EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 November 2012
EMA/749769/2012
Directorate

Speaker biographies

Workshop on clinical-trial data and transparency, 22 November 2012

Table of contents

Peter Høngaard Andersen 2
Virginia Barbour 3
Giovanni Buttarelli 4
Hans-Georg Eichler 5
Susan Forda 6
Ben Goldacre 7
Peter C Gøtzsche 8
Gerhard Otto Grill 9
François Houÿez 11
Guido Rasi 12
Mark Walport 13

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8545
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Peter Høngaard Andersen

Dr Peter Høngaard Andersen is Senior Vice President of External Scientific Relations & Patents at H. Lundbeck A/S. Lundbeck is a CNS focussed Pharmaceutical Company headquartered in Copenhagen, Denmark.

Dr Andersen was employed in Lundbeck R&D in 1999 and was until 2011 Executive Vice President of Research. Prior to joining Lundbeck he was Vice President and Director of Drug Discovery in Acadia Pharmaceuticals and prior to that he held various positions at Novo Nordisk from 1983-1997, latest as Corporate Project Director.

Dr Andersen has been involved in start-up of a number of biotech's in Medicon Valley over the years. Currently, he is Chairman of the Board of Directors in the Biotech Research & Innovation Centre in Copenhagen, Epitherapeutics Aps and Prexton Therapeutics SA. He is Chair of the Research Directory Group in EFPIA and is member of the Innovative Medicine Initiative Governing Board.

Dr Andersen holds degrees in chemistry, biochemistry and medicine from University of Copenhagen.

Virginia Barbour

Dr Virginia Barbour was one of the founding co-editors of PLoS Medicine, and was appointed the journal's first Chief Editor in 2008. She is also Medicine Editorial Director at PLoS.

She studied Natural Sciences at Cambridge University, and then medicine at UCL and Middlesex Hospital School of Medicine, London. She gained a DPhil from Oxford University for research into globin gene regulation.

She is Chair of the Committee on Publication Ethics, and is a member of the Ethics Committee and a Director of the World Association of Medical Editors.

Her interests include open-access, the rigorous reporting of research and taking an evidence-based approach to the priorities of global health.

Giovanni Buttarelli

Giovanni Buttarelli (1957) has been Assistant European Data Protection Supervisor since January 2009. He was appointed by a joint decision of the European Parliament and the Council of 14 January 2009 for a term of five years.

Before entering his office, he was Secretary General to the Italian Data Protection Authority since 1997. Member of the Italian judiciary, he has attended to many committees on data protection and related issues at international level.

In 1984 he obtained ("cum laude") his Degree in Law at the University of Rome "La Sapienza". He previously served from 1976 at the Municipality of Frascati mainly as Head of two registry offices.

From 1984 to 1990 he collaborated with the Chair of Criminal Procedure at Rome University.

He has been a member of the Italian judiciary from 1986. From 1986 to 1990 he served at the Courts of Rome and Avezzano (here, as monocratic judge “pretore”).

From 1990 to 1997 he worked at the Legislation Department of the Italian Ministry of Justice where he contributed to drafting and following up many regulatory provisions, in particular concerning criminal law, criminal procedure and data protection. He was a member of several inter-Ministerial committees also concerning immigration, racial discrimination, Community fraud, de-criminalisation, reformation of tax, computer crime laws, and access to confidential records and digitalisation of public administrative agencies.

During the EU Italian Presidency period (1996), he chaired the European Union Council Working Group which drew up Directive no. 97/66/EC on the protection of privacy in the telecommunications sector.

In 1997, after the entry into force of the first Italian Data Protection Act, which he had contributed to drafting, he was appointed as Secretary General of the Italian Garante. He played an active role as a member of the Committee that drew up the 2003 Personal Data Protection Code..

In the 2002 to 2003 period he was the President of the Joint Supervisory Authority set up in pursuance of the Schengen Agreement, after being its Vice-President in 2000-2001.

The experience on data protection includes the participation in many bodies at European Union level (including Art. 29 Working Party, Art. 31 Committee of Directive n. 95/46/EC and Taiex programs), and at the Council of Europe (in particular, also as a consultant, T-PD; CJ-PD, DH-S-Ac, Venice Commission), as well as the contribution to many hearings, meetings and workshops held also by Parliaments and to specialized book journals and papers.

He currently teaches on privacy at the Lumsa University, Rome.

Hans-Georg Eichler

Hans-Georg Eichler, M.D., M.Sc., is the Senior Medical Officer at the European Medicines Agency in London, United Kingdom, where he is responsible for coordinating activities between the Agency's scientific committees and giving advice on scientific and public health issues. From January until December 2011, Dr Eichler was the Robert E. Wilhelm fellow at the Massachusetts Institute of Technology's Center for International Studies, participating in a joint research project under the MIT's NEWDIGS initiative. He divided his time between the MIT and the EMA in London.

Prior to joining the European Medicines Agency, Dr Eichler was at the Medical University of Vienna in Austria for 15 years. He was vice-rector for Research and International Relations since 2003, and professor and chair of the Department of Clinical Pharmacology since 1992. His other previous positions include president of the Vienna School of Clinical Research and co-chair of the Committee on Reimbursement of Drugs of the Austrian Social Security Association. His industry experience includes time spent at Ciba-Geigy Research Labs, U.K., and Outcomes Research at Merck & Co., in New Jersey.

Dr Eichler graduated with an M.D. from Vienna University Medical School and a Master of Science degree in Toxicology from the University of Surrey in Guildford, U.K.

He trained in internal medicine and clinical pharmacology at the Vienna University Hospital as well as at Stanford University.

Susan Forda

Dr Susan Forda trained as a pharmacist. After completing a PhD in neuropharmacology, she worked as a post-doctoral research fellow at St George's Hospital Medical School, University of London. She later joined Beecham, subsequently SmithKline Beecham Pharmaceuticals, as a regulatory associate in their Worldwide Regulatory Affairs Department. Over a period of nine years she held various positions. She was also, briefly, the UK affiliate's corporate affairs director.

Seventeen years ago she joined the Lilly European regulatory group. She is now responsible for all regulatory aspects of Lilly's current and future products outside the United States.

In May 2003 she was awarded an MSc in the Economic Evaluation of Healthcare.

Sue participates in industry association regulatory initiatives and is currently Chair of the European Federation of Pharmaceutical Industries and Associations (EFPIA) "Scientific, Regulatory Manufacturing Policy Committee".

Ben Goldacre

Ben Goldacre is a doctor, academic, writer and broadcaster.

He is currently a Research Fellow in Epidemiology at LSHTM, working on problems in clinical trials, and the use of electronic health records in trials research. He has previously been a research fellow at Nuffield College Oxford, and Kings College London NIHR Biomedical Research Centre.

He has written for the Times, the Telegraph, the BMJ, and wrote the Bad Science column in the Guardian for a decade. His work uses flaws in evidence presented by journalists, government reports, the pharmaceutical industry and alternative therapists to explain basic statistical and scientific concepts to a lay audience.

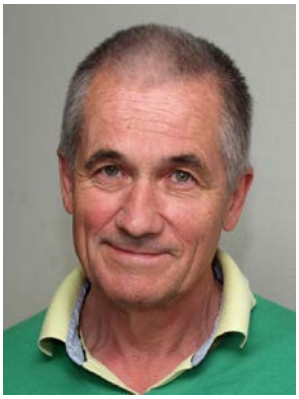
His first book Bad Science (2008) sold over 500,000 copies in 24 countries and reached #1 in the UK non-fiction charts. His second book Bad Pharma (2012) about the misuses of evidence in medicine has just been published. He has made various documentaries for Radio 4 and appeared on QI, Any Questions, Newsnight, Start The Week, the Today Programme, PM, and many more.

He also works on evidence based policy, and recently co-authored a Cabinet Office paper on increasing the use of randomised trials in UK government, winning an Institute for Government award. He has served on various panels and boards, including the NIHR Pharmaceutical Panel.

He studied preclinical medicine at Magdalen College, Oxford, leaving with a First in Physiological Sciences; and clinical medicine at UCL. He has an MA in Philosophy from Kings College London, an MSc in Epidemiology from London School of Hygiene and Tropical Medicine, and is a Member of the Royal College of Psychiatrists.

His work is archived at www.badscience.net and he is @bengoldacre on twitter with 230,000 followers.

Peter C Gøtzsche



Professor Peter C Gøtzsche graduated as a master of science in biology and chemistry in 1974 and as a physician 1984. He is a specialist in internal medicine; worked with clinical trials and regulatory affairs in the drug industry 1975-1983, and at hospitals in Copenhagen 1984-95. He cofounded The Cochrane Collaboration in 1993 and established The Nordic Cochrane Centre the same year. He became professor of Clinical Research Design and Analysis in 2010 at the University of Copenhagen.

Peter has published more than 50 papers in" the big five" (BMJ, Lancet, JAMA, Ann Intern Med and N Engl J Med) and his scientific works have been cited over 9,000 times. He is author of "Rational Diagnosis and Treatment. Evidence-Based Clinical Decision-Making" (2007) and "Mammography Screening: truth, lies and controversy" 2012).

Peter has an interest in statistics and research methodology. He is a member of several groups publishing guidelines for good reporting of research and has co-authored CONSORT for randomised trials (www.consort-statement.org), STROBE for observational studies (www.strobe-statement.org), PRISMA for systematic reviews and meta-analyses (www.prisma-statement.org), and SPIRIT for trial protocols (http://www.equator-network.org). Peter is an editor in the Cochrane Methodology Review Group.

Gerhard Otto Grill

Date of birth:

15 March 1959

Place of birth:

Altötting/Bavaria (Federal Republic of Germany)

Nationality:

German

University Education:

1979 - 1984 Studied law at the University of Munich; passed (on 22 January 1985) the "Erste Juristische Staatsprüfung" (first state examination), achieving the overall result "good" (13, 29 points)

1985/86 Studied European law at the College of Europe in Bruges/Belgium; passed the examinations, achieving the overall result: "excellent"; "Diploma of Advanced European Studies"

Legal Training:

Preparatory legal training ("Vorbereitungsdienst") from 10 October 1986 until 7 July 1989; passed (on 7 July 1989) the "Zweite Juristische Staatsprüfung" (second state examination), achieving the overall result "fully satisfactory" (9, 50 points)

Professional experience:

- Part-time assistant at the University of Munich (1 February 1985 - 31 August 1985; 1 June 1986 - 31 October 1988; 1 May 1989 - 31 August 1989)
- McKenna & Co Solicitors, London (1 September 1989 - 31 October 1990)
- Directorate-General Competition of the European Commission, Brussels (1 December 1990 - 31 May 1992)
- Legal Secretary of Advocate-General Lenz at the Court of Justice of the European Communities, Luxembourg (1 June 1992 – 6 October 1997)
- Directorate-General Competition of the European Commission Brussels (6 October 1997 – 14 April 1999)

- Office of the European Ombudsman, Strasbourg (since 15 April 1999); appointed Head of unit (2006) and Director (2011)

Other activities:

- Between 1984 and 1989 various posts at the Junge Europäer (Young Europeans – the youth group of the Europa-Union); from 1987 until 1989 chairman of the section Upper Bavaria
- Various speeches and lectures (in German, English and French) mainly on topics related to Community law (Luxembourg, Maastricht, Strasbourg, Vienna, St. Gallen, London, New York, Berlin, Dresden etc.)
- Lecturer in European law at the University of Saarbrücken (1995-1997 and 1998-2001)
- Since 1995 member of the Schriftleitung of the commentary on EU law edited by Messrs von der Groeben, Thiesing and Ehlermann (now Mr Schwarze)

Main publications:

- Commentary on the competition rules (Articles 81 - 86) of the EC Treaty [now Articles 101-106 TFEU], in: Carl-Otto Lenz (ed.), Kommentar zum EG-Vertrag, 1994 (5th edition 2010)
- Commentary on the rules on free movement or workers (Articles 39 – 41) of the EC Treaty, in : Von der Groeben/Schwarze (eds), Kommentar zum EU-/EG-Vertrag, 6th edition, 2003

Languages:

German, English, French, Italian

François Houÿez

François Houÿez is working at the European Organisation for Rare Diseases EURORDIS. He joined the Eurordis team in May 2003, and is Director of Health Policy, including services to Patients, European Legislation and actions in the field of public health for rare diseases.

He represents EURORDIS at the Patients' and Consumers' Working Party at the European Medicines Agency (EMA), topic leader on risk communication, and has been appointed external expert for the evaluation of marketing authorisation applications.

He pioneered patient advocacy with the European Medicines Agency as part of the first patients' delegation that engaged dialogue with the Agency back in 1996 and has continuously been involved in the agency activities during the last 16 years.

He has worked both as a volunteer and as an employee for a variety of organisations fighting AIDS at national and international levels.

A special emphasis of his work has been patients' rights advocacy. As such, he chaired the European Community Advisory Board and was involved in the discussions with sponsors of 77 clinical trials both at European or national level (as TRT5 scientific coordinator in France).

He leads the Eurordis "Drug Information, Transparency and Access" task force.

François is also a patient.

Guido Rasi

Professor Guido Rasi has been Executive Director of the European Medicines Agency since November 2011, and was a member of its Management Board in the three years prior to this. He was also Director-General of the Italian Medicines Agency from 2008 to 2011 and member of the Management Board from 2004 and 2008.

From 1990 to 2008 Professor Rasi worked in research at the Institute for Experimental Medicine of the National Research Council in Rome. He had a teaching and research experience at the University of California, Berkeley in 1999. He was made full professor of microbiology at the University of Rome 'Tor Vergata' in 2008.

Professor Rasi holds a degree in medicine and surgery, with specialisation in internal medicine, allergology and clinical immunology from the University of Rome. From 1978 to 1990, he worked as a physician in hospital, research and private practice.

Mark Walport

Sir Mark Walport FRS FMedSci is Director of the Wellcome Trust, which is a global charitable foundation dedicated to achieving extraordinary improvements in health by supporting the brightest minds.

Before joining the Trust he was Professor of Medicine and Head of the Division of Medicine at Imperial College London. He has been a member of the Prime Minister's Council for Science and Technology since 2004. He is also a member of the India UK CEO Forum, the UK India Round Table and the advisory board of Infrastructure UK and a non-executive member of the Office for Strategic Coordination of Health Research. He is a member of a number of international advisory bodies. He has undertaken independent reviews for the UK Government on the use and sharing of personal information in the public and private sectors: 'Data Sharing Review' (2009); and secondary education: 'Science and Mathematics: Secondary Education for the 21st Century' (2010).

He received a knighthood in the 2009 New Year Honours List for services to medical research and was elected as Fellow of The Royal Society in 2011. Mark Walport will become the Government Chief Scientific Adviser on 1 April 2013.