Conference Report

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

Conference Centre, University of Sussex, 19 July 2013

Summary

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 and global health, participants divided into smaller groups to debate specific topics. The general format was for invited experts to give short presentations, followed by wider discussion with the audience. The diversity of disciplines represented coupled with the theme ensured lively and thought-provoking discussion and a number of key points emerged from the day.

Key points

1. Much of global health policy now revolves – in one way or another – around enhancing access to, and developing, new pharmaceuticals. Over the course of a dramatic and quite remarkable decade, pharmaceuticals have become absolutely central to global health. We have moved towards a predominantly **pharmaceutical model** of global health policy.
2. This pharmaceutical model of global health is **approaching a crucial juncture**. Parallel pressures – ranging from a deteriorated economic environment, through to declining rates of innovation, and diminishing returns on research and development – are converging to raise questions about the sustainability of this model of global health policy for the 21st century.
3. There are key **knowledge gaps** – particularly around the social, economic, political, cultural, legal and ethical factors shaping international access to pharmaceuticals. Rolling out pharmaceuticals on a large-scale basis has proved to be a complex social process – especially in areas where infrastructure and regulation are lacking. Building on what has been achieved, and moving forward, will require more multidisciplinary approaches to maximise the global health benefits that can be harnessed from pharmaceuticals.
4. Current **funding models** for new drug discovery and development are widely perceived as insufficient. Across a range of pressing global health issues, market forces are not yet aligning sufficiently well with perceived global health priorities, and are currently not producing enough innovative medicines at affordable and/or desirable prices. There is considerable appetite amongst many different stakeholders for fresh thinking and approaches here.
5. The decade ahead will likely be less dramatic but in many ways also more critical for global health policy. It can continue to build on the pharmaceutical approach, but, in order to succeed, will need to rekindle high-level political commitment in high-, middle- and low-income countries alike. Success will also be heavily dependent on the discovery of new and sustainable models for innovative drug development. If these do not materialise, securing the future of global health policy may well rest in trying to think global health – not so much without – but certainly also **beyond** the limits of **pharmaceuticals**.

Conference Resources

Panel videos: http://www.sussex.ac.uk/globalhealthpolicy/events/forthcomingevents/annualconf2013/panels
Photographs: http://www.flickr.com/photos/99321119@N02/
Video blog: http://www.youtube.com/watch?v=zBsH1E9IEXk
Social media: http://storify.com/GlobalHealthSus/highlights-from-the-pharmaceuticals-global-health

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Guiding questions

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?

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 the President's Emergency Plan For AIDS Relief (PEPFAR) through to the Global Fund. In short, the dramatic decade we have witnessed in global health has mainly revolved around pharmaceuticals. 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.

Scanning the horizon, however, this predominantly 'pharmaceutical' model of global health also faces multiple challenges and pressures now. 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, while the rise of generic producers is also 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 advocacy and 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?

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

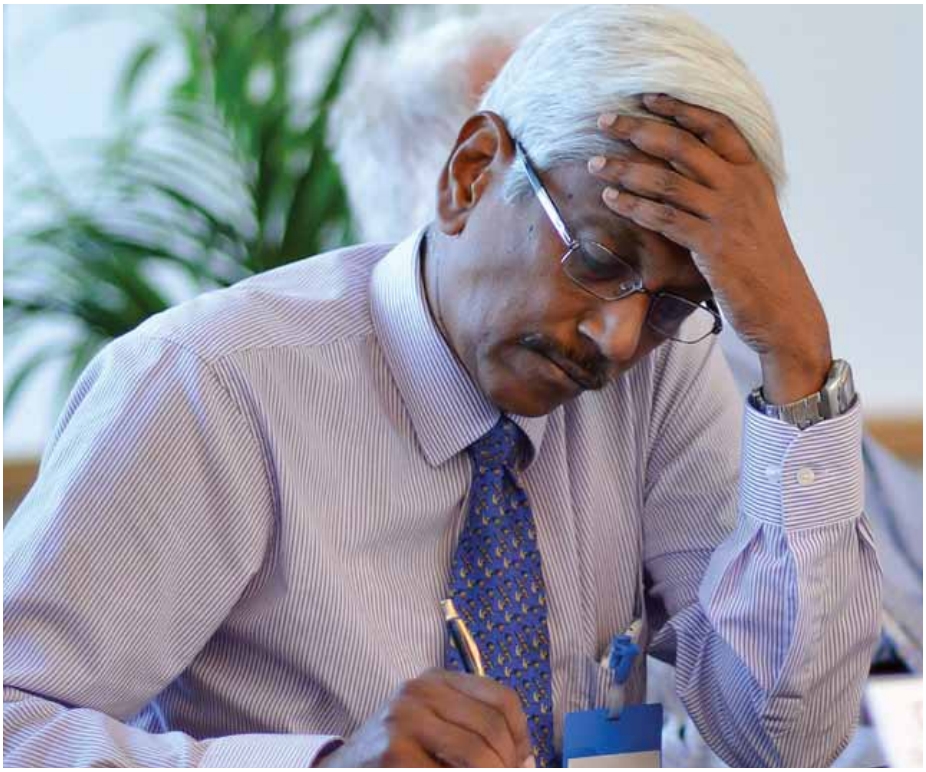
In opening the conference and introducing the keynote speaker, **Alvaro Bermejo**, Executive Director of the International HIV/AIDS Alliance, recalled Louis Pasteur's dictum that through harnessing the power of science and medicine it was in the power of man to eradicate infections from earth. Pasteur's 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 health that has emerged from these changing approaches and practices has itself also become the object of study by social scientists. They have drawn on ethnographic research methods and wider social theories to analyse the ways in which global health programmess also constitute exercise in power and create new forms of dependency. The keynote ended with reflections on the recent turn towards eradicating AIDS – leading to the question of whether 'eradication' was the most appropriate model or metaphor through which to approach the international HIV/AIDS response.

The plenary panel took up many of these themes. **Manica Balasegaram**, Executive Director of the Access Campaign at Médecins Sans Frontières (MSF), recalled how MSF opened its first HIV project in 1996, when triple therapy was not widely available. The priorities for MSF at the time were to persuade countries to start national HIV programmes, and to persuade wealthier countries to contribute to these efforts. Overall, these efforts have been successful in raising the number of people receiving treatment globally. However, even today there are still millions in need of treatment – so in that sense we are only halfway there. In reflecting on the remarkable achievement of the past decade, a unique constellation of factors can be credited, including: 1) the market entry of generic medicines, which reduced prices and changed the construct of how patients were managed at the clinical level; 2) the unprecedented global activism which was critical in changing prevailing mind-sets about what was acceptable; 3) the unprecedented mobilisation of donor funds – most notably through PEPFAR and the Global Fund; and 4) the increased solidarity between low and middle income countries, where the latter increasingly became main suppliers of drugs to low-income countries. All of these efforts have prevented many deaths, and shifted the debate about access to treatment from *if* to *how*. They are fragile achievements, however, given the continued issues around intellectual property protection, the lack of equivalent activism on many other global health issues, and the tougher economic environment. The way forward will be to move away from seeking to reward innovation through high prices. Instead, we need to find different ways of funding and rewarding innovation and innovators.

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 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 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?

Paul Nightingale, Science and Technology Policy Research, University of Sussex, highlighted how problems of funding in the biotech sector have shaped business models and industrial organisation in this sector. The increasing importance of venture capital and grants have contributed to the compression of companies' lifecycles and a focus on growing and selling projects within short time frames. Rather than competing with large pharmaceutical companies, smaller biotech firms have become part of their supply chain. Nightingale suggested that drug development in this difficult environment would require public funding of extended early stage research.

Simon Ward, Director, Translational Drug Discovery Group, University of Sussex, focused on the problem of declining innovative productivity, highlighting specifically the weak link in R&D between Phase II and Phase III trials. Opportunities for improved innovative productivity lie in an improved understanding of disease biology and, based on that, fewer and more targeted projects. Open innovation models bear the risk of companies being reluctant to share key data, while models that have worked well, such as Tres Cantos, the Structural Genomics Consortium, and the Translational Drug Discovery Group at Sussex recognise the value of basic science research. Funding for this kind of work usually comes largely from the public sector with industry bringing in the necessary expertise.

Lindsey Wu, Senior Analyst, Policy Cures, outlined global trends in investment in research for neglected disease drugs pointing out that the largest portion is provided by the public sector. She highlighted the vulnerability of this work due to a dependency on only two funders, the US National Institutes of Health and the Bill and Melinda Gates Foundation. An interesting development was, however, increased public-private collaborations in developing countries to foster innovative capacity, such as the South African H3D initiative and a set of programmes established by the Indian Department of Biotechnology. An inherent risk in public funding was, however the mismatch between long development timelines and frequently short political time horizons.

Giuliano Russo, Instituto de Higiene e Medicina Tropical, Brazil, presented a case of South-South collaboration where the Brazilian government collaborates with Mozambique in the establishment of a factory for HIV/AIDS medicines in Maputo. Russo highlighted that, contrary to widely held views, the factory was able to produce medicines at competitive prices. A key problem was, however, its focus on HIV/AIDS medicines as this market was already filled by drugs donated through global health initiatives, such as PEPFAR. He concluded that a lack of flexibility of international drug financing arrangements might be a key hurdle for local pharmaceuticals production in low-income countries.

Rachelle Harris discussed new business models in the area of pricing. She noted progress in intra-country tiered pricing, which was now experimented with by 7 out of the top 20 pharmaceutical companies listed on the Access to Medicine Index. While tiered pricing between countries (inter-country tiered pricing) was even more widespread and increasing further, she noted that price drops were not always very significant here, and few companies applied the schemes across a wide product portfolio and, at the same time, across many countries because of concerns about product diversion and external reference pricing.

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.

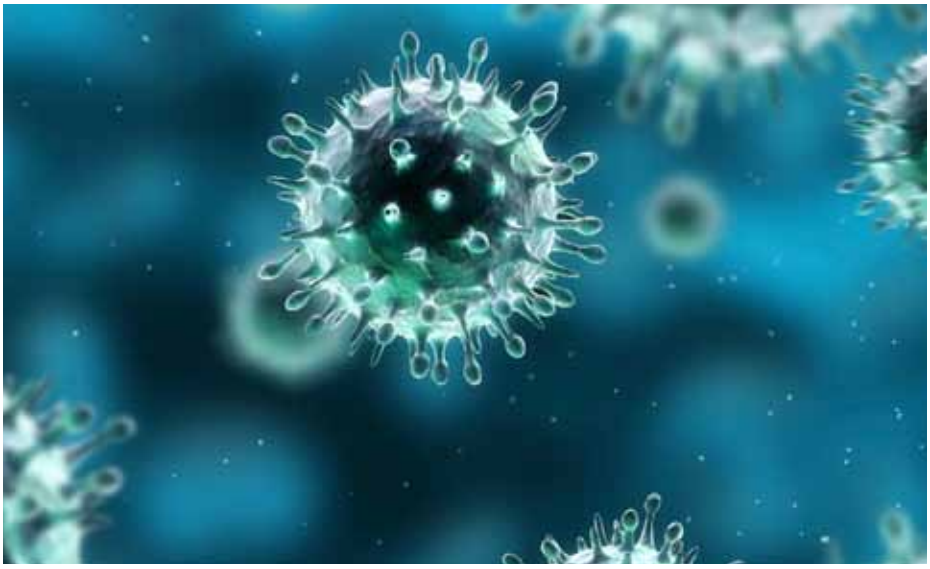
Trudie Lang, Director of the Global Health Network, Oxford Centre for Tropical Medicine, emphasised the vital importance of conducting research in low-income settings, despite the difficulties that might be encountered. Building capacity to conduct relevant research, harnessing funding from externally-sponsored 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 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 discussed 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 (LMICs), 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?

The glaring disparity between high-level policy and state regulation and the unregulated markets and usership practices found in many parts of the world was highlighted in this panel. Forces driving informal markets in LMICs include – as **Ian Harper** showed for Nepal – state enforcement capacity, the proliferation of 'little pharma' and multiple brands of the same generic drug, lobbying of government, and cultural practices such as 'bonusing'. Regional trade dynamics shape medicines availability, and high-level policy such as the WHO could dis-able small producers by imposing difficult drug protocols.

Gerry Bloom, Institute of Development Studies, illustrated problems of information deficit – 200,000 village doctors in Bangladesh acting below the government's radar, though Multi National Corporations (MNCs) maintained a database on them. Similarly, information about drug use is lacking, raising the question of what forms of state-producer-user partnerships might be possible, and a need for governments to acknowledge 'bad practices'. The arrival of new stakeholders such as telecoms MNCs providing e-health further complicates the situation.

Set against this are the powerful forces of the globally dominant pharma regulators. **Alex Faulkner**, Centre for Global Health Policy, University of Sussex, and **John Abraham**, King's College, University of London, illustrated the extension of the regulatory reach of the EMA to new biomedical products and its growing influence in India and China via projects linked to manufacturing standards, and a set of evidence – challenged by an industry view – showing the trend toward accelerated drug approvals, regulators' dependence on industry fees, surrogate measures of efficacy, and failure to conduct post-market follow-up.

Paul Martin, University of Sheffield, argued that market failure, illustrated for example by disinvestment in CNS drug development in the West, should be addressed by re-imagining pharmaceutical futures with an increased policy focus on academia in drug discovery, biosimilars, more effective use of existing drugs, and prioritisation of neglected diseases. The role of local ethics committees and the status of 'unmet need' sitting between unregulated practices and state policy are further important issues for the future.

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? 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?

Peter Bogner, President of the Global Initiative on Sharing All Influenza Data (GISAID), presented its data – the most comprehensive collection of influenza data to date. He recalled the history of the Initiative, which came out of the realisation that developing countries faced difficulties accessing vaccines from commercial companies even though they had provided the virus material necessary for the production of the vaccine in the first place. As a lesson from this experience, Bogner highlighted that the Initiative grants access to virus material only under the condition that no restriction be placed on the use of any products using this material.

Charles Clift, Centre on Global Health Security, Chatham House, presented on the Medicines Patent Pool, which acts as a 'one stop shop' to license patents for HIV/AIDS medicines. He explained that the Pool focuses on newer medicines, which cannot be produced in generic form by Indian companies, because they were introduced into the market after India had established patent protection for pharmaceutical products. The key challenges for the Pool include, according to Clift, that it has to convince patent holders of the benefit of joining while not losing the support of civil society groups, many of whom are critical of the existing IP regime and demand more transparency than the Pool can provide in the negotiations with companies.

Phoebe Lee, University of Sussex, presented a range of fundamental research questions about the current global IP regime, including how an appropriate balance between innovation and access could be achieved and how IP rights could be harnessed by public health and national security interests. As a potential way forward she suggested to apply risk analysis to IP, including risk assessment through pre-grant opposition, risk management through the use of a precautionary approach to IP, and risk communication through patient and citizen involvement in innovation, for example.

Ken Shadlen, London School of Economics, presented on the issue of secondary patents, which are an important element of pharmaceutical companies' lifecycle management strategies. To limit the use of secondary patents governments can use both ex-post mechanisms, such as litigation, and ex-ante mechanisms, such as pre-grant opposition and extended legal standards of patentability. Shadlen then discussed the case of Novartis' cancer drug Glivec, which had been denied a patent in India because of a provision in the country's patent act that requires medicines to show enhanced efficacy in addition to the standard patentability criteria of newness and innovation. He argued that the effect of this legal provision on the ability of pharmaceutical companies to obtain patents in India might be overestimated in the current discussion, and that it would not make India a patent free zone any more than legal incentives to generics producers to challenge patents had this effect in the US.

Panel 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 2001 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. Meanwhile 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 (AMR). Against that background, this panel discussed: What new medicines are being developed in the context of 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?

Anthony Kessel, Public Health England, provided an overview of the problem of AMR. He started by outlining the history of antimicrobial development and resistance, and pointed to declining rates of new antimicrobials becoming available in the UK in recent years. He described antimicrobial resistance as a 'super-wicked' policy problem – also highlighting the difficulties of designing new medicines under market conditions – where the costs of research and development were high, where there was an uncertain outcome, and where the medicines would only be used for a short period of time. However, a new national strategy on AMR is due for publication soon, and there will be a need to find new ways of incentivizing drug development.

Paul Russel, Defence Science & Technology Laboratory, Porton Down, UK, provided an overview of the problem of bioterrorism, and the challenges involved in developing medical countermeasures. He also described some of the practical difficulties in administering medical countermeasures – especially in situations where a large number of people need treatment in a short period of time. The intravenous administration of antibiotics would be a case in point. There are also further questions about the cost and logistics involved in stockpiling such medical countermeasures. As in other areas discussed at the conference, there is a further problem here that the uncertain threat of bioterrorism and pandemics are not really sufficient to incentivise drug development under commercial market conditions.

Jonathan Van Tam, Leader, Health Protection Research Group, University of Nottingham, presented new data about the efficacy of antivirals drawn from the 2009/10 H1N1 influenza pandemic. His presentation also raised wider questions about the way in which medical countermeasures for pandemic influenza are developed. The antivirals widely stockpiled, and then used in 2009/10, were initially developed more as a kind of 'lifestyle' drug, that is, as a

way of managing the unpleasant symptoms of flu. But in the context of growing concerns about pandemic threats, antivirals became rapidly transformed into public health drugs – and this has created many of the tensions and controversies around the drugs that have since emerged. However, all of this has also raised wider questions about how future drug development will occur in this field.

Adam Kamradt Scott, University of Sydney, spoke on the issues of EBM, and detailed some of the political processes through which antivirals became such a prominent part of the response to pandemic threats. An interesting finding of his was how the rise of Evidence Based Medicine (EBM) favoured an emphasis on pharmaceutical interventions. However, he also raised questions about why there is not more research into other possible pharmaceutical responses for managing flu. Indeed, he noted greater scope for looking at balance of pharmaceutical and non-pharmaceutical solutions, and indeed other types of pharmaceutical solution.

The discussion following the presentation also highlighted a disjuncture between the desire to create ever-wider access to pharmaceuticals on the one hand, and the emergence of problems of overuse of pharmaceuticals – like antimicrobial resistance – on the other.

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 relationto 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?

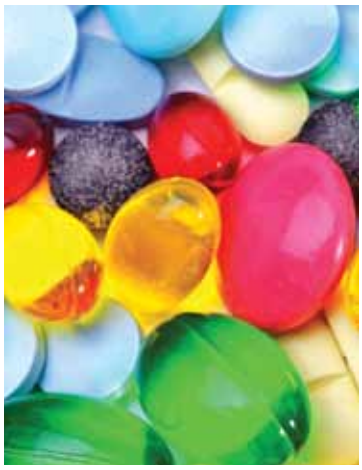
Drawing on the work of Miller, Rose and Epstein, **Catherine Montgomery** of Oxford University explored the transient group of research subjects and their relatives created by a randomised clinical trial on the efficacy of a vaginal microbicide gel in stopping HIV transmission conducted by British researchers 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 palsy and brain injury. In the West, Bieke is often viewed as a rogue actor selling unproven therapies to a gullible, vulnerable public. In contrast, in China, Bieke is held in high esteem among the public and political leaders. Indeed, for them, Bieke is a successful company: it is led by a doctor who was trained in the USA; it offers a welcome choice for Chinese patients with ailments for which there is no recognised treatment; and the research conducted by the company has led to patents and publications.

Hakan Seckinelgin, London School of Economics, explored the ways Congolese refugees in South Sudan used to their advantage the therapeutic benefits accessible in camps run by UNHCR and World Vision. In particular, he showed how, although regional conflicts have died out, there are still refugees remaining in the camp and indeed new ones coming in. These remaining and new refugees are part of large family networks, most of whose members have returned to the Congo, who collect goods provided by World Vision, especially ARVs, before selling them in local markets and sending them back to their families in the Congo.

Alice Street, University of Edinburgh, discussed the development and selling of neutriceutals in North India. Neutriceuticals are fortified foods with added minerals and vitamins developed by large food conglomerates like Horlicks, Pepsi and Coke in response to discourses in global health arguing that food alone does not provide essential micronutrients, in particular in relation to chronic diseases. Alice explored the science and politics behind neutriceuticals, showing how the companies, following a business model articulated around 'low margins, high volume' and 'doing well by doing good' have sought to sell them to poor people across India.

Kathryn Jones, De Montfort University, Leicester, analysed the relations between patient groups and pharmaceutical companies in the UK. She showed how many patient groups have contacts with and are funded by the industry. This is perhaps not that surprising given that they often lobby for similar ends (e.g. having access to particular drugs). The delicate issue is that the relations between patients groups and industry are not very transparent, with less than 35 percent of organisations acknowledging they receive funding from the industry and very few having a clear policy governing their relations with the industry.



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