EMA)*	**5'**
18:30	**End of meeting**	

List of speakers

Emer Cooke	European Medicines Agency (EMA)
Karl Broich	Heads of Medicines Agencies (HMA)
Monica Dias	European Medicines Agency (EMA)
Klaus Kruttwig	European Medicines Agency (EMA)
Francesco Giorgino	European Association for the Study of Diabetes e.V. (EASD)
Euan Woodward	European Association for the Study of Obesity (EASO)
Elisabeth Dupont	International Diabetes Federation Europe (IDF Europe)
Jacqueline Bowman	The Foundation for the Rights of Citizens with Obesity (PA-AP)
Ancella Santos	The European Consumers' Organization (BEUC)
Stefano Del Prato	European Diabetes Forum (EUDF)
Mary McCarthy	European Union of General Practitioners (UEMO)
Jorge Batista	Pharmaceutical Group of the European Union (PGEU)
Elspeth Kay	Therapeutic Goods Administration (TGA, Australia), on behalf of the Drug Shortages Global Regulatory Working Group
Hugues Malonne	Heads of Medicines Agencies (HMA)
Sybille Schotte	The Federal Agency for Medicines and Health Products (FAMPH, Belgium)
Jakub Velik	State Institute for Drug Control (SUKL, Czechia)
Domenico Di Giorgio	Italian Medicines Agency (AIFA)
Guri Wilhelmsen	Norwegian Medical Products Agency (NoMA)
Robert Kosko	U.S. Food and Drug Administration (FDA)
Emily Pegg	Eli Lilly and Company
Emel Mashaki Ceyhan	Novo Nordisk
Jukka Westerbacka	Sanofi
Björn Eriksson	Heads of Medicines Agencies (HMA)
Juan Garcia Burgos	European Medicines Agency (EMA)
Diego Pernas	Spanish Agency of Medicines and Medical Products (AEMPS)
Yngvil Knudsen	Norwegian Medical Products Agency (NoMA)
Anthony Lostracco	Health Canada (HC)
María Jesús Lamas	Heads of Medicines Agencies (HMA)

About the speakers

Emer Cooke

Executive Director, EMA

Emer Cooke is the Executive Director of the European Medicines Agency, based in Amsterdam.

She also holds the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA).

Previously, she was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020.

Ms. Cooke is a pharmacist with master's degrees in science and business administration from Trinity College Dublin. She has over 30 years' experience in international regulatory affairs and held management positions at the European Medicines Agency as Head of Inspections and Head of International Affairs respectively from 2002 until 2016. From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission, where intra-alia, she was responsible for international collaboration, EU enlargement and the orphan medicines regulation.

Karl Broich

President of BfArM

Prof. Broich is a physician (neurology, psychiatry, cognitive behavioural therapy) and has been President of the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn since 2014.

His current activities in the European network of regulatory authorities are Member of the Management Board of the European Medicines Agency (EMA MB), Chair of the Network Portfolio Advisory Group (NPAG). He is also co-chair of the EMA's Darwin EU Advisory Board and Co-chair of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG).

His scientific focus is on clinical psychopharmacology, imaging of neurodegenerative diseases and other potential biomarkers and dementia, and clinical trial methodology, among others. Prof. Karl Broich is author and co-author of more than 250 papers (original scientific papers, reviews, book contributions).

Monica Dias

Head of Supply and Availability of medicines and medical devices, EMA

Dr. Dias is Head of supply and availability of medicines and devices at EMA since October 2021. She is Co-Chair of the HMA/EMA Task Force on Availability and she is the Chair of the Medicine Shortages SPOC Working Party. Dr. Dias studied pharmacy in Lisbon, Portugal and obtained her PhD from the University of Cardiff, UK. Dr. Dias joined the European Medicines Agency in 2004. She worked in the Quality Office for 10 years. In 2013 she joined the Office of the Deputy Executive Director at EMA where she was Principal Policy and Crisis Coordinating Officer. She was involved in the development of policies and coordinated the Brexit operational preparedness activities at EMA, including the impact of Brexit on the availability of Centrally Authorised products. Dr. Dias was also coordinating at EMA the activities of the HMA/EMA Task Force on the availability of authorised medicines since November 2016. During the COVID-19 pandemic Dr. Dias coordinated activities in relation to shortages due the pandemic both at EMA and with the NCAs. She was subsequently responsible for the implementation of the extended mandate of EMA, Regulation 2022/123, in the area of shortages of medicines and devices.

Klaus Kruttwig

Medicines and Medical Devices Shortages Specialist, EMA

Klaus Kruttwig is a Biologist and Regulatory affairs specialist and joined the European Medicines Agency in September 2020. Klaus works in the Supply and Availability of Medicines and Devices workstream at EMA since December 2021 as a Medicines and Medical Devices Shortages Specialist.

Francesco Giorgino

Professor of Endocrinology and Chairman of the Department of Precision and Regenerative Medicine and Ionian Area, University of Bari Aldo Moro

Chief, Division of Endocrinology

Francesco Giorgino is Professor of Endocrinology and Chairman of the Department of Precision and Regenerative Medicine and Ionian Area at the University of Bari Aldo Moro, Bari, Italy. He is also Chief of the Division of Endocrinology at the University Hospital Policlinico Consorziale in Bari. Professor Giorgino received his M.D. degree from the University of Bari Aldo Moro and his Ph.D. degree from the University of Naples Federico II, in Italy. After completing clinical training in endocrinology at the University of Catania, Italy, he worked at the Joslin Diabetes Center and Harvard Medical School in Boston, MA, USA, as a postdoctoral research fellow and visiting scientist (1990-1994). He has received scientific awards from various institutions, including the Juvenile Diabetes Research Foundation International (JDRF)

Fellowship (New York, NY, USA), the Mary K. Iacocca Foundation Fellowship (Boston, MA, USA), the Glaxo-Wellcome Award from the European Association for the Study of Diabetes (EASD), the Aldo Pinchera and Cassano Awards from the Italian Society of Endocrinology, and the Alcmeone Award from the Italian Society of Diabetology. He has been President of the Italian Society of Endocrinology (2019-2021) and is currently Senior Vice-President of the European Association for the Study of Diabetes. His research interests include the mechanisms of insulin resistance and beta-cell dysfunction in type 2 diabetes and the effects of diabetes drugs on pancreatic islets and the cardiovascular system. He has an H-index of 73 and over 20,000 citations (Google Scholar).

Euan Woodward

Executive Director, EASO

Euan Woodward is the Executive Director of EASO, the European Association for the Study of Obesity. He is responsible for the development and implementation of the organisation's strategic plan, supporting its 37 National Associations, Board of Trustees, Executive Committee and Working Groups. He coordinates all EASO activities undertaken in three tracks of Research, Education and Policy. He manages the European Congress on Obesity, EASO Education programmes, and represents EASO in several EU Research Projects and Policy actions. He coordinates national capacity building and advocacy programs. He has worked with EASO since 2005.

Elisabeth Dupont

Regional Manager, IDF Europe

Elisabeth has been active for more than 20 years in international health cooperation, with a specific focus on cancer and palliative care in LMICs. She has worked with NGOs and the US National Cancer Institute, focusing on programme design and implementation, knowledge sharing, and alliances and partnerships building. She joined International Diabetes Federation Europe (IDF Europe) four years ago and since then, with the support of the Board, her team and a strong network of youth diabetes advocates and diabetes associations, is engaged in European health policy, to improve the lives of people with diabetes and those at risk. She is the mother of four young adults.

Jacqueline Bowman-Busato

Co-Founder, Engagement and Projects Lead, PA-AP

Jacqueline Bowman brings almost three decades of experience in shaping and transforming EU, national, regional and global health policy into reality.

As a lawyer by education, with an MBA and expertise in Strategic Communications, she formerly led policy for the European Association for the Study of Obesity advocating on behalf of and building policy capacity for 20000+ Health Practitioners, Public Health professionals, researchers and students

specialised in the research, prevention, diagnosis, treatment and long term management of the chronic disease of obesity. An expert with the European Commission, the European Medicines Agency, and the Belgian anti-discrimination Agency Working Group on equality data, Jacqueline is dedicated to improving obesity health outcomes and health system performance.

In her volunteer role at the Foundation, she drives strategy and engagement, advocating for the legal rights of people living with obesity.

A peer-reviewed author, Jacqueline's personal experiences with autoimmune Hashimoto's and obesity enrich her professional insights. Fluent in French and with basic Dutch skills, she represents a blend of Guyanese (South America), British, and Belgian heritage.

Ancella Santos

Senior Health Policy Officer, BEUC

Ancel·la Santos is Senior Health Policy Officer at the European Consumer Organisation (BEUC), which brings together 44 consumer organisations from 31 countries. She follows closely EU pharmaceutical policy and defends consumer interests in this area.

Before joining BEUC in May 2019, Ancel·la served as Senior Policy Advisor for Health Action International. She has over ten years' experience representing the positions of non-profit umbrella organisations before the EU institutions and at the European Medicines Agency's Patients' and Consumers' Working Party. From 2011-2013 Ancel·la worked at the Siemens AG Representation Office in Brussels, in the healthcare sector.

She holds a Bachelor's degree in Political Sciences and Public Administration, a Master of Science in International and European Politics, and a Master in Journalism.

Stefano Del Prato

Chair of the European Diabetes Forum

Stefano Del Prato is a retired Professor of Endocrinology and Metabolism at the School of Medicine, University of Pisa and Chief of the Section of Diabetes, University Hospital of Pisa, Italy till last November. Currently he is affiliate Professor of Medicine at the Interdisciplinary Research Center "Health Science" of the Sant'Anna School of Advanced Studies in Pisa and affiliate physician at the "Fondazione Toscana Gabriele Monasterio", Pisa. He graduated from the University of Padova, Italy and undertook postgraduate specialization in Endocrinology and Internal Medicine. He has been Professor of Medicine at the University of Texas, San Antonio, TX, USA. Professor Del Prato's main research interests have always been the physiopathology and therapy of type 2 diabetes and insulin resistance. He is a member of many societies and associations including the European Association for the Study of Diabetes (EASD) and the American Diabetes Association. He acts as referee for numerous journals and has served on the Editorial Boards of major scientific journals in the field of diabetes and metabolism. Professor Del Prato is past Vice-President of the EASD, past Chairman of the European Foundation for the Study of Diabetes (EFSD), past President and Honorary President of the Italian Society of Diabetology, and immediate past-President of the EASD. Currently is the President of the European Diabetes Forum. He served as Chairman of the Scientific Committee of the World Diabetes Congress in Dubai, UAE, in 2011. He has authored over 550 articles (PubMed) in peer-reviewed international journals and has been awarded several honors including the Prize of the Italian Society of

Diabetology for outstanding scientific activity, the Honorary Professorship at the Universidad Peruana Cayetano Heredya in Lima, the 10th Lifetime Contribution Oration Award from the Madras Diabetes Research Foundation, India. He has been bestowed the honor of Commander of the Order of the Italian Republic for Scientific Merits.

Mary McCarthy

UEMO Representative

Mary McCarthy is the Former Vice-President (2016-2022) of UEMO, the European Union of General Practitioners, represents GPs in 26 European member states. It develops policy and projects to support family medicine and share best practice; provides an opportunity to look at other health systems and to learn from them. She is also a member of One Health Project (AMR).

Jorge Batista

Senior Professional Affairs Advisor, PGEU

Jorge Batista is the current Senior Professional Affairs Advisor of the Pharmaceutical Group of the European Union (PGEU), representing the voice of community pharmacists in Brussels. He represents PGEU and European Community Pharmacists in different international fora and is a member of the European Medicines Agency (EMA) Healthcare Professionals Working Party.

Before joining PGEU, Jorge was the Secretary General of the Portuguese Pharmaceutical Society, having also occupied the position of International Affairs Lead, and Pharmacist responsible for the Professional Development Programme in the same organisation.

He is currently a PhD candidate in International Health at the Portuguese Institute of Hygiene and Tropical Medicine, specializing in Health Policies and Development.

Elspeth Kay

Assistant Secretary of the Pharmacovigilance Branch, TGA

Elspeth Kay PSM is the Assistant Secretary of the Pharmacovigilance Branch of the Therapeutic Goods Administration (TGA), which is Australia's regulator for medicines, medical devices and biologicals. The Pharmacovigilance Branch helps to ensure that medicines maintain an appropriate level of quality, safety and efficacy following entry into the Australian marketplace and operates the TGA's medicine shortages program, which provides information about medicine shortages and seeks to mitigate their impacts.

Hugues Malonne

Chief Executive Officer, FAMHP

Hugues Malonne obtained his Pharmacist degree, PhD in Pharmaceutical Sciences and Executive Master in Management of Health and Care Institutions from the University of Brussels (ULB).

That is also the place where he started his career in academia as a Professor before moving into the industry. After a successful international career as a pharmaceutical executive (Italy, China, Luxembourg, Switzerland), he returned to Belgium.

With his expertise in market access, public-private partnerships, public policy and government affairs, Hugues Malonne joined the Federal Agency for Medicines and Health Products (FAMHP) in 2017 as Director General and successively headed the POST and PRE authorisation departments.

Throughout his career, he has maintained close links with the academic world and continues to teach at ULB and UNamur.

Since 1 September 2023, he is the new FAMHP Chief Executive Officer. He took on this role with confidence and enthusiasm, convinced that he will continue to work in collaboration with all his employees to guarantee a quality service for all, and to maintain the role of the FAMHP as a guardian of public health.

Hugues Malonne has a keen interest in addressing drug shortages at a global level and exploring innovative therapies such as Advanced Therapy Medicinal Products (ATMP) and vaccines. He is the current Co-chair of the HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use. He is dedicated to finding solutions to ensure the availability of essential medicines and promoting the development and accessibility of cutting-edge treatments to improve public health.

Sybille Schotte

Scientific file manager, Unavailabilities Entity (FAMPH, Belgium)

Scientific file manager at the Federal Agency for Medicines and Health Products and member of the Medicine Shortages Single Point of Contact (SPOC) Working Party.

Sybille Schotte is a pharmacist and gained 7 years of experience in the field, before joining the Belgian Federal Agency for Medicines and Health Products in 2021.

She works for the Unavailabilities Entity, which focuses on solutions and measures to prevent shortages of medicines. She is also a member of the Medicines Shortages SPOC Working Party for Belgium.

Jakub Velik

Head of the Shortage and Availability Department (SUKL, CZ)

Head of the Shortage and Availability Department, State Institute for Drug Control, Czechia, member of Joint HMA/EMA Task Force on Availability of Authorised Medicines (TF AMM) and representative of Czechia in the SPOC WP and MSSG.

Domenico Di Giorgio

Director, Inspection & Certification Department (AIFA)

Head of Inspection & Certification Department and of the Pharmaceutical Crime Counteracting Office at the Italian Medicines Agency (AIFA). Between 2009 and 2011 he represented AIFA in the negotiation and implementation of the EU Directive 2011/62 and of the MEDICRIME Council of Europe Convention.
As an expert in pharmacrime counteracting, he published many books (for CoE/EDQM, WHO and the Italian State Library), chaired the EDQM/Council of Europe Committees CMED (Counterfeit medicines) and CDPPH (Steering Committee Pharmaceuticals), developed and coordinated EC funded projects such as FAKESHARE I and II and MEDI-THEFT, and was elected as European vice Chair of the WHO Member State Mechanism.

He is dealing with medicines shortages since 2015, as coordinator of the "National Ad Hoc Forum on Short Supply of Medicines"; he is the coordinator of the European Joint Action on medicines shortages "CHESSMEN – Coordination and Harmonization of the Existing Systems against Shortages of Medicines – European Network", involving 22 Countries.

Guri Wilhelmsen

Senior advisor, Unit for authorisations and security of supply, (NoMA)

Guri Wilhelmsen works as a senior advisor at the Norwegian Medical Products Agency (NoMA) within the unit for authorisations and security of supply.

She represents NoMA in the Medicinal Shortages SPOC Working Party (MS SPOC WP).

Trained pharmacist with previous experience from primary pharmacy, pharma industry (mainly with clinical trials and external affairs) and non governmental organization within the HCP field.

Robert Kosko

Senior Program Management Officer, FDA

CDR Robert Kosko, a commissioned officer in the United States Public Health Service, currently serves as a Senior Program Management Officer for the Drug Shortage Staff within the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER). As a drug supply subject matter expert, he provides guidance related to actual or potential drug shortages to senior representatives from CDER, the FDA, other Federal Agencies, and regulated industry. He has been a member of the Drug Shortage Staff since 2012 and serves as the FDA's international drug shortage lead. He holds a Doctor of Pharmacy degree, a Master of Public Health degree, and is certified in regulatory affairs and public health.

Emily Pegg

Associate Vice President - Medical, Northern European Hub, Eli Lilly

Dr Emily Pegg is a medical doctor who trained at Oxford University and University College London before working in the NHS. She has spent the last 11 years as a Pharmaceutical Physician working at Novartis, Takeda and now at Eli Lilly. She has worked across a range of therapeutic areas including Neurology, Rare Disease, Oncology and Diabetes and is a member of the Faculty of Pharmaceutical Medicine. She is currently the Associate Vice President for Medical for the Northern European Hub, based in London.

Emel Mashaki Ceyhan

Vice President, Global Regulatory Affairs, Novo Nordisk

Dr. Emel Mashaki Ceyhan is a Global Regulatory Affairs Vice President at Novo Nordisk, Denmark, and has more than 22 years of professional experience within the pharmaceutical industry and academic research. She worked in several global pharmaceutical companies, where she has held various leadership, regional, and global roles, across in R&D, medical and regulatory affairs. She worked as an assistant professor in various universities and contributed to academic research projects together with the Centre for Innovation in Regulatory Science (CRIS).

Emel is a pharmacist by background and holds a MSc. in Clinical Pharmacy & Pharmacology, an MBA and a PhD in Pharmaceutical and Regulatory Science from Cardiff University in the UK.

Jukka Westerbacka

Sanofi Global Medical Head, Established Products

Jukka Westerbacka received MD degree in 1997 (University of Helsinki) and received PhD degree in 2001 after which he lead clinical study projects at Karolinska Hospital, Sweden, in collaboration with Universities in Edinburgh and Cardiff as a project lead of the Academy of Science of Finland.

As a diabetologist he has worked in primary and secondary care as well as at the university endocrinology clinics with patients with diabetes and obesity and related cardiovascular diseases. He has published over 80 articles in peer-reviewed journals. Dr Westerbacka joined Sanofi in 2014 as medical advisor and later medical lead in diabetes in Nordic-Baltic region and he is currently working in Sanofi's head office in Paris as a global medical head of Sanofi's Established Products franchise including e.g. diabetes and CV products .

Björn Eriksson

Director General, MPA

Björn Eriksson has served as Director General of the Swedish Medical Products Agency, MPA, since 2021. He has served as a member of the management board of the MPA since 2018. Earned his medical degree with a speciality in Cardiology and a PhD in Cardiology and Clinical physiology from Karolinska Institute. He has held clinical and research positions at Karolinska University hospital (1996-2005) and he has been working with clinical research in the pharmaceutical industry (2005-2010).

Managerial experience includes being head of clinical departments in Östersund and at Akademiska University hospital in Uppsala. In 2013 he was appointed Regional County Director for Region Jämtland-Härjedalen and thereafter Hospital Director for Skåne University hospital, Lund and Malmö. During the first year of SARS Covid-19 pandemic, he served as Health Care Director in Stockholm. In the EU regulatory network, he is a member of the EMA Management Board and a member of the HMA Management Group where he has special responsibilities- for clinical trials.

Juan Garcia Burgos

Head of Public and Stakeholders Engagement Department, EMA

Juan García Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences.

In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.

Diego Pernas

Head of communications and PR (AEMPS)

Diego Pernas holds a degree in Communication Sciences from the University of Santiago de Compostela (ES) and has developed his professional career in various media and communication departments. Since 2019 he is Head of communications of Spanish Agency of Medicines and Medical Products (AEMPS), Chair of the Working Group of Communication Professionals (WGCP) of HMA and member of the HMA/EMA Task Force on the Availability of Authorised Medicines (TF-AAM) on the Thematic Working Group on Communication

Yngvil Knudsen

Communication adviser, NoMA

Yngvil Knudsen works as a communication adviser at The Norwegian Products Agency (NoMA).

Member of the Working group of Communication Professionals (WGCP) in the network with representatives from the National Competent Authorities (NCA) and EMA.

Co-chair for the thematic working group 2 on communication in the HMA/EMA task force on availability of the authorized medicines for human and veterinary use.

Master's degree in Media and Communication Studies from the University of Oslo with previous work experience in journalism.

Anthony Lostracco

Manager of the Drug Shortages Unit, Health Canada

Anthony Lostracco has been the manager of the Drug Shortages Unit within Health Canada for the past four years. During this time, he has worked to detect and mitigate drug shortages and to establish policies for their prevention and more effective management. Before this role, Anthony was a GMP inspector for over ten years. Prior to joining the government, he spent a decade in various quality and production roles in the industry. Anthony holds a degree in Chemical Engineering.

María Lamas

Executive Director, AEMPS

María Jesús Lamas Díaz is executive director of the Spanish Agency for Medicines and Medical Devices (AEMPS) since 2018 and, as such, she is responsible for its direction, management, and coordination of actions. She is also a member of the network of Heads of European medicine agencies (HMA) and the Management Board of the European Medicines Agency (EMA). Furthermore, she is the representative of Spain in the HERA Board (European Health Emergency Preparedness and Response Authority), and it should be noted that she represents Spain on the Steering Board of the European Vaccine Strategy led by the European Commission. She is a member also of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and its equivalent in Medical Devices (MDSSG), both aimed to prevent and manage the shortages of medicines and medical devices, respectively. In the field of health technology assessments, she is a member of the Heads of HTA Agencies Group (HAG). She leads several working groups within the regulatory network. She got a Ph.D. in Pharmacogenetics from the University of Santiago de Compostela, she is a clinical specialist in hospital pharmacy and holds a certificate in clinical oncology pharmacy from the Board of Pharmaceutical Specialties (BPS) and the American Pharmaceutical Association (APhA). Until she took over the direction of the AEMPS, she was the head of the Pharmacy department at the University Hospital in Santiago de Compostela. During her clinical career, she funded her research Group on Pharmacology at the Health Research Institute (IDIS – ISCIII), where she also coordinated the Platforms and Methodology Area. Formerly, she was Director of Research at the learned Spanish Society of Hospital Pharmacy (SEFH) from 2012 to 2016.