



On Friday 19th July 2013 more than 150 experts from the fields of policy, research, the pharmaceutical industry, foundations, government, journalism, and non-governmental organisations gathered at the University of Sussex for its 3rd Annual Global Health Conference focused this year on 'Pharmaceuticals and Global Health: Inequalities and Innovation in the 21st Century'. It was co-organised by the University of Sussex Centre for Global Health Policy, the Wellcome Trust- Brighton and Sussex Centre for Global Health Research, and the Global Health Working Group of the British International Studies Association,

with additional support from Brighton and Sussex Medical School, the European Research Council and the University of Sussex Research Themes. Following a keynote and plenary panel on 'Successes, Challenges and Outlook' for pharmaceuticals



Context

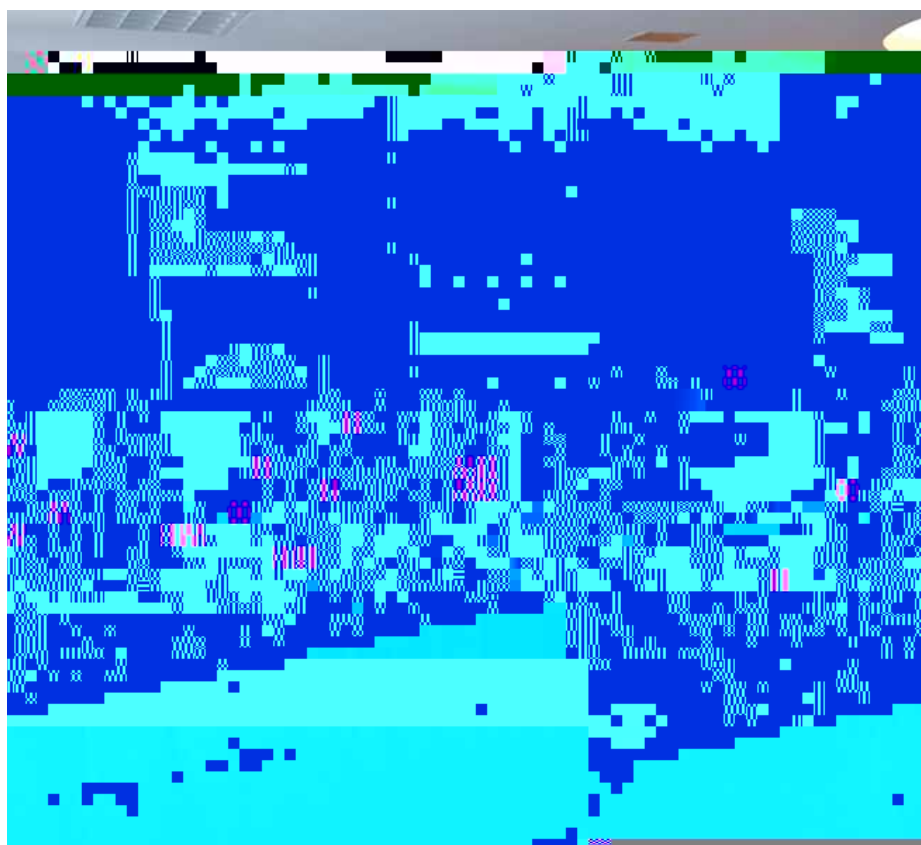
Widening access to life-saving interventions such as drugs and vaccines around the world has been a crucial – if not *defining* – aspect of global health policy over the past decade. What started with a historic movement to make anti-retroviral therapy (ARVs) available to millions of people living with HIV/AIDS in low- and middle-income countries, has rapidly evolved into a much broader model for improving health globally. Increasing access to essential medicines, and the need to develop new medicines for global health, has become a priority for international organisations, bi- and multi-lateral aid programmes, non-governmental organisations, foundations, researchers and advocacy groups. This quest for more equitable access to pharmaceuticals has even spawned a number of new initiatives, institutions and funding streams – from

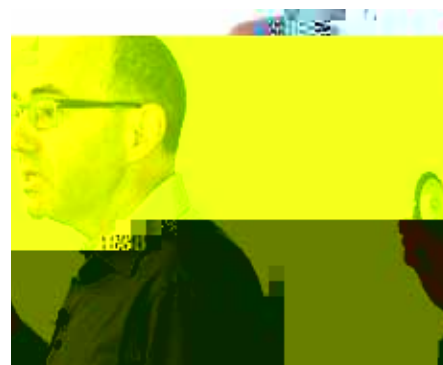
Keynote Address and Plenary Panel: Pharmaceuticals and Global Health – Successes, Challenges and Outlook

In opening the conference and introducing the keynote speaker, **Alvaro Bermejo**, Executive Director of the International HIV/AIDS Alliance, recalled Louis Pasteur's dictum that through harnessing the power of science and medicine it was in the power of man to eradicate infections from earth. Pasteur's sentiment was echoed more recently in the context of HIV/AIDS when Hilary Clinton announced that an AIDS-free generation is within our reach. In different ways, and despite being made decades apart, the two statements point to an enduring vision of a world kept free of infectious disease through the power of pharmaceutical interventions. Yet, and in reflecting on the international response to HIV/AIDS in particular, this emphasis on biomedical interventions has often occurred without adequate consideration of wider social, economic and political constraints. The conference's multi-disciplinary orientation, and its inclusion of social science perspectives, was therefore particularly welcome. And there could be no better starting point for opening this discussion on pharmaceuticals and global health than HIV/AIDS – given its role in redefining what we understand by global health.

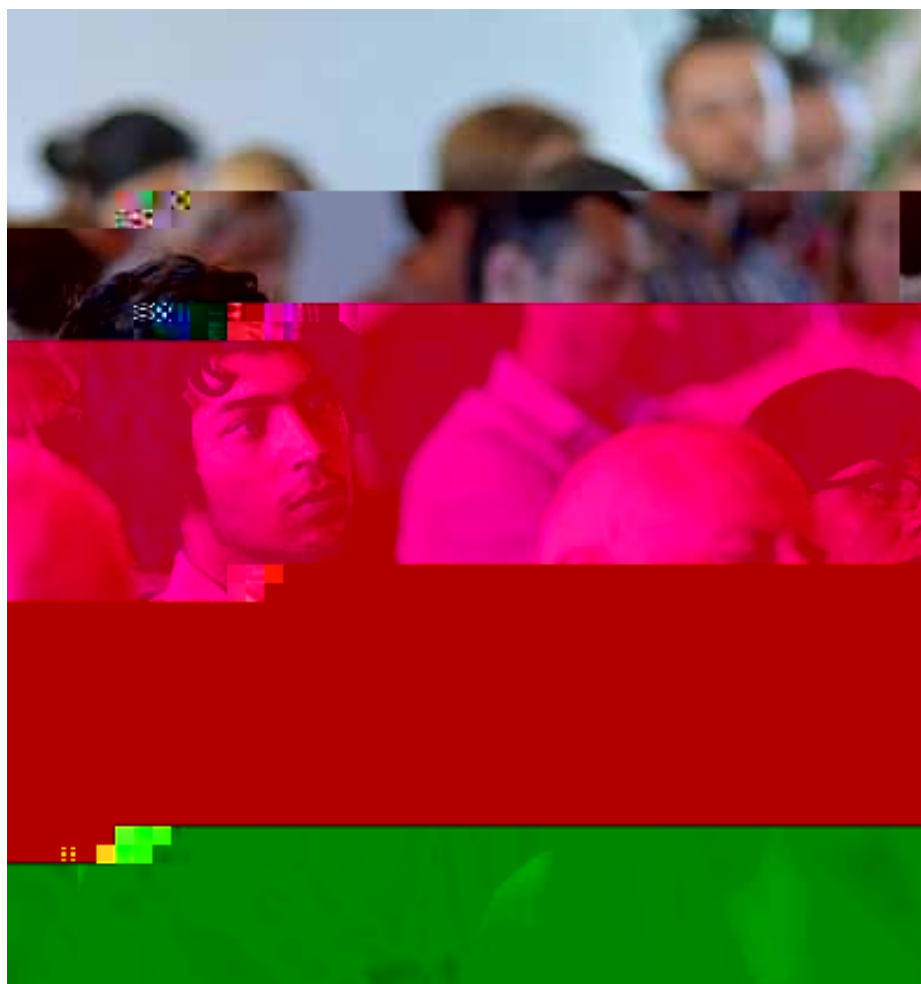
In his keynote address, **Vinh-Kim Nguyen**, University of Montreal, further developed this point, arguing that HIV/AIDS is not only a valuable prism through which to understand the emergence of 'global health' – but also for tracking the direction in which it is travelling. One of the main facets setting global health apart from its predecessor – 'international' health – was its preoccupation with the transnational elements of disease. This has also given rise to a number of different approaches for managing health *globally* – such as the socio-economic drivers of disease, an appreciation of the role of international inequality in producing disparate health outcomes, and the rise of a medical humanitarianism movement focusing on health as a human right. Global health has further set itself apart by a much greater emphasis on evidence-based medicine, not least through recourse to randomised control trials and participatory research.

At the same time, the new field of global





Thomas Cueni, Director-General of Interpharma, highlighted the changing role of the pharmaceutical industry in the global movement to improve access to medicines in low-income countries. Having learned from past mistakes, including being perceived as having filed a lawsuit against Nelson Mandela, the industry has understood that it needs to be an important partner in improving access. That role includes engaging in multi-stakeholder initiatives, voluntary licensing, drug donation programmes, and selling many drugs at cost in low-income countries. Overall, Cueni argued, the pharmaceutical industry has learned that it needs to be part of the solution, rather than part of the problem, when it comes to increasing access to medicines. However, significant challenges remain – not least because developing new medicines remains a very costly and risky business. Another key, and so far unresolved problem is the undifferentiated pricing structure of the industry. This problem would persist as long as wealthy countries did not accept that they have to pay higher prices for medicines than poorer countries. Only then could tiered pricing be applied on a broader scale and help improve access.





Brian Tempest, former CEO of Ranbaxy and Chairman Hale & Tempest Co Ltd., highlighted key factors currently shaping the global pharmaceutical industry. Concerns about healthcare costs were increasing not only in OECD countries but also in emerging markets. There was also concern within the industry, notably among R&D-based pharmaceutical companies, due to declining returns on R&D investment. In addition, Tempest pointed out, the industry was facing a new patent cliff – this time in biologics. Different from the patent cliffs that the industry experienced in the early 2000s, generic versions of biologics ('biosimilars') would not quickly become available because of the more complex nature of biosimilar development and more complex regulatory requirements. Looking at the generics sector, Tempest observed that many of the largest generics companies from Israel, the US and Western Europe did not have a strong footprint in low-income countries. By contrast, Indian companies still invested strongly in those regions. With regard to the future direction of the global IP regime, Tempest predicted more compulsory licenses in emerging market countries. He closed his presentation by raising the question of whether a tiered patent system, which would take into account differences between high-, middle- and low-income countries, was a model for the future.



Krisantha Weerasuriya, Secretary, Expert Committee on Selection and Use of Essential Medicines, World Health Organization, discussed the concept of essential medicines. The idea behind this concept was that a limited range of selected medicines could lead to better health care. He highlighted the success of the WHO list of essential medicines, which has been around for over three decades, and in many ways was the predecessor of Health Technology Assessment. Yet, the essential medicines concept has been adopted more widely in high-income countries than in low-income countries. Among the key challenges for a wider adoption of the concept of essential medicines, according to Weerasuriya, was limited political will and limited infrastructure for implementation. He concluded by raising the question of whether the concept of essential medicines may be suitable to guide the development of new medicines, a process that was currently left largely to the market. He suggested that this question would become increasingly relevant in the context of recent attempts to achieve universal healthcare coverage. A major issue in this debate would be which medicines were to be delivered as part of universal healthcare coverage.





Panel 2: The Ethics of Evidence: Challenges Related to Treatment in Low-income Settings

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 programmes. 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 another barrier to accessing treatment. Finally, given the need for trials in low-income settings, many issues arise concerning contextualisation of trial ethics to the specific setting. This panel debated 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.

Adamu Addissie, School of Public Health, Addis Ababa University, outlined his Phase 1 research into ethical issues identified by health researchers in relation to their research in clinical and community settings throughout Ethiopia. Only two-thirds had undertaken formal training in research ethics, and less than 15% considered that the best interests of participants were considered in the research process. Problems relating to language barriers, power differentials, and undue emphasis on recruitment and rules were thought all to impair the ethics of research conducted.

Trudie Lang, Director of the Global Health Network, Oxford Centre for Tropical Medicine, emphasised the vital importance of conducting

research in low-income settings, despite the difficulties that might be encountered. Building capacity to conduct relevant research, harnessing funding from externally-sponsored studies to drive internally-designed research and sharing research tools and protocols are all fundamental to the mission of the Global Health Network.

Bobbie Farsides, Brighton & Sussex Medical School, delivered her presentation via a film which outlined the background to, and the process of development of, Rapid Ethical Appraisal. This is a form of rapid ethnographic assessment by which researchers may identify key issues relating to a community's perception of research prior to undertaking a study, and has been used in the Gambia, Kenya and Ethiopia.

Melanie Newport, Brighton & Sussex Medical School, summarised the results of Rapid Ethical Appraisals conducted in Ethiopia and Cameroon. Communities in North West Cameroon had greater familiarity with research concepts from prior exposure to agricultural research. Communities in southern Ethiopia preferred researchers to approach them through a patient association, whereas those in Cameroon favoured approaches via local chiefs (*Fons*).

In the discussion that followed, led by Dermot Maher of the Wellcome Trust, the origins of Rapid Ethical Appraisal were unpicked, and several other areas important to Ethics of Evidence highlighted, including plagiarism, data fabrication and publication issues.





Panel 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 regimen. 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 asked: Which strategies have governments used to increase access to low-cost generic medicines and what challenges they have encountered?

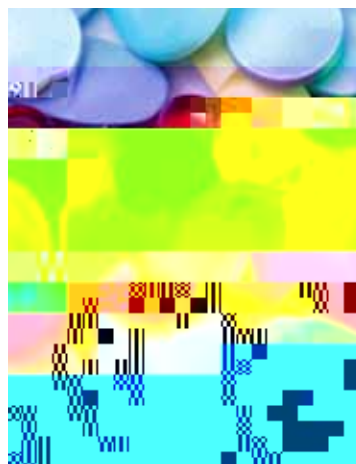
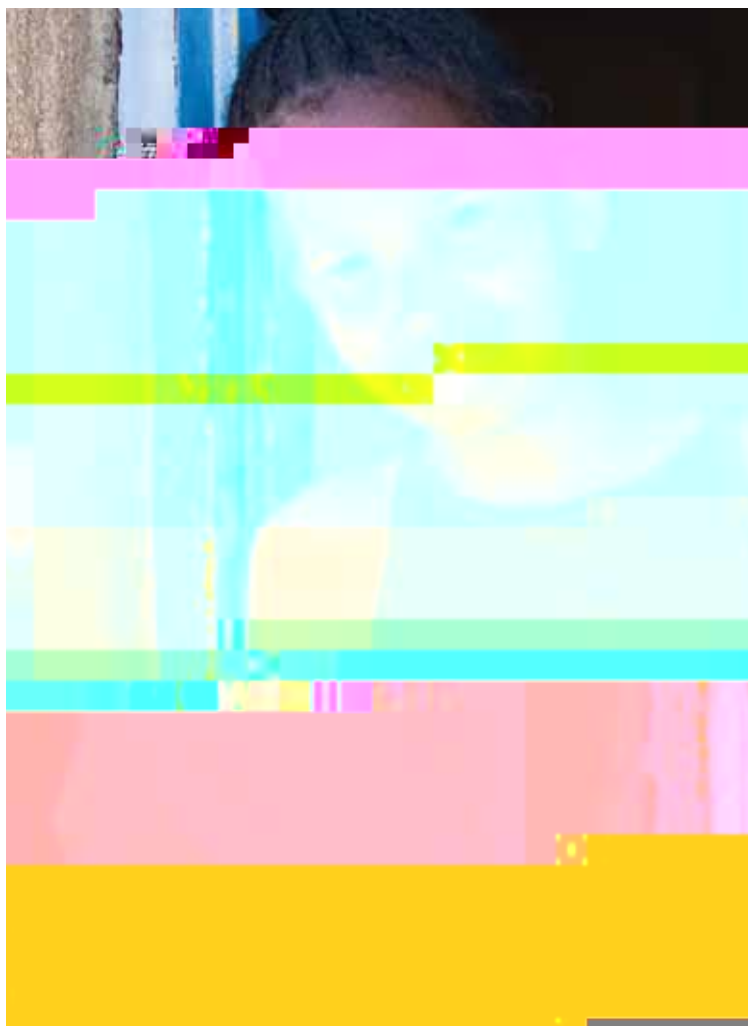
Panel 6: Pharmaceutical Selves: Drugs, Research Subjects and Patients in Global Health

Patients and research subjects are central to pharmaceuticals' activities. 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 experiences and views about particular diseases and drugs. Drawing upon notions such as 'biosociality', 'therapeutic citizenship' and 'pharmaceutical selves' this panel examined 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?

Drawing on the work of Miller, Rose and Epstein, **Catherine Montgomery** of Oxford University explored the transient group of research subjects and their relatives created by a randomised clinical trial on the efficacy of a vaginal microbicide gel in stopping HIV transmission conducted by British researchers in Zambia. In particular, she examined the anxieties about the trial among both the participants and their male partners. These anxieties were often expressed through narratives of blood stealing. They also related to males' feeling of exclusion

from the trials as well as to wider economic changes whereby South African investors had taken over the industrial sugar estate on which most participants and their partners worked and slashed existing pension schemes.

Margaret Sleeboom-Faulkner, Director, Centre for Bionetworking, University of Sussex, continued the theme by examining the contrasting perceptions of a Chinese biotech company (Bieke Biotech) selling a variety of stem cell treatments to the general public for a series of medical conditions including cerebral



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