EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework

16-17 April 2024
Hybrid meeting - WebEx/Room 1D, EMA, Amsterdam

Background and objectives

There is renewed international interest in the use of psychedelic substances as potential treatments for various mental health conditions, such as treatment-resistant depression, addictive disorders, post-traumatic stress disorder, and end-of-life psychological distress.

This multistakeholder workshop will bring together patients, healthcare professionals, academia, regulators, and industry to discuss the development and therapeutic use of psychedelic substances to address unmet medical needs in the area of mental health. These interdisciplinary discussions will cover a range of important topics including research methodology, regulatory processes and requirements and the relevance of real-world data.

The aims of the workshop are to:

- Hear the views of stakeholders and experts on the therapeutic potential of psychedelics;
- Provide further clarity on defining the safe and effective use of psychedelics;
- Inform on regulatory challenges associated with the development and evaluation of psychedelic medicines;

- Define how the current EU regulatory framework can be applied to support the research and development of psychedelic medicinal products.

Participation in this multistakeholder event will be by invitation only, but all those interested are welcome to follow the live broadcast. A video recording will be published after the event.

Multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework

Day 1 – 16 April 2024, 13:00 – 18:00 (CEST)

Chaired by Steffen Thirstrup (EMA)

12:45 Joining and technical checks

13:00 Welcome and opening speech

Opening remarks from EMA Executive Director **10'**
Emer Cooke (EMA)

Outline of the day and objectives **10'**
Steffen Thirstrup (EMA)

13:20 Session 1: From development to patient use: opportunities & challenges

Chair: Pavel Balabanov (EMA)

European regulatory perspective of psychedelic drugs in psychiatry **10'**
Marion Haberkamp (BfArM)

Australian regulatory perspective of psychedelic drugs in psychiatry **10'**
Robyn Langham (TGA)

American regulatory perspective of psychedelic drugs in psychiatry **10'**
Marta Sokolowska (FDA)

Legal status of psychedelics and impact in research and development **10'**
Tadeusz Hawrot (PAREA)

Challenges with Health technology assessment after approval **10'**
Carlos Martín Saborido (MISAN)

National experience with medical use of psychedelics **10'**
Jiří Horáček (NUDZ)

14:40 Q&A

Questions from the audience **30'**

15:10 Coffee break

15:40 Panel discussion: perspectives from multi-stakeholders

Facilitator: Pavel Balabanov (EMA)

Panel discussion **65'**

Additional panellists:

Ian Roullier (PsyPAN)
Geert Dom (EPA)
Nanco Hefting and Guy Goodwin (EFPIA)
Liesbeth Vandam (EMCDDA)
Suzanne Dickson (EBC)
Kathy Soltys (HealthCanada)

Interventions from the audience **60'**

17:45 Closing remarks

Wrap up **10'**

Steffen Thirstrup (EMA)

18:00 End of Day 1

Multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework

Day 2 – 17 April 2024, 09:30 – 16:00 (CEST)

Chaired by Steffen Thirstrup (EMA)

09:15 Joining and technical checks

09:30 Welcome and opening remarks

Outline of the day **5'**
Steffen Thirstrup (EMA)

09:35 Session 2: Trial design for psychedelic assisted therapies

Chair: Bruno Sepodes (CHMP)

Identification of methodological issues and how to overcome them **10'**
Gitte Knudsen (University of Copenhagen)

Panel discussion: **40'**
Kim Kuypers (Maastricht University)
Tomáš Páleníček (NUDZ)
Carolina Seybert (Champalimaud Foundation)

10:30 Coffee break

11:00 Q&A and discussion

Questions from the audience **60'**

12:00 Lunch

13:00 Session 3: Ensuring safe and effective real world use

Chair: Sabine Straus (PRAC)

What are the safety and efficacy considerations for potential approval?

Drawing from ongoing trials and existing clinical experience **10'**
Ewa Bałkowiec-Iskra (Medical University of Warsaw)

Set and setting research: potential implications for future approval **10'**
Maria Beckman (Karolinska Institute)

Psychedelic treatments; questions from clinical research and implementation **10'**
Robert Schoevers (University Medical Center Groningen)

Clinical experience learned from approved esketamine and potential implications for psychedelics **10'**
Philip Gorwood (University of Paris-Cité, Sainte-Anne Hospital, France)

What can patient and public involvement in research contribute to safe and effective use? **10'**
Isabel Dziobek (HU Berlin)

14:00 Coffee break

14:30 Q&A and discussion

Questions from the audience **60'**

15:30 Next steps towards a regulatory framework and closing remarks

Chair: Steffen Thirstrup (EMA)

Remarks by session chairs **20'**
Pavel Balabanov (EMA)
Bruno Sepodes (CHMP)
Sabine Straus (PRAC)

Wrap up **10'**
Steffen Thirstrup (EMA)

16:00 End of workshop

List of speakers

Emer Cooke	European Medicines Agency
Steffen Thirstrup	European Medicines Agency
Pavel Balabanov	European Medicines Agency
Marion Haberkamp	Federal Institute for Drugs and Medical Devices
Robyn Langham	Therapeutic Goods Administration
Marta Sokolowska	Food and Drug Administration
Tadeusz Hawrot	Psychedelic Access and Research European Alliance
Carlos Martín Saborido	Ministry of Health of Spain
Jiří Horáček	National Institute of Mental Health
Ian Roullier	Psychedelic Participant Advocacy Network
Geert Dom	European Psychiatric Association
Nanco Hefting	European Federation of Pharmaceutical Industries and Associations
Guy Goodwin	European Federation of Pharmaceutical Industries and Associations
Liesbeth Vandam	European Monitoring Centre for Drugs and Drug Addiction
Suzanne Dickson	European Brain Council
Kathy Soltys	Health Canada
Bruno Sepodes	Committee for Medicinal Products for Human Use
Gitte Knudsen	University of Copenhagen
Kim Kuypers	Maastricht University
Tomáš Páleníček	National Institute of Mental Health
Carolina Seybert	Champalimaud Foundation
Sabine Straus	Pharmacovigilance Risk Assessment Committee
Ewa Bałkowiec-Iskra	Medical University of Warsaw
Maria Beckman	Karolinska Institutet
Robert Schoevers	University Medical Center Groningen
Philip Gorwood	GHU Paris Psychiatrie et Neurosciences
Isabel Dziobek	Humboldt University of Berlin

About the speakers

Emer Cooke

Executive Director, European Medicines Agency

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.

Steffen Thirstrup

Chief Medical Officer, European Medicines Agency

Steffen Thirstrup is a medical doctor with a PhD in pharmacology and broad clinical experience in general internal medicine. He has a track record of working with the EU regulatory network. He previously led the Division for Medicines Assessment and Clinical Trials at the Danish Health and Medicines Authority and was the Danish member of EMA's human medicines committee (CHMP). He was also a member of EMA's Committee for Advanced Therapies (CAT), the Chairperson of the CHMP's Respiratory Drafting Group and Co-Chair of the European Commission Working Group on Market Access of Biosimilars.

Prof. Thirstrup is Affiliate Professor at the University of Copenhagen and has worked across a broad range of therapeutic areas throughout different stages of medicine development. Before joining EMA, Prof. Thirstrup worked at the pharmaceutical consultancy company NDA Group, first as a medical advisor and from April 2014 as a board director.

Since June 2022 Prof Thirstrup has been the Chief Medical Officer at the European Medicines Agency, Amsterdam, The Netherlands.

Prof Thirstrup is author of more than 40 scientific papers, guidelines and text-book chapters as well as co-editor of 5th edition of Basal og Klinisk Farmakologi (Medical school pharmacology textbook in Danish).

Pavel Balabanov

Head of office for Therapies for Neurological and Psychiatric Disorders, European Medicines Agency

As an experienced clinical neurologist with a PhD, Pavel Balabanov transitioned from a consultant role in Bulgaria to a regulatory neuroscience expert, and then to leading the EMA's office for Neurological and Psychiatric Disorders therapies. His EMA tenure includes leading the process for drafting guidelines for new drugs targeting Multiple Sclerosis, Duchenne Muscular Dystrophy, and ALS.

Dr Pavel Balabanov has fostered stakeholder collaboration through workshops on drug development and clinical trials. Formerly, he was engaged at neurological product management at EMA, and contributed to the EMA's Scientific Advice section, guiding applicants to align with regulatory standards.

Marion Haberkamp

Head of Unit Neurology, Psychiatry, Ophthalmology, Federal Institute for Drugs and Medical Devices, Germany

Dr.med. Marion Haberkamp is a medical doctor and board certified specialist in internal medicine with a neurological and psychiatric background. After working as a clinical senior assessor in the field of CNS, she has been Head of the Unit Neurology, Psychiatry and Ophthalmology at the Federal Institute of Drugs and Medical devices (BfArM) in Bonn, Germany since 2017. As a member of the Central Nervous System Working Party (CNSWP) at the European Medicines Agency (EMA) in Amsterdam, she is involved in the drafting of regulatory guidelines. As a long-standing former member and now expert of the Scientific Advice Working Party (SAWP) she has experience in providing centralised advice on neurological and psychiatric drug developments and has participated in multiple qualification procedures on innovative methods in the context of research and development.

Robyn Langham

Chief Medical Adviser of the Therapeutic Goods Administration, Australia

Professor Langham is the Chief Medical Adviser of the Therapeutic Goods Administration in Australia. She is a nephrologist and clinician researcher, focusing on drug development of novel anti-inflammatory and anti-fibrotic agents. Professor Langham is also a director of the Australian Medical Council and chairs the Human Research and Ethics Committee at the Royal Children's Hospital in Melbourne.

Marta Sokolowska

Deputy Center Director for Substance Use and Behavioral Health, US Food and Drug Administration's Center for Drug Evaluation and Research, United States of America

Marta Sokolowska, Ph.D., is the Deputy Center Director for Substance Use and Behavioral Health in US Food and Drug Administration's Center for Drug Evaluation and Research. She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs.

Dr. Sokolowska joined FDA in 2018. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Tadeusz Hawrot

Founder and Executive Director, Psychedelic Access and Research European Alliance

Tadeusz is dedicated to advancing brain health and has over 15 years of experience collaborating with European Union institutions. He has led policy and advocacy initiatives for organizations such as the European Brain Council and the European Federation of Neurological Associations.

He firmly believes in the power of partnerships and has been instrumental in establishing various alliances at both national and international levels.

His work extends beyond Europe, having collaborated with global organizations like the WHO. Tadeusz has played a key role in the formation of the OneNeurology global partnership and contributed to the WHO's global action plan on neurological conditions.

As the Founder and Executive Director of the Psychedelic Access and Research European Alliance (PAREA), Tadeusz is dedicated to driving systemic change in Europe's healthcare system. He is passionate about addressing the urgent, unmet needs in mental health by investigating the therapeutic potential of psychedelics.

Carlos Martín Saborido

Advisory member, Ministry of Health, Madrid, Spain

Dr Martín Saborido is a Health Economist working on HTA economic evaluation and RWE applied to HTA. He has been working as research associate at the Spanish Health Technology Assessment Agency mainly doing HTA reports and in the Regional HTA Unit in Madrid as health economics research fellow. Internationally, Dr Martin has been working in the Liverpool Review and Implementation Group (University of Liverpool) in UK assessing economic evaluations on behalf of NICE and doing HTA reports for the NIHR Health Technology Assessment programme. He worked as Public Health Economist in the Joint Research Centre (European Commission) developing economic evaluations in the public health frame. At the private sector, he worked at several Pharma Consultancies as RTI Health Solutions and World Health Management. In the academic ground, he has lectured Statistics, Research Methods and Economic Evaluation of Health Technologies, mentoring and guiding several PhD and MSc thesis. In 2020 gained a permanent position as Scientific Officer in the Department of Health Economics at the National School of Public Health in Madrid. In April 2021 was appointed as Advisory member at the Ministry of Health in the Area of Pharmacy, working on strategy and innovation of pharma policy and price & reimbursement.

Jiří Horáček

Head of the Centre for Advanced Studies of Brain and Consciousness, National Institute of Mental Health, Klecany, Czechia

Prof. MUDr. Jiří Horáček, Ph.D. is the Head of the Department of Psychiatry and Medical Psychology at the 3rd Medical Faculty of Charles University and the Head of the Centre for Advanced Studies of Brain and Consciousness at the National Institute of Mental Health (NIMH). He is a researcher, psychiatrist and psychotherapist. He also currently holds the position of President of the Czech Neuropsychopharmacological Society (CNPS). Prof. Horáček acted as coordinator for mental health agenda during the Czech Presidency of the Council of the European Union (CZ PRES) in 2022.

His research activities include the study of psychedelics, theory of consciousness and brain imaging, and treatment options for depression and existential distress in cancer patients and in palliative care. He has edited several books and authored more than 200 scientific articles.

Prof. Jiří Horáček has received several international awards, including. "Senior Research Fellow of the Bedfordshire CMHR in association with the University of Cambridge".

Ian Roullier

Co-founder, Psychedelic Participant Advocacy Network, London, United Kingdom

Ian Roullier is the co-founder of the Psychedelic Participant Advocacy Network (PsyPAN). Ian's participation in clinical trials run by Imperial College (2015) and King's College (2019), both examining the effect of psilocybin on depression, naturally led to his dedication to helping destigmatise these treatments and safeguard participants receiving them. PsyPAN works with organisations providing psychedelic-assisted therapy to draw upon the vast lived experience of participants and help create a sector-wide model of best practice with participant wellbeing placed at its heart. PsyPAN also aims to provide much-needed community and connection for people who have received these treatments. Ian's advocacy work has included giving public talks alongside Dr. Rosalind Watts (Imperial College/ACER Integration), addressing MEPs and policy makers at the European Parliament and having his journey featured on Oprah, the BBC and in Michael Pollan's bestseller 'How To Change Your Mind'. Ian is also part of the King's College PsiDeR trial steering committee and an ACER Integration sharing circle facilitator.

Geert Dom

President, European Psychiatric Association (EPA)

Prof. dr. Geert Dom is professor of psychiatry at the University of Antwerp and the medical director of the psychiatric center Multiversum, Boechout, Belgium. He is the current president of the European Association of Psychiatry (EPA) and the immediate past-president of the European Federation of Addiction Societies (EUFAS). His research and teaching focusses on the pathogenesis and treatment of addictive disorders and public mental health interventions.

Nanco Hefting

Chief Specialist in Global Clinical Development, Therapeutic Area Psychiatry, H. Lundbeck A/S, Copenhagen, Denmark

Nanco Hefting is employed as Chief Specialist in Global Clinical Development, Therapeutic Area Psychiatry at H. Lundbeck A/S, Copenhagen, Denmark. In his capacity as clinical lead for development projects, he is deeply involved in the design, conduct and reporting of Phase II-IV clinical trials and regulatory interactions in the field of psychiatry, particularly in depression.

Nanco represents the European Federation of Pharmaceutical Industry Associations (EFPIA) as a member of their Clinical Research Expert Group (CREG). In addition, he is member of the Executive Committee of the International Society for CNS Clinical Trial Methodology (ISCTM) and a member of the American Society for Clinical Psychopharmacology (ASCP).

Guy Goodwin

CMO, Compass pathways, Emeritus Professor of Psychiatry at the University of Oxford, UK

Guy Goodwin is CMO, Compass pathways and Emeritus Professor of Psychiatry at the University of Oxford, UK. His research interests are the treatment of mood disorder and the potential to improve treatment using new technology and new drugs, notably the psychedelics.

He is a Fellow of the American College of Neuropsychopharmacology, has previously held the position of President of the British Association for Psychopharmacology and the European College of Neuropsychopharmacology (ECNP).

Liesbeth Vandam

Head of Support to Policy Sector, European Monitoring Centre for Drugs and Drug Addiction, Portugal

Liesbeth Vandam holds a master's degree in European criminology and criminal justice systems and a PhD in Criminology, focusing on drug use among released prisoners (Ghent University, Belgium).

Liesbeth joined the EMCDDA in 2011 as scientific analyst and since 2017 has been head of the support to policy sector within the EMCDDA's public health unit.

She has (co-)authored several scientific publications on illicit drug monitoring, cannabis policies, drugs and prison, drug policy evaluation and drug related crime.

Suzanne Dickson

President, European Brain Council, Brussels, Belgium

Suzanne L Dickson is a neurobiologist and Professor of Neuroendocrinology at the University of Gothenburg. She is President of the European Brain Council and Secretary of the European College for Neuropsychopharmacology. She advocates for the strengthening of European partnerships in brain research, through increased support, knowledge exchange and stakeholder engagement, in order to make

advances that can help the 179 million Europeans living with a brain disorder, mental and neurological alike.

She graduated with a Ph.D. in Neuroendocrinology from the University of Cambridge in 1993, where she later became Senior Lecturer in Physiology. She is a leading figure in neuroendocrinology and works within many European Union and international organisations and societies to promote research, facilitate grant funding and training of Early Career Scientists. Her research employs neural circuit mapping techniques to unravel the neurobiology of appetite, of relevance for eating disorders at both ends of the body weight spectrum.

Katherine Soltys

Director, Office of Clinical Trials, Pharmaceutical Drugs Directorate, Health Products and Food Branch, Health Canada

Dr. Soltys is the Director of the Office of Clinical Trials in the Pharmaceutical Drugs Directorate of the Health Products and Food Branch, at Health Canada. In this role, she oversees all activities related to the approval and pharmacovigilance of clinical trials involving pharmaceuticals in Canada, as well as Health Canada's Special Access Program. She also represents Health Canada internationally as a member of ICH and the ACCESS Consortium.

Before joining the Office of Clinical Trials in 2022, Dr. Soltys served as Director, Marketed Pharmaceuticals Bureau where she was responsible for the post-market surveillance of prescription pharmaceuticals in Canada. Prior to that, Dr. Soltys served as an Oncology Medical Evaluator, and then Manager, in the pre-market Oncology Pharmaceutical Review Division of Health Canada. In this role, Dr. Soltys represented Health Canada on several international regulatory initiatives regarding Patient Reported Outcomes, including the SISAQOL Consortium (Setting International Standards for the Assessment of Quality of Life data), led by the EORTC (European Organization for the Research and Treatment of Cancer). Dr. Soltys has also co-authored several peer-reviewed publications in this area.

Dr. Soltys received her MD degree and completed her post-graduate training at the University of Saskatchewan. She also completed a Post Graduate Certificate in Pharmacoepidemiology and Pharmacovigilance at the London School of Hygiene and Tropical Medicine. In addition to her regulatory work, Dr. Soltys maintains part time clinical practice at The Ottawa Hospital Cancer Centre, with a focus on the care of patients with lung cancer and gastrointestinal cancer.

Bruno Sepodes

Vice-Chair of the CHMP, Co-Chair of ETF

Full Professor of Pharmacological Sciences (Universidade de Lisboa, Portugal). In 2008 joined the COMP as member nominated by the EC under EMA recommendation, and between 2012 and 2018 was the Chair of the COMP. After joining the CHMP in 2012, Bruno became Vice-Chair of this Committee in 2018, currently serving his second mandate. Since 2019, Bruno is a member of the ICH Assembly representing EC Europe and in 2022, became Co-Chair of ETF at EMA.

Gitte Moos Knudsen

Clinical Professor and Chief Physician, University of Copenhagen, Denmark

Gitte Moos Knudsen, Professor in neurobiology, neurologist, Chair Neurobiology Research Unit, Copenhagen University Hospital Rigshospitalet, Copenhagen, Denmark. Director of BrainDrugs Alliance. Past-president of the European College of Neuropsychopharmacology (ECNP) and chair of the ECNP thematic working group on psychedelics. I am a translational neurobiologist and clinical neurologist with interest in advanced methodological developments that I subsequently apply in my research to address pertinent neurobiological and clinical issues. My scientific interests include blood-brain barrier transport, neurobiology with particular emphasis on molecular brain imaging and pharmacological interventions. My lab has a particular research focus on experimental medicine and neuropharmacology, addressing pertinent and basic questions regarding human brain disease mechanisms and prediction of brain responses to categories of neuromodulatory interventions as well as treatment efficacy. For this purpose, we use PET brain scanning to image brain receptors and receptor occupancy, and fMRI to evaluate drug effects on the brain hemodynamic response as well as the brains regional interactions, i.e., functional connectivity. BrainDrugs started in 2019, is based on a Lundbeck Foundation grant, and is a precision medicine alliance focusing on major depression and epilepsy.

Kim Kuypers

Associate Professor, Maastricht University, Netherlands

Kim PC Kuypers is affiliated with Maastricht University's Faculty of Psychology and Neuroscience as an Associate Professor. Her research focuses on the neurobiology of flexible cognition, empathy, and well-being. She uses a psychopharmacological model to study the effects of psychedelics on these behaviors and their underlying biology, spanning short-term, medium-term, and long-term impacts. Next to that she also conducts surveys to understand motivations, experiences, and patterns of psychedelic use. In the future, Kim aims to focus on identifying biological markers of positive responses to psychedelics but also to understand the impact of nutritional interventions on mental wellbeing. Her ultimate goal is to contribute to personalized understandings of the relationships between psychedelics, nutrition, and mental well-being.

Tomáš Páleníček

Head of Psychedelic Research Centre, National Institute of Mental Health, Czech Republic

Dr Páleníček completed his MD at the 3rd Faculty of Medicine at Charles University (The Czech Republic) in 2001 and obtained his PhD in 2009 in neuroscience at the same university. In 2010 he obtained certification in electroencefalography (Clin. Neurophysiol. and Neurological Soc.ČLS JEP) and since 2012 he has been licensed in psychiatry (no. MU-LF-0054-ZO).

Tomas Palenicek, MD, PhD, began his career in 2001 at the former Prague Psychiatric Center in preclinical research focusing on the neurobiology of psychedelics such as LSD, psilocin, mescaline, 2C-B and MDMA, and on the neurobiology of psychosis in animal models. He has been trained in psychiatry and clinical electroencephalography (EEG) and has contributed to the pilot clinical research with ketamine. During the last decade, he has been the principle investigator in the first projects performed in the Czech Republic to

study the acute effects of cannabis and psilocybin in healthy volunteers, and has been involved in studies with ketamine in depressed patients. His research expertise is mainly focused on behavioural pharmacology, electrophysiology and subsequent analysis of brain activity. He is currently leading a team of young scientists from the National Institute of Mental Health in the Czech Republic, investigating the neurobiology of how psychedelics, cannabinoids and other psychoactive substances affect brain processing, emotionality, cognitive function and music - from cell cultures to human experiments. Currently, as the principal investigator, he is working on several projects that aim to evaluate the therapeutic potential of psychedelics psilocybin, ketamine and MDMA in the Czech Republic. His research also received several international awards and he has presented the results of his research at several prestigious international conferences.

Carolina Seybert

Clinical Psychologist, Champalimaud Foundation, Lisbon, Portugal

Carolina Seybert graduated as a clinical psychologist from the Instituto Universitário de Ciências Psicológicas, Sociais e da Vida (ISPA) in Lisbon. She concluded her doctoral studies at the University of Ulm, Germany, where she studied psychotherapy processes and techniques form different therapy approaches. As part of this study, she spent a year at the Massachusetts General Hospital in Boston (MGH-Harvard Medical School) conducting an in-depth analysis of psychotherapy sessions and outcomes. She later returned to the USA and trained in psychotherapy at the Washington Centre for Psychoanalysis in Washington DC, USA. She completed her post-doctoral work while comparing CBT and psychodynamic interventions for depression at the International Psychoanalytic University in Berlin.

After returning to Portugal in 2018, she taught at the ISPA in Lisbon and completed a second post-doctoral work at the Neuropsychiatry Unit, Clinical and Research Centres of the Champalimaud Foundation, where she currently works as a clinical psychologist. It was there that she developed an interest onthe safety and efficacy of treatments with psychedelics and psychological interventions. Her current research seeks to understand the role of psychological interventions on psychedelic treatment and long-term outcomes as well as the safety and efficacy of psychedelics.

Sabine Straus

PRAC chair, Medicines Evaluation Board, Netherlands

Dr. Sabine Straus has been with the Medicines Evaluation Board (MEB) in the Netherlands since 1997, where she started as an assessor Pharmacovigilance.

Prior to working at the MEB she held different positions in the pharmaceutical industry, the last one as medical director. She holds a PhD from the Erasmus Medical Center in Rotterdam (title "Drugs, Qtc prolongation and sudden cardiac death"). Since the start of the Pharmacovigilance Risk Assessment Committee (PRAC) in 2012 she has been the Dutch PRAC member and staff member at the MEB. In that period she co-chaired the Signal Management Review Team (SMaRT), and has been active in several drafting groups for guidance and guidelines. Since 2018 she chairs the PRAC.

In addition to her work at the MEB she holds a position as associate professor at the Erasmus Medical Center, department of Medical Informatics in Rotterdam.

Ewa Bałkowiec-Iskra

Associate Professor, Medical University of Warsaw, Poland

Ewa Balkowiec-Iskra graduated from the Medical University of Warsaw, earning an M.D. degree in 2000, followed by Ph.D. (with distinction) and D.Sc. degrees in Pharmacology in 2004 and 2011, respectively.

Throughout her entire academic career, she has been associated with the Department of Experimental & Clinical Pharmacology, where she currently holds the positions of Associate Professor with Habilitation and Head of the Laboratory of Pain Neuropharmacology. She completed specialization in Psychiatry in the Division of Psychiatry of the Nowowiejski Hospital in Warsaw.

Since 2017 she has been a CHMP and SAWP member, since 2022 – ETF and CNSWP member and CNSWP Vice Chair.

She has been closely involved in activities of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, serving as: an external expert (since 2006), a member of the Medicinal Products Committee (since 2013), a chair of the Medicinal Products Committee (since 2021), and a member of the scientific advisory board for the periodical 'Almanach' (since 2016).

Maria Beckman

Senior Researcher, Karolinska Institutet, Sweden

Maria Beckman is a licensed clinical psychologist with a PhD in medical science. She works at the Centre for Psychiatry Research at the Department of Clinical Neuroscience at Karolinska Institutet in Stockholm. Her research is mainly about the relationship between therapist and patient in-session behaviors and outcomes, and quality assurance and implementation of evidence-based psychotherapy methods. She works with the psychotherapeutic framework in two Swedish trials with psilocybin for depression together with Professor Johan Lundberg (PSIPET and CAPSI), and in two upcoming trials together with associate professor Dea Siggaard Stenbæk at the Copenhagen University Clinic for Psycheldelic Research.

Robert Schoevers

Head of Dept. of Psychiatry at University Medical Center Groningen, Netherlands

Robert Schoevers is professor and head of the University Center for Psychiatry at University Medical Center Groningen, and director of the interdisciplinary Research School of Behavioural and Cognitive Neurosciences (BCN).

Being trained as an MD and psychiatrist at Amsterdam UMC, he became a specialist in the field of epidemiology and treatment of mood disorders and has authored over 400 scientific publications. At the UMCG he pioneered generic oral esketamine treatment for severe depression since 2014, and now leads several national studies looking at both efficacy, working mechanisms and patient experiences and maintenance oral esketamine treatment, seeking to optimise patient outcomes and potentially providing evidence for subsequent formal registration. His psychedelic treatments and mechanisms research group is the leading site for clinical psychedelic research in the Netherlands. Together with an international consortium of clinicians, researchers, patients and carers and health advocacy organisations prof. Schoevers recently initiated the

PsyPal study (psilocybin therapy for psychological distress in palliative care patients) funded by EU Horizon. In the Netherlands, he is building the Psynapse consortium that seeks to accelerate innovation in psychiatric treatments. In addition to his work as a psychiatrist, he has been a mental health advocate, wrote a book on depression together with an expert by experience and has previously made documentaries and TV programs on medical subjects and mental health.

Philip Gorwood

Professor, GHU Paris Psychiatrie et Neurosciences, Sainte-Anne Hospital, France

Professor Gorwood studied medicine from 1982-1988, and specialised in psychiatry in 1988. He is currently full Professor of Psychiatry at GHU Paris Psychiatrie et Neurosciences, in Sainte-Anne Hospital and Head of the CMME department [60 beds], teaching at the University of Paris Cité. He is also Head of one team research at the Institute of Psychiatry and Neuroscience of Paris devoted to the genetic vulnerability of psychiatric and addictive disorders. Professor Gorwood has published over 350 scientific articles (h-index=52) and has been quoted as the presently "most frequently quoted French psychiatrist" (Ioannidis et al., 2019). He has served on 16 editorial boards for journals in psychiatry, neuroscience and genetics, and was editor-in-chief of the journal European Psychiatry (IF=3.9), from 2005 to 2017. He is the past-president (2021-2023) of the European Psychiatric Association (EPA). In 1992, Professor Gorwood received the Lilly 'First Communication' award and later in 1997, the French Association for Biological Psychiatry 'Best Communication of the Year' award. In 1999, he received the Association of European Psychiatry 'Young Researcher' award; in 2000 the French National Academy of Medicine for the best research on addiction, and in 2016 the FONDAMENTAL award as the best researcher of the year in psychiatry.

Isabel Dziobek

Head of Department of Clinical Psychology of Social Interaction and Outpatient Clinic for Psychotherapy, Humboldt-Universität zu Berlin, Germany

Isabel Dziobek's interests and works lie in the field of social cognitive and affective neuroscience of mental disorders, the development of targeted diagnostics and interventions as well as patient and public engagement.

Prof. Dziobek got her diploma in Psychology from University of Bochum and her diploma thesis focussed on the effects of MDMA on cognition. She continued to do a Ph.D. in cognitive neuroscience at the New York University School of Medicine from 2001-2005, followed by a postdoctoral fellowship at the Max Planck Institute for Human Development in Berlin. From 2009-2014 she headed the junior research group "Understanding Interaffectivity" at Freie Universität Berlin, followed by an associate professorship for Social Cognition in 2014 at the Berlin School of Mind and Brain at Humboldt-Universität zu Berlin. Since 2018 she is full professor of Clinical Psychology of Social Interaction at the Institute of Psychology at HU Berlin and head of the outpatient clinic for psychotherapy.

Prof. Dziobek has published more than 150 scientific papers in peer-reviewed journals and has co-authored several works on the socio-emotional effects of psychedelics. She is PI and head of the Center for Patient and Public Involvement at the German Center for Mental Health (DZPG), has conducted numerous multicenter third-party funded studies and received several awards for her work, among others the Charlotte and Karl-Bühler Price of the German Society for Psychology in 2014.