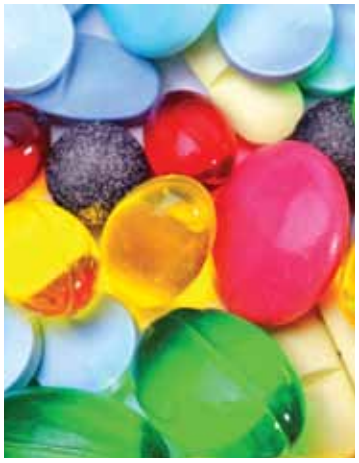

Annual Conference

Pharmaceuticals and Global Health: Inequalities and Innovation in the 21st Century

Date: 19 July 2013
Time: 9:30am-6:30pm
Venue: University of Sussex Conference Centre

For details of how to register please visit:
www.sussex.ac.uk/globalhealthpolicy

This event is jointly hosted by:

University of Sussex
Centre for Global Health Policy

brighton and sussex medical school

University of Brighton

erc
European Research Council

BISA

wellcome trust
Centre for Global Health Research

Annual Conference

Pharmaceuticals and Global Health: Inequalities and Innovation in the 21st Century

Widening access to life-saving medicines around the world has been a crucial – if not *defining* – aspect of global health policy over the past decade. What started with a historic movement to make anti-retroviral therapy (ARVs) available to millions of people living with HIV/AIDS in low-income countries, has rapidly evolved into a much broader model for improving health globally. Increasing access to essential medicines has become a priority for many international organisations, bilateral aid programmes, non-governmental organisations, private foundations and advocacy groups. These efforts have saved millions of lives and recently even emboldened the United Nations General Assembly to set out the aspiration of universal access to affordable and quality health-care services.

Looking forward, however, this 'pharmaceutical' model of global health also faces multiple challenges. The deteriorated international economic environment is putting financial pressures on the sustainability of programs already initiated, as well as jeopardising future spending commitments for global health. At the same time, the pharmaceutical sector is undergoing significant changes with industry analysts observing decreasing rates of innovation, and with the rise of generic producers also profoundly transforming the international landscape of pharmaceutical production. All the while protracted political controversies have arisen over public access to clinical trial data that forms the principal source of evidence about the efficacy and safety of key medicines used in global health. After a decade of remarkable expansion of global health programs, there is now considerable concern about the future sustainability of this model for addressing global health inequalities. Will we be able to treat ourselves to global health in the 21st century?

This interdisciplinary one-day conference brings together experts from the fields of policy, research, the pharmaceutical industry, foundations, journalism, and non-governmental organisations in order to identify new ways of adapting global health policy to these compounding challenges.

Key questions to be addressed on the day include:

- What are the key successes of this pharmaceutical model of global health in ameliorating global health inequalities over the past decade?
- What challenges have emerged about the efficacy and sustainably of rolling out medical treatments in low-income countries?
- What are the impacts of these global health initiatives on local communities?
- And what are the new business models that could deliver innovative medicines for global health in the future?

Who Should Attend?

- Pharmaceutical companies researching and developing medicines used in global health
- Policy makers from government and international organisations concerned about access to, and regulation of, medicines
- Social scientists analysing the social, economic, political, legal, security, cultural and ethical aspects of pharmaceutical use
- Non-governmental organisations dedicated to improving international access to medicines
- Foundations, donors, research funders and scientists interested in new models of innovation and drug discovery
- Media, reporters and journals covering global health and/or pharmaceuticals
- Think tanks and research institutes with global health programmes

Why Should You Attend?

- Learn about and share the latest thinking on access to medicines and pharmaceutical innovation in global health
- Network with other experts and leaders on pharmaceuticals in global health drawn from industry, government, research, non-governmental organisations, and the media
- Tailor your day by selecting from a range of themed and specialised panels on access, innovation, regulation, intellectual property, ethics, and health security/protection

Programme

9:30 -10:00	Arrival and registration
10:00 – 10:15	Opening remarks
10:15 – 11:15	**Public Keynote Lecture:** **Eradication: the science and politics of a "world without AIDS"** **Professor Vinh-Kim Nguyen**, University of Montreal **Chair: Dr. Alvaro Bermejo**, Executive Director of International HIV/AIDS Alliance and Board Member of the Global Fund
11:15 – 12:45	**Plenary Panel:** **Pharmaceuticals and Global Health: successes, challenges and outlook** **Dr. Manica Balasegaram**, Executive Director of MSF's Access Campaign **Dr. Kalipso Chalkidou**, Director, NICE International **Thomas Cueni**, Director-General, Interpharma **Dr. Brian Tempest**, former CEO of Ranbaxy, Chairman Hale & Tempest Co Ltd **Dr. Krisantha Weerasuriya**, Expert Committee on Selection and Use of Essential Medicines, World Health Organization
12:45 – 1:45	Lunch
1:45 – 3:15	**Concurrent Panel Session:** **Panel 1** **The Pharmaceutical Industry and Global Health: Emerging Models of Pharmaceutical Development and Production** **Panel 2** **The Ethics of Evidence: Challenges Related to Treatment in Low- and Middle-Income Countries** **Panel 3** **Designing Pharmaceutical Markets: Pharmaceuticalisation, Regulation and Global Health**
3:15 – 3:45	Tea break
3:45 – 5:15	**Concurrent Panel Session:** **Panel 4** **The Price of Life: Intellectual Property, Patents and Standards in Global Health** **Panel 5** **Medical Countermeasures: Pharmaceuticals, Antimicrobial Resistance and Global Health Security** **Panel 6** **Pharmaceutical Selves: Drugs, Research Subjects and Patients in Global Health**
5:15 – 5:30	Closing Comments
5:30 – 6:30	Wine Reception
6:30	End of conference

Speakers and Participants

Keynote speaker

Professor Vinh-Kim Nguyen
Medical anthropologist and HIV physician, Department of Social and Preventative Medicine at the University of Montreal. He is author of *The Republic of Therapy: Triage and Sovereignty in West Africa's Time of AIDS* (Duke University Press).

'Eradication: the science and politics of a "world without AIDS"'

Professor Vinh-Kim Nguyen is an HIV physician and medical anthropologist. As both a practitioner and researcher, he is concerned with the relationship between science, politics and practice in global health. Since 1994 he has worked extensively with community organisations responding to the HIV epidemic in West Africa as a trainer and physician. This informed his anthropological work on the global response to HIV with a concern for the forms of triage and sovereignty they embody. He continues to follow the evolving scientific and political response to HIV in his current work which focuses on molecular epidemiology, global health and social theory. He practices at the Clinique médicale l'Actuel and in the Emergency Department at the Jewish General Hospital in Montréal (Canada). He teaches at the Department of Social and Preventive Medicine at the University of Montreal, where he is Associate Professor, and recently established a Chair in Anthropology and Global Health at the College of Global Studies in Paris. He is the author of *The Republic of Therapy: Triage and Sovereignty in West Africa's Time of AIDS*; co-author, with Margaret Lock, of *An Anthropology of Biomedicine* and also the co-editor, with Jennifer Klot, of *The Fourth Wave: Violence, Gender, Culture, and HIV in the 21st Century*, as well as numerous articles in biomedical and anthropological journals.

Keynote Chair

Dr. Alvaro Bermejo
Executive Director of International HIV/AIDS Alliance and Board Member, The Global Fund to Fight AIDS, Tuberculosis and Malaria.

Confirmed Speakers and Participants (Selected)

Professor John Abraham King's College London
Dr Adamu Addissie School of Public Health, Addis Ababa University, Ethiopia
Professor Peter Aggleton National Centre in HIV Social Research, University of New South Wales
Dr Manica Balasegaram Executive Director, Access Campaign, Médecins Sans Frontières (MSF)
Dr Alvaro Bermejo Executive Director of International HIV/AIDS Alliance and Board Member of the Global Fund to Fight AIDS, Tuberculosis and Malaria
Dr Gerry Bloom Institute of Development Studies
Peter Bogner President, The GISAID Initiative
Dr Kalipso Chalkidou Director, NICE International
Dr Charles Clift Centre for Global Health Security, Chatham House
Professor Pete Clifton University of Sussex
Professor Jon Cohen Brighton & Sussex Medical School
Thomas Cueni Director-General, Interpharma
Dr Gail Davey Brighton and Sussex Medical School
Professor Stefan Elbe Director, Centre for Global Health Policy
Professor Bobbie Farsides Brighton and Sussex Medical School
Dr Alex Faulkner Centre for Global Health Policy, University of Sussex
Dr Sophie Harman Queen Mary, University of London
Dr Ian Harper Department of Anthropology, University of Edinburgh
Rachelle Harris Policy Adviser, Access to Medicines (Human Development Department), Department for International Development
Dr Kathryn Jones Health Policy Research Unit, De Montfort University
Dr Adam Kamradt-Scott Centre for International Security Studies, University of Sydney
Dr Ann Kelly University of Exeter
Professor Anthony Kessel Director of Public Health Strategy, Health Protection Agency
Professor Melissa Leach Institute of Development Studies
Dr Trudie Lang Centre for Tropical Medicine, University of Oxford
Dr Pheobe Li University of Sussex
Dr Hayley MacGregor Institute of Development Studies
Dr Dermot Mahe Wellcome Trust
Professor Paul Martin University of Sheffield
Dr Catherine Montgomery Institute for Science, Innovation and Society (InSIS), University of Oxford
Professor Melanie Newport Brighton and Sussex Medical School
Professor Vinh-Kim Nguyen University of Montreal
Professor Paul Nightingale Science and Technology Policy Research Unit, University of Sussex
Dr David Reubi School of Geography, Queen Mary, University of London
Dr Anne Roemer-Mahler Centre for Global Health Policy
Dr Paul Russel, Defence, Science and Technology Laboratory
Dr Giuliano Russo Instituto de Higiene e Medicina Tropical (Lisbon/ Portugal) and Sussex/IDS
Professor Brian Salter King's College London
Dr Hakan Seckinelgin London School of Economics
Dr Ken Shadlen London School of Economics
Professor Margaret Sleeboom-Faulkner Director, Centre for Bionetworking, University of Sussex
Dr Alice Street School of Social and Political Science, University of Edinburgh
Professor Huw Taylor University of Brighton
Dr Brian Tempest former CEO of Ranbaxy, Chairman Hale & Tempest Co Ltd
Professor Jonathan Van Tam, Leader, Health Protection Research Group, University of Nottingham
Professor Simon Ward, Director, Translational Drug Discovery Group, University of Sussex
Dr Krisantha Weerasuriya Secretary, Expert Committee on Selection and Use of Essential Medicines, World Health Organization
Lindsey Wu Senior Analyst, Policy Cures

Panel themes

1

The Pharmaceutical Industry and Global Health: Emerging Models of Pharmaceutical Development and Production

Pharmaceutical companies have contributed significantly to global health, supplying over 1,200 new medicines in the last sixty years, many of which have played an important part in improving the health of people around the world. Producers of generic medicines have similarly played a crucial role in improving global health by making many drugs much more affordable. That is especially true in response to the HIV/AIDS pandemic in low- and middle-income countries, where generic drugs represent more than 80% of donor-funded anti-retroviral therapies (ARVs). Yet the pharmaceutical industry is also undergoing profound structural transformations. Despite advances in biotechnology heralding the promise of revolutionising human health, analysts in fact report declining innovative productivity and that an investment focus on non-communicable diseases (as well as predominantly large markets) are limiting the industry's contribution to global health. Pharmaceutical development and production are further affected by a range of additional pressures – such as growing safety concerns, challenges to the international intellectual property rights regime, and by the rapid rise of new competitors from emerging markets. Global health policy will be profoundly shaped by, as well as actively shape, many of these fundamental transformations in the pharmaceutical industry. So what are the new models of innovation that are emerging within the industry? How can industry collaborate with public and not-for-profit organisations in the development of new therapies for global health? How will these industry changes impact upon the future of global health and visa versa?

2

The Ethics of Evidence: Challenges Related to Treatment in Low- and Middle-Income Countries

Widening access to treatment has brought with it a range of new dilemmas. Treatment effectiveness in one population may differ from that in another, for reasons related to genetics, politics or cultural understandings of disease. These differences are rarely explored prior to the roll-out of new programs. Drivers of global treatment initiatives may use distribution as their key metric, while on the ground, clinical and social outcomes are neglected. Treatment for conditions rarely found in high-income countries may have developed ad hoc and not have benefitted from rigorous testing. Imposing a requirement for trials in these situations may benefit patients, but equally it may act as yet one more barrier to accessing treatment. Finally, given the need for a trial in a low-income setting, many issues arise concerning contextualisation of trial ethics to the specific setting. This panel will debate a range of issues concerning the gathering and use of evidence around treatment in low-income countries, exploring to what extent treatments used in one context ought to be tested before use in another; the ethical issues related to generating evidence from pragmatic trials, and the consequences of not conducting such trials; 'standard care' and control groups; global concepts of 'Good Clinical Practice'; and contextualising ethics of clinical trials.

3

Designing Pharmaceutical Markets: Pharmaceuticalisation, Regulation and Global Health

The influence of medicines on many aspects of everyday life is increasing around the world. This trend towards increased global pharmaceutical consumption has been widely noted by experts and the public alike – especially in relation to controversial advances of drug therapies into existing and novel medical conditions such as attention deficit hyperactivity disorder (ADHD). Yet over the past decade global health policy has emerged as another crucial driver behind increased use of pharmaceutical products by making many medicines much more widely available internationally. The social forces behind this global trend towards 'pharmaceuticalisation' remain predominantly Western in origin, and diffused by multinational companies with strong clinical connections, significant experience of international regulation, and marketing presence – though this dynamic may be challenged with growing production in 'Rising Powers' countries. The multidimensional generation and diffusion of this pharmaceutical 'power' is also deeply unequal, challenging us to identify its different effects across different societies and cultures, in disease applications, local health economies and more broadly. At the same time, the transnational nature of pharmaceutical production and marketing is also creating new challenges for regulators, prompting major regulatory bodies such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to seek to extend their reach. Thus the FDA is now claiming a global role in standard setting, whilst the EMA is expanding its remit to include important biomedical innovations such as cell therapy. This panel discusses the drivers, limits and consequences of 'pharmaceuticalisation' in the context of global health. What institutional and cultural forms does it take, how is it promoted or resisted in low- and middle-income countries, and how do different regulatory regimes shape pharmaceutical markets and consumers? Finally, what interventions might stimulate this pharmaceutical imperative to tackle global health needs and inequalities more effectively?

4

The Price of Life: Intellectual Property, Patents and Standards in Global Health

The growth of the pharmaceutical industry has gone hand in hand with the expansion of legal systems for the protection of intellectual property (IP) rights. Whilst the granting of such IP rights is still largely a matter of national legislation, the World Trade Organization (WTO) agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) established internationally binding minimum standards for all WTO member states. In addition, a fast growing web of bilateral and regional free-trade and investment treaties is further strengthening the protection of IP rights at the international level, notably in the fields of data exclusivity (the protection of trial data) and the linkage of patent and registration procedures. From the outset, the creation of this international intellectual property regime has proved controversial in the context of global health, and continues to do so, because it is widely perceived as restricting access to medicines in low-income countries. Even after the move towards increased use of generic ARVs, Indian pharmaceutical companies (which contribute more than 80% of ARVs bought through international development aid) are unable to produce generic versions of newer drugs for second- and third-line treatment HIV/AIDS treatment regimes. On the other hand, several – mostly low- and middle-income countries – have invoked flexibility provisions in TRIPS when they implemented the agreement into national law, including by issuing compulsory licenses, using more narrowly defined patentability criteria, and allowing for pre-grant opposition. Against the background of a number of ongoing controversies around intellectual property, this panel asks: Which strategies have governments used to increase access to low-cost generic medicines and what challenges they have encountered? What impact does the increasing emphasis on data exclusivity have on access to medicines – given that TRIPS provides for flexibilities only with regard to patent protection? How do product development partnerships for neglected disease drugs deal with the tightening web of international IP standards? And how has the growing investment of originator companies into generics businesses and into the pharmaceutical markets of emerging economies affected their IP strategies?

5

Medical Countermeasures: Pharmaceuticals, Antimicrobial Resistance and Global Health Security

The areas of health protection and global health security have emerged as crucial sectors attracting substantial public investment for the development and acquisition of innovative medicines. One driver for this is the growing concern about the possibility of a bioterrorist attack – fears fuelled not only by the attacks of 11 September 2011 and 7 July 2005, but also by the anthrax letters posted to prominent addresses in the United States in the autumn of 2001. A parallel driver is the need to prepare populations against the threat of naturally occurring pandemics (SARS, H5N1, H1N1) that threaten lives and prosperity. Here we have seen considerable public investment in the creation and stockpiling of antiviral medications (like Tamiflu and Relenza) as well as (pre)-pandemic vaccines. As in other areas of global health, unequal international access to these new medicines has proved diplomatically divisive, prompting protracted disputes about the difficulties that low-income countries face in accessing such medicines, even where – as in the case of pandemic flu – they freely share the virus samples needed by the international community to produce these new vaccines. More recently, several medical countermeasures have also attracted other – but no less contentious – controversies. In the case of antivirals, for example, there is an on-going struggle for widening public access to the clinical trial data about the efficacy and safety of Tamiflu – especially given the substantial investments that went into creating large stockpiles. Pandemic vaccines have similarly attracted attention because of the emergence of rare – but significantly elevated – health risks. All the while existing medicines widely used for health protection, especially antibiotics, are becoming less effective – as recently highlighted by the World Health Organization in relation to anti-microbial resistance. Against that background, this panel discusses: What new medicines are being developed in the context health security? What forms of collaboration between government and industry are required to successfully develop new medicines? How can international inequalities over access to these new medicines be addressed?

6

Pharmaceutical Selves: Drugs, Research Subjects and Patients in Global Health

Patients and research subjects are central to pharmaceuticals. This is certainly the case in relation to drug making in regulated markets, as regulators will not permit drugs to enter the market before clinical trials are successfully conducted on human subjects. This use of these subjects is a highly disputed area characterised by media reports denouncing the exploitation of human 'guinea pigs', ethical guidelines claiming to protect vulnerable populations and severely ill patients demanding to be given drugs that have yet to be approved. But the centrality of patients is also evident in relation to drug taking. They are the target of pharmaceutical companies' direct-to-consumer advertising and bottom-of-the-pyramid sale strategies. So too, they are the beneficiaries of the right to health and access to medicines campaigns conducted by NGOs. And they are the members of the patient groups and internet-based communities that discuss and exchange about particular diseases and drugs. Drawing upon notions such as 'biosociality', 'therapeutic citizenship' and 'pharmaceutical selves' this panel will examine the complex linkages between patients, research subjects and pharmaceuticals. What are the different figures of the patient and research subjects that are imagined in relation to pharmaceuticals in global health? Who contributes to their making and how? And in what ways do patients and research subjects participate, resist and reshape the making and taking of drugs?