Antimicrobial Resistance: Stepping up to the Challenge

**Eleanor Malone**

*Editor, Scrip Intelligence*

Eleanor Malone is Editor of Scrip Intelligence, the leading source of news and analysis for the global pharmaceutical industry. For the past 15 years she has written widely about the many different aspects of the biopharmaceutical and medical technology industries, and has appeared on TV and radio to comment on developments ranging from M&A to Ebola. Scrip takes a special interest in the issue of antimicrobial resistance. It participates in the BioInfect conference in the UK and has created a dedicated microsite on the topic, [http://www.scripintelligence.com/amr/](http://www.scripintelligence.com/amr/).

**Mario Ottiglio**

*Director, Public Affairs, Communications & Global Health Policy, IFPMA*

Mario Ottiglio is Director, Public Affairs, Communications & Global Health Policy at the IFPMA where he has been working since 2007 in positions of increasing responsibility. At IFPMA, Mr. Ottiglio leads on interactions with key stakeholders such as governments, international organizations and civil society and coordinates IFPMA Members’ policy positioning on current global health issues. He is also the IFPMA policy lead on the WHO Global Strategy and Plan of Action for Public Health, Innovation and IP. Prior to joining the IFPMA, he worked as a consultant, both for governments and private firms. An Italian national, he holds an MA in Political Science from the Naples Eastern University.
**Stephan Harbarth**

**Infection Control Programme, Geneva University Hospitals**

Stephan Harbarth earned in 1993 his medical degree from Ludwig-Maximilians-University in Munich, Germany, and completed his residency in internal medicine and tropical medicine at Munich University Hospitals. After serving as a clinical fellow in the Infectious Diseases Division and Infection Control Program in the Department of Internal Medicine at Geneva University Hospitals, Dr Harbarth completed his master's degree in epidemiology at Harvard University in Cambridge, Massachusetts. He is board certified in infectious diseases and was appointed associate professor in 2010. Dr Harbarth's work has garnered several awards, including the ICAAC Young Investigator Award from ASM (2003), the Young Investigator Award from ESCMID (2006), the Swiss Society for Infectious Diseases Award for epidemiological research (2008), and the SHEA Investigator Award in 2011.

**Control of MRSA and multidrug-resistance**

Over the last two decades many institutions around the globe have experienced an increase in hyperendemic multidrug-resistant microorganisms such as MRSA and ESBL-producing enterobacteriaceae. Our group is currently conducting several clinical and epidemiological studies to evaluate key questions related to the control of the acquisition, transmission and infection by multidrug-resistant microorganisms. We participate in several large-scale EU-funded studies (SATURN, R-GNOSIS, Rapp-ID, AIDA, COMBACTE) to address this important public health threat. We collaborate closely with the Genomics Research Laboratory at HUG, based on a productive translational research platform. The most notable examples of our research are the evaluation of different MRSA control interventions (JAMA 2008, BMJopen 2013), the advanced analysis of epidemiologic trends and the burden of multiresistant microorganisms (JAC 2011, ICHE 2013), the conduct of epidemiologic studies linking patient data with molecular investigations (Clin Infect Dis 2011, ICHE 2014), the evaluation of antibiotic stewardship interventions (Lancet Infect Dis 2010, JAC 2011) and several placebo-controlled, randomised clinical trials to decolonise MRSA and ESBL carriers (JAC 2013).

**Marie-Françoise Gros**

**Head of Medical Affairs, bioMérieux**

Marie-Françoise Gros has a primary degree in Medicine (Grenoble University) and a MBA (Lyon Business School). After a first experience as a medical doctor both in hospital and in private practice (as a General Practitioner), she joined the in vitro diagnostics industry: Abbott Diagnostics where she was in charge of blood banks, and then bioMérieux. After an experience in strategic marketing (molecular diagnostics/ DNA chip technology), she took the responsibility of Corporate Director of Medical Affairs and Communications. As Head of Medical Affairs, she is managing a team that is in charge of clinical trials, assessment of medical value of new product opportunities, medical & scientific communication, Medical Scientific Liaison, product safety/ patient risk management and Global Health. Her primary focus and interest is antimicrobial resistance: she coordinates the AMR initiatives within the company, working closely with R&D and Marketing to help define the future products, develop internal awareness about AMR, as well as developing education/communication strategies for external audience (healthcare workers, General Public).
**Marco Cavaleri**  
**Head of Anti-infectives and Vaccines, Scientific and Regulatory management Department, European Medicines Agency**

Marco Cavaleri, Head of Anti-infectives and Vaccines, Scientific and Regulatory management Department at EMA, is responsible for the management of pre- and post-authorisation activities of centralised applications/marketing authorisations, and particularly the Safety and Efficacy part, related to medicinal products in the above-mentioned therapeutic areas.

Marco Cavaleri is a Pharmacologist who spent several years in industry in R&D mainly in the area of antibacterials and antifungals covering different positions in preclinical and clinical development. In 2005 he joined the EMEA as Scientific Administrator in the Scientific Advice and Orphan Drugs Sector, specifically being in charge of anti-infectives and vaccines scientific advice procedures. He returned to the Agency in 2008 as Group Leader Anti-infectives in the Safety & Efficacy Sector, Pre-Authorisation Human Unit following a short period in industry leading clinical and preclinical development in the area of Gastroenterology and Infectious Diseases. In 2009 he was appointed as Head of Section for Anti-infectives and vaccines in the Safety & Efficacy Sector, Human Medicines Development and Evaluation Unit.

**Charles Penn**  
**Coordinator, Antimicrobial Drug Resistance, World Health Organization**

Charles Penn joined the World Health Organization, Geneva at the start of the 2009 influenza pandemic, and was initially responsible for the use of antivirals in influenza management. He currently oversees programmes on antimicrobial resistance, and clinical management and infection prevention and control, particularly for outbreaks and epidemics caused by respiratory viruses. He also chairs WHO’s Guidelines Review Committee, which monitors the quality of all of WHO’s health guidelines.

Charles has extensive experience in infectious diseases, gained through a PhD in virology from the University of Cambridge, followed by research on human and avian influenza viruses at Cambridge University and the UK Institute for Animal Health. In 1988 Charles joined Glaxo (now GSK) to lead research on influenza and HIV, first as a Senior Research Associate and later as Senior Medical Strategy Head. During this time he saw two new antiviral medicines from discovery through to regulatory approval (lamivudine for HIV, and zanamivir for influenza),

In 1998 he moved to the (now) Public Health England Centre for Emergency Preparedness and Response, as Director for Research and Development. Activities included infectious disease diagnosis through the Special Pathogens Reference Unit, vaccines research and development, and epidemic and intervention modelling in infectious diseases.
John Rex
Senior Vice President and Head of Infection, Global Medicines Development, AstraZeneca Pharmaceuticals

John H. Rex, MD is Senior Vice President and Head of Infection, Global Medicines Development at AstraZeneca Pharmaceuticals. Since September 2012, Dr. Rex has also been a Non-Executive (Independent) Director, F2G, Ltd. Based in Manchester, UK, F2G Ltd is dedicated to discovery and development of new and clinically superior drug classes to treat life-threatening systemic fungal infections in at-risk patient populations. Through his work at AZ and F2G, Dr. Rex and his colleagues have antibacterial and antifungal molecules in all phases of development from Phase 1 through registration and marketing.

During his time in Industry, Dr. Rex has led multiple Industry interactions with FDA, EMA, and other external groups with a focus on enhancing available development pathways and the approaches to value for antimicrobial agents. His key activities have included lead authorship of a publication describing an updated approach to regulatory paradigms for antibacterial agents, co-authorship of other publications on the challenge of antimicrobial resistance, founding and ongoing participation in creation and implementation of the New Drugs For Bad Bugs (ND4BB) program within the Innovative Medicines Initiative (IMI) in Europe (including founding participation in the design of DRIVE-AB, a new ND4BB topic focused on evaluation and implementation of novel business models for antibiotics), a 4-year term as Industry Representative on the FDA Anti-Infective Drugs Advisory Committee (AIDAC, 2007-2011), ongoing active leadership within the antimicrobial working groups for EFPIA and PhRMA, ongoing roles (currently Vice-Chair of the Area Committee on Microbiology) with the Clinical Laboratory Standards Institutes (CLSI), membership in the Brookings Council on Antimicrobial Drug Development, and (2014) a role as an advisor on Antimicrobial Resistance to PCAST, the President’s Council of Advisors on Science and Technology.

Dr. Rex is also a Highlights Advisor for Nature Reviews Microbiology, is a member of the Wellcome Trust Seeding Drug Discovery Committee, serves on several editorial boards, was formerly an Editor for Antimicrobial Agents and Chemotherapy, and is an Emeritus Editor for www.doctorfungus.org, a nonprofit web site devoted to dissemination of information about medical mycology.

Dr. Rex has an MD from Baylor College of Medicine and is board-certified in Internal Medicine and Infectious Diseases. Before moving to Industry in 2003, Dr. Rex was Professor of Medicine at UT Medical School-Houston with a focus on translational studies of novel antifungal agents and hospital epidemiology.