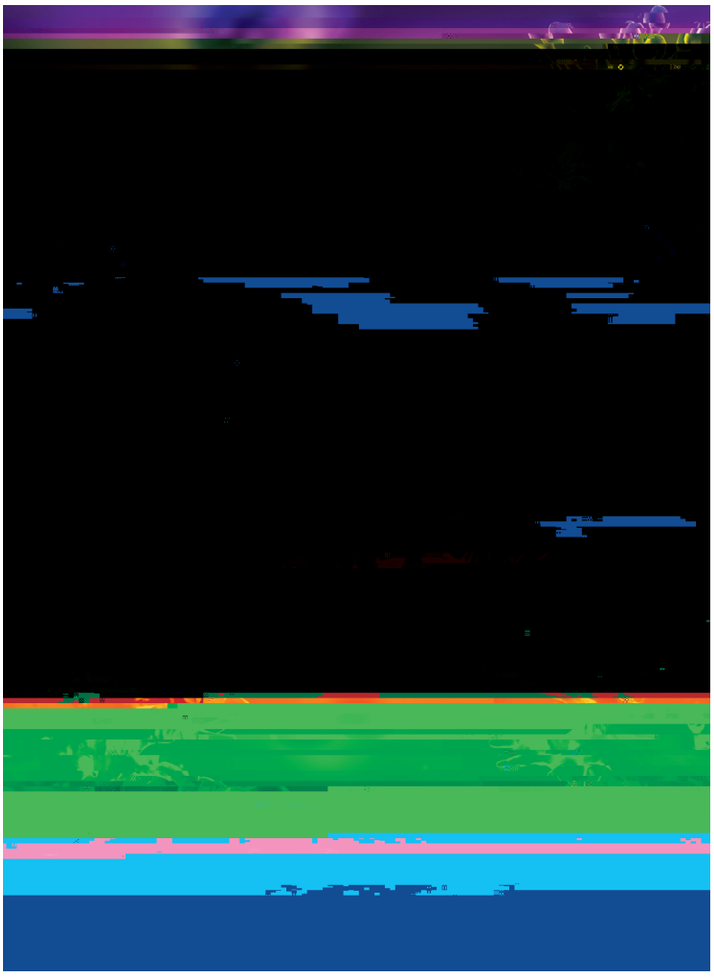

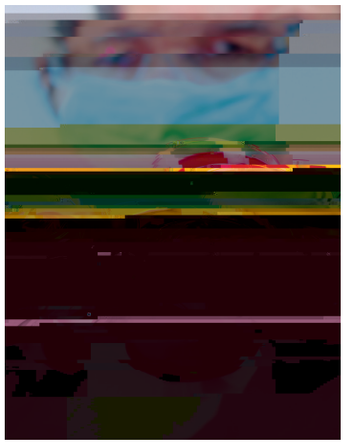

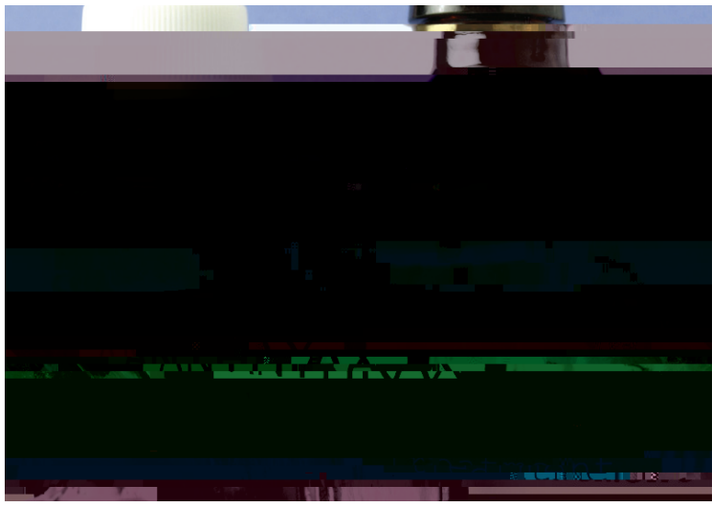

Summary Report

Pharmaceuticals and Security: Strengthening Industry Engagement

Future directions in public-private collaboration for health security

A Roundtable Discussion hosted by the Centre for Global Health Policy, University of Sussex

Stefan Elbe & Anne Roemer-Mahler

Friday 7 February 2014

The Royal Institution of Great Britain, Mayfair, London

www.sussex.ac.uk/globalhealthpolicy

UNIVERSITY OF SUSSEX

Table of Contents

Roundtable on

Pharmaceuticals and Security: Strengthening Industry Engagement

Future directions in public-private collaboration for health security

The Centre for Global Health Policy at the University of Sussex convened an international expert roundtable to consider the future of cross-sectoral collaborations for strengthening global health security. Comparing experiences across the areas of pandemic preparedness, biodefense and emerging infections, roundtable participants included representatives from international organizations, government, industry, non-governmental organizations, cross-sectoral partnerships, and the university sector. This report summarizes the experiences shared by participants during the meeting, which was convened on 7 February 2014 at the Royal Institution of Great Britain in London. The event was held under the Chatham House rule, and was supported by research grants funded by the European Research Council (ERC) and the Economic and Social Research Council (ESRC) of the United Kingdom.

Executive Summary

Political demand for new pharmaceuticals has intensified at the outset of the twenty-first century. Developing new medicines, and widening access to them, has become a key policy objective across the areas of global health, international development and bio-security. Often, however, this increased political demand is not matched by an equally strong market demand, generating a significant gap between perceived public health needs and what pharmaceutical markets are supplying. To bridge that gap, extensive efforts have been invested in creating new collaborations between the public sector, private non-for-profit organizations and pharmaceutical companies. This roundtable gave participants the opportunity to exchange their experiences and take stock of cross-sectoral partnerships across three key areas of global health security: biodefense, pandemic preparedness, and neglected tropical diseases. This report summarizes the views shared by the participants about the nature and sustainability of such cross-sectoral collaborations aimed at strengthening health security.

Partnerships

Participants agreed that cross-sectoral partnerships remain crucial to pharmaceutical development in the area of global health security, especially in contexts where development costs are high and resources are limited. Based on the experiences of the past decade, however, they also urged a greater degree of realism about expectations, finding that such partnerships are difficult to achieve in practice, and that the risks of failure are far from insignificant. In particular, expectations need to be calibrated to the specific functions that partnerships can fulfill – depending, for example, on the specific health and scientific problem being addressed, the detailed characteristics of the drug target, the nature of the product, the size of the market, as well as the types of organizations involved in the partnership.

Participants thought that partnerships could be strengthened to better meet medical need in areas where there is no significant commercial market. They also felt that partnerships could further improve risk-sharing practices, could help engage low- and middle-income countries, and could usefully exploit the opportunities emerging from technological change.

Participants emphasized market certainty and reliable government procurement as some of the most important incentives for stimulating industry engagement with partnerships for health security. Indeed, in the absence of a viable commercial market, governments and global health initiatives continue to play a key role in creating greater market certainty. Participants did, however, also identify significant additional opportunities to broaden the business case for partnerships – through, for example, advancing new technological development, repurposing existing products, and gaining access to new markets. Participants also discussed stockpiling as a particular kind of market guarantee.

The appropriateness of stockpiling was thought to vary according to political priorities and risk perceptions, the technological and regulatory capacities of individual governments, as well as market and product characteristics.

Introduction

Political demand for pharmaceuticals has increased over the past decade, as governments, international institutions, and non-governmental organizations seek to provide populations with greater access to key medicines. HIV/AIDS was undoubtedly a significant initial driver of this trend, but the focus soon broadened to include malaria, tuberculosis, and neglected tropical diseases. The insecurities generated by emerging infectious diseases (including pandemic influenza), coupled with the growing fear of bioterrorism, only heightened such political demand for new pharmaceuticals further still. This increased emphasis on drugs and vaccines places pharmaceutical companies in a pivotal role, as they possess both the technological know-how for pharmaceutical development and the ability to finance costly clinical trials.

The experience of the past decade also suggests, however, that the priorities of commercially operating pharmaceutical companies are often not naturally aligned with this heightened political demand. Many pharmaceutical companies have determined the commercial incentives for investing in the kind of medicines that governments and global health initiatives increasingly desire to be too weak. Lower profit margins compared to other therapeutic areas, difficult demand forecasts, and high opportunity costs are just some of the factors weighing on industry calculations. A significant gap thus remains between political demand and market supply in many areas of global health policy.

Political demand

- **medical countermeasures for bioterrorism**
- **(re-)emerging infectious diseases**
- **neglected tropical diseases**
- **pandemic influenza**

Market demand

- **comparatively low profit-margins**
- **difficulty to forecast demand**
- **opportuniity costs**

As a way of bridging that gap, substantial efforts have been devoted to enhancing collaboration between the public sector, the private non-for profit sector, and pharmaceutical companies. This high-level roundtable invited leaders from government, the pharmaceutical industry, global health initiatives and academia to take stock of such collaborations across three key areas of global health security: pandemic preparedness, biodefense, and neglected tropical diseases. Participants were especially encouraged to reflect upon how the following broader developments were likely to shape the future prospects of such collaborations:

- a changing ecosystem of research and development making both intra- and cross-sectoral partnerships a more common feature of the pharmaceutical development landscape;
- the rise of biotechnology companies and pharmaceutical producers from emerging markets as more significant actors;
- the emergence of increased regulatory demands, including in the areas of product safety and reimbursement; and
- the persistence of political controversies around the stockpiling of medicines and vaccines.

Over the course of the day, participants assessed how these changes are shaping the nature, incentives and sustainability of cross-sectoral collaborations for health security.

Participants agreed that cross-sectoral partnerships remain necessary for pharmaceutical development in the area of global health security, especially in contexts where development costs are high and resources are limited. Based on the experiences of the past decade, however, they also urged a greater degree of realism about expectations. Despite many notable successes, partnerships can be difficult to achieve in practice, and the risks of failure are far from insignificant. While their objective is to maximize benefits and to minimize risks, those objectives can also be at cross-purposes for different partners. And even a strong partnership is, in and of itself, no guarantee of a successful outcome in terms of developing a new pharmaceutical product. Especially in the ss-9sksn0ananeciae andpom( )0r82 TdTdevllful

For partnerships to succeed, benefits need to accrue to all parties. From a business perspective, participants agreed that the creation of a market remains key for a win-win scenario to emerge. Push incentives, such as R&D grants and technology transfer, can be very useful in creating such a broader business case. Participants also cautioned, however, they are ultimately of limited use if there is no market at the end. On the industry side, several participants confirmed that their companies' engagement in partnerships was due to a combination of push and pull incentives. However, it was also felt that in order to be more effective in future, incentives will need to take opportunity costs into account more fully. While some (especially larger) companies may be able to absorb opportunity costs under corporate social responsibility programs, or by repurposing existing products, this is often not viable for the majority of companies.

In areas where commercial market demand is low, participants thought that reliable procurement by governments and global health initiatives is crucial to the success of partnerships. Several participants recalled instances where expectations on the part of companies had not been met by governments. For instance:

- the initial commitment made by governments from the African meningitis belt to buy a meningitis A vaccine if it was priced below US$ 0.5 has not been fulfilled.
- In the United States, several companies invested in the development of medical countermeasures encouraged by a fund of US$5.6 billion for R&D and procurement of medical countermeasures, which had been made available through Project Bioshield in 2004. After this money sunset, however, the annual procurement fund consists currently of US$ 250 million. According to participants, this has caused a great deal of unease among companies that – having made significant investments in development – they now find that insufficient monies are available for the procurement of their products.

Where there is a history of governments and global health initiatives pulling out of such commitments, companies will find it more difficult to make the necessary R&D and manufacturing investment decisions.

Related challenges identified by participants include that the policy priorities of governments can change quite rapidly, that government budget-planning cycles tend to be shorter than in the pharmaceutical industry, and that risk perception varies significantly across countries. Notable government investments such as Project Bioshield, the Advance Market Commitment for a pneumococcal vaccine in 2007, and national stockpiles for pandemic preparedness reflect the focus on health security in the aftermath of the anthrax attacks in the United States, the HIV/AIDS pandemic in developing countries, and the global H1N1 and

Sustainability

Sustainability emerged as an ongoing issue in the development and manufacture of pharmaceuticals for which no commercial demand exists. In the absence of recurrent commercial market revenues, other funding sources have to bear the development and manufacturing costs. The capacities and interests of those funding sources, in turn, have to be identified and maintained. Here participants identified three opportunities for making such partnerships more sustainable in the future through:

- Promoting greater regulatory certainty (particularly for manufacturers of biodefense products and for developing countries manufacturers of pandemic influenza vaccines)
- Strengthening intergovernmental collaboration through global joint programming and greater harmonization of policy priorities,

Price Pressure

Monoclonal Antibodies for Pandemic Influenza

Opportunities to combine emergency use and commercial use applications may also emerge in the area of monoclonal antibodies for pandemic influenza. It was suggested that a manufacturing facility used for the production of a monoclonal antibody with a commercial application, such as against tumor necrosis factor (TNF) associated with autoimmune disorder, could also be used to produce a monoclonal antibody for the H5 influenza virus strain. Crucially, the switch in production could be done without vast retooling because, as long as the workforce is trained, there are mechanisms for switching from one product to the other.

BARDA's Push for Broad-Spectrum Drugs

Attempts to push commercial applications for emergency use products have also been undertaken by BARDA, which has increasingly promoted a strategy of developing broad-spectrum drugs. Participants reported that the agency's expectation is that they will support the development process up to licensure, but that the pull incentive will come from the commercial market. Participants pointed out, however, that there is big risk involved in developing broad-spectrum antivirals, and very deep pockets are required for such an endeavor.

A commercially viable business model is challenging for the majority of pharmaceuticals required in the fields of neglected tropical diseases, emerging and re-emerging infectious diseases, and biodefense. Currently, a small number of governments and non-for-profit organizations bear the bulk of the development and procurement costs. Given the need of governments to justify public expenditure, especially in times of austerity measures, the pressure on manufacturers to reduce prices is considerable.

Outside of the area of biodefense, a growing trend has been for governments and global health initiatives to turn towards pharmaceutical companies in low- and middle-income countries as suppliers of low cost medicines and vaccines. Some of those companies are able to produce at considerably lower costs than their counterparts in high-income countries. The reasons for that include relatively lower labor costs, lower profit-margins, and high volumes. On the downside, however, participants also reported that such price pressure from governments and global health initiatives is creating a situation where this business model is becoming less sustainable.

Nor has proved easy to offset the low margins of their business for low-income countries by charging higher prices in middle-income countries. Some governments, for example, appeared to reduce national immunization programs once they were no longer eligible for GAVI funding or demanded to be charged the same rates as GAVI. Finally, participants reported that developing countries pharmaceutical companies may face stiff competition from the market entry of state-owned companies from China which are able to sell below cost because of government subsidies.

The Regulatory Environment

A weak regulatory environment was perceived by several participants as another significant challenge for the sustainability of partnerships – especially in the fields of pandemic preparedness and biodefense. Producers of medical countermeasures face unclear regulatory pathways for products that cannot be tested in clinical trials. In the United States a dedicated regulatory environment has now emerged for medical countermeasures, which allows for the stockpiling and approval of such products by using animal models.

Indeed, promoting procurements prior to FDA approval was highlighted by participants as a key achievement of Project Bioshield. However, the absence of similar regulatory pathways in other countries is seen as a key barrier to market entry internationally.

Insufficient regulatory capacity, albeit of a very different kind, was also flagged up by participants as a significant barrier to market entry and sustainability for many pharmaceutical companies in low-income countries. Roundtable participants reported that manufacturers of influenza vaccines, which WHO seeks to engage through the Global Action Plan for Influenza Vaccine (GAP), are frequently confronted with national regulators that do not possess the requisite expertise, capacity and experience to approve such vaccines. In addition to working with manufacturers in low-income countries on a sustainable business case for pandemic influenza preparedness, WHO therefore also works in parallel on increasing the capacity of regulators in these countries.

Intergovernmental Collaboration

Several participants also explored greater intergovernmental collaboration as a driver of enhanced sustainability for cross-sectoral collaboration in the area of health security. Industry participants, for example, highlighted that global joint programming and greater harmonization of policy priorities, markets and regulation could enhance the sustainability of cross-sectoral collaboration in a range of areas – including for antibiotics and medical countermeasures. It was noted that WHO can facilitate international stockpiling and has done so for antiviral medicines such as oseltamivir, for instance. In the field of biodefense, Australia, Canada, the United Kingdom and the United States have also signed a Memorandum of Understanding, and government participants reported that this was providing direction and support to national programs.

Finally, governments are also looking into increasing shared procurement to enhance purchasing power for medical countermeasures and to achieve savings on administrative costs. In the field of pandemic preparedness, such efforts led to the EU Decision on Serious Cross Border Threats to Health, which includes provisions to establish voluntary joint procurement of medical countermeasures in the European Union. Industry participants acknowledged the need for intergovernmental coordination of purchasing to avoid access problems in emergency situations. Some industry participants cautioned that large tenders contributed to lowering prices, which, in turn, might affect profit margins and investment incentives. Others, however, pointed out that large tenders can provide sustainable and more navigable markets. Enhancing the sustainability of health security partnerships thus emerged as an ongoing challenge in the discussion.

Further Information

School of Global Studies
University of Sussex
Brighton BN1 9SJ

T +44 (0)1273 876615

E globalhealthpolicy@sussex.ac.uk

www.sussex.ac.uk/globalhealthpolicy

www.facebook.com/globalhealthsussex

Follow @GlobalHealthSus

Watch