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Pharmaceutical Innovation for Infectious Disease Management

From Troubleshooting to Sustainable Models of Engagement

We need to ensure scalable and sustainable approaches for pharmaceutical innovation in response to infectious disease threats to public health

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.¹ The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation.

Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that

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industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives.

This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic.

In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector.² It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with

partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.^{3,4} Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.^{3,5,6}

The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in

developing products that would be affordable in the world's poorest countries.⁷ Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.^{8,9} Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.¹⁰

Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated

with Ebola and Zika outbreaks.¹¹ However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.¹² There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would

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qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.¹³

The emerging threats raise important policy questions about how government and the pharmaceutical industry can work together to ensure that pharmaceutical industry innovation is incentivised sustainably and at scale. This is important to help mitigate against current and emerging threats becoming crises further down the line. At present, there are no clear and specific criteria to determine when a disease can trigger the types of healthcare-innovation-related policy actions that have been deployed in response to the COVID-19 crisis. For example, this applies to criteria for securing financial resources for innovation-related activities, reforming regulation to accelerate trials and regulatory approval processes, and securing reimbursement mechanisms that help enable industry engagement and the search for rapid solutions. The WHO guidance on

what constitutes a pandemic phase does provide guidance on national policy response options, but not specifically as they relate to healthcare innovation activity.¹⁴ There are also questions as to whether such policy initiatives and incentives should only be applied in crisis situations, or also as part of proactive government and industry efforts to innovate in the areas of public health threats in order to prevent future global calamities. A crisis and ‘emergency mode’ response may be inevitable for some diseases, but more can be done to mitigate against the need for such a response – especially in cases where emerging threats and their consequences can be foreseen and are known to be a risk. We need to anticipate and act now in terms of how we plan and incentivise better for the future, and how we distinguish between different types of infectious disease threats and phases in framing incentives and regulation.

Innovative financial instruments must be integral to any sustainable and scalable approach to incentivising pharmaceutical innovation for tackling emerging threats to public health from infectious diseases

The pharmaceutical industry has a responsibility to both its shareholders and to society at large.

Incentivising the pharmaceutical industry to innovate solely on the grounds of being a socially responsible sector is unlikely to lead to a sustainable and scalable approach for innovating in response to emerging infectious disease threats. There are also potential challenges to the types of innovation (i.e. how radical or incremental) a reliance on

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incentives rooted solely in a social responsibility argument can lead to. Donating existing compounds for testing is important, but it is different to at-scale, industry-wide intensive investment in R&D geared at developing highly innovative diagnostics, medicines and vaccines. Even in the case of COVID-19, there are significant differences in the scale of innovative activity that focuses on repurposing existing products and technologies – for example, through testing existing antiviral compounds for potential therapeutic value – and more radically innovative R&D efforts aimed at developing something that acts on the COVID-19 virus in fundamentally novel ways.

Commercial incentives are needed, alongside those rooted in the pursuit of health as a public good. Commercial

challenges have been barriers to innovation in vaccine R&D and in the antimicrobial space, for example. Developing vaccines can be a technically complex effort that influences success rates, and it can take a long time. The returns on investment are not guaranteed for diverse reasons, such as unpredictable market size, the risk that by the time a product is developed it may be obsolete (for example if medicines are developed in the meantime, or due to competition with improved care standards), or uncertainty as to whether some vaccines will be recommended by authorities for inclusion in immunisation schedules.^{15,16} Antimicrobials also have an uncertain market due to the risk of the pathogens that they target developing resistance, uncertain prescriber behaviours and risks of low volumes of use (meaning reserve of stock for future use, which lowers prices).¹⁷

Various incentive mechanisms for addressing the commercial barriers to pharma innovation in the infectious disease-related public-health space are being considered, and have been for some time. The focus has been on identifying financial instruments that can do good as well as facilitate returns. Existing incentive mechanisms have helped with many global health challenges, but there are issues with their scalability and questions about the timeliness with which they can mobilise industry involvement. Examples of incentives include various push incentives (for example R&D tax credits, public investment in clinical trials infrastructure, provisions for exceptional depreciation of manufacturing equipment, patent exclusivity extensions for qualified infectious disease products) and pull incentives (mainly revolving around securing a guaranteed market through guaranteed purchase funds, advanced market commitments or prize funds, and accelerating approvals and product uptake through fast-track

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approval mechanisms). These incentives seek to reduce the risks associated with the costs of R&D and market risks.¹⁷ The pooling of intellectual property— a mechanism where two or more patent owners license one or more of their patents to each other or third parties – can also help enable innovation (although they are not an incentive per se). IP pools can apply to both new and mature technologies and help remove some of the barriers to further downstream innovation, as well as enable better access to new medicines, for example in developing countries.^{18–20}

Innovative financial instruments have gained attention in more recent times, including the subscription-based ‘Netflix model’ and the use of vaccine bonds. While these hold promise in terms of facilitating timely innovation activity within industry, they require global-level engagement and buy-in, ex-ante robust estimates on likely degree of need (i.e. volume) of specific products, and transparent resource allocation processes and criteria, in order to realise their full potential as financial instruments. In the ‘Netflix subscription model’, pharmaceutical companies are paid a monthly fee (usually by healthcare authorities) in exchange for health authorities securing access to specific innovations upfront.^{21,22} The effectiveness of this model depends in part on securing sufficient monthly fees, which may require investments at an international scale. The

upfront investment is intended to incentivise innovation because the payment received by industry is independent of the future volume of sales and of prescribing behaviours, which de-risks R&D and trials for pharma.²¹

For example, in the United Kingdom, the National Institute for Health and Care Excellence (NICE), NHS England and NHS Improvement government agencies are testing a subscription-based model in which they intend to pay pharmaceutical companies upfront for access to antibiotics that meet their criteria (with payment depending on the value of the antibiotics to the NHS)²³. However, antimicrobial resistance is not a UK challenge only, it is a global one – thus models such as this only make sense as an incentive if they are adopted globally. A further challenge is that the model is more aligned with single-payer systems like the NHS, unless there is involvement and commitment from multiple payers in multiple-payer systems.²¹

In the United States, this Netflix model has also been used to negotiate access to Hepatitis C antivirals, with some US states paying a fixed monthly cost for access to direct-acting antivirals from pharmaceutical companies, as opposed to paying on a volume-based prescription basis.²⁴ Given the large cost that these subscriptions can impose on government authorities, one of the challenges associated with the ‘Netflix model’ is to achieve as accurate

as possible an estimate of the degree of need on which to base subscription fees; another revolves around negotiating industry commitment to appropriate treatment rates.²⁵ Subscription-based models also raise questions about how to ensure clear, open and transparent processes for awarding contracts to specific pharmaceutical companies – given that many may be operating in the same competitive space – and how to agree on an appropriate duration of a subscription. There are also questions as to whether there is an appropriate cap that can be set on maximum volume commitments from industry for specific products.

The ‘vaccine bond model’ is another finance instrument that mobilises long-term pledges from governments and other stakeholders to a finance facility (i.e. the International Finance Facility for Immunisation), which in turn allows the facility to raise funding on the capital market in the form of investments (bonds) and with a competitive rate of return for investors. The investments are then channelled to GAVI (Global Alliance for Vaccines and Immunizations) to support childhood immunisation efforts in the developing world. In this model, future pledges from governments (or other stakeholders) to vaccine manufacturers to guarantee purchase for their products could help to ensure access and affordability, and translate into an ability to raise funds and ensure cash flow for industry to engage with supplying vaccines for immunisation efforts today.^{26,27}

Although the ‘vaccine bond model’ has been applied mainly to secure access to existing innovations, it could in principle be applied to incentivise R&D and innovation development. However, such a model requires trust in the institutions who coordinate funding flows – GAVI is one such trusted institution. There is increasing interest to apply this financing instrument to the fight against

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COVID-19 as well. Organisations such as the Coalition for Epidemic Preparedness Innovations (CEPI) – which focuses on the development of epidemic vaccines and on access – could represent a potential global mechanism through which funding is channelled.²⁸ Whereas the model shows great promise, it has not been evaluated for scalability and sustainability.

In considering innovative financial incentives for tackling emerging infectious disease threats to public health, decision makers also need to reflect on where the resources for their implementation should come from (for example to what extent government funding alone should be expected to contribute to R&D in a subscription-based model, or whether this should be extended to other actors).

Decisions on who the appropriate investors should be – for example, in order to achieve scale – are likely to influence how various incentive mechanisms are structured and governed.

A range of other issues – extending beyond financial considerations – need to be tackled in a global and coordinated manner, to ensure pharmaceutical innovations for emerging infectious disease threats have the intended impact. We need a systems view on the innovation challenge at hand, and on critical success factors

One such issue relates to access to data and data sharing. Industry needs access to healthcare data to better understand the disease threats and to improve the speed, efficiency and effectiveness by which it can identify potentially effective candidate therapies, to inform clinical trial design, create appropriate approaches to patient stratification and trial recruitment, and to access the latest research evidence.²⁹ Diverse data types are needed, spanning genomic, proteomic, cellular and molecular level data, epidemiological data, patient-level data from electronic healthcare records (e.g. on symptoms, test results, prescriptions and patient outcomes) and population-level data.

In the context of urgent infectious disease threats and global pandemics such as COVID-19, or in cases where innovation is urgently needed to prevent a crisis in the future, both public and private sector actors are likely to

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need access to large amounts of linked healthcare data at a particularly rapid pace (when compared to ‘business as usual’).³⁰ This can only be made possible through innovative governance mechanisms that can ensure data quality, interoperability, public support and appropriate and trusted safeguards for privacy, security and ethical practice. Alongside technical and operational challenges, this raises questions about who the most appropriate and most trusted custodians for such data may be, especially in a global and coordinated (as opposed to only national) effort. Identifying such custodians and building the infrastructure needed to support their delivery is a major policy challenge, but also a critical success factor for innovation efforts. Complexities in governing data use by industry in a publicly acceptable way may be further accentuated by a landscape where a very large number of companies are working on the challenges in parallel, and together with public sector actors. To address this, we need to accelerate learning from prior efforts to build effective health

data ecosystems.^{29,31} The experiences of the European Medical Information Framework (EMIF), which sought to enable secure and coordinated access to patient-level data for research purposes across a federated context, may offer particularly fertile ground for practical and actionable learning.³² The European Commission has recently launched a COVID-19 data platform, although the extent to which it considers industry access to data, and the types of data it proposes to collect, are not yet entirely clear (in the public domain). For example, would such a data sharing platform be confined to epidemiological and pre-clinical research, clinical trial and basic science data alone, or would it extend to health services and patient level data contained in electronic health records?^{33,34}

Of course, the pharmaceutical industry will not only need access to data – it will also need to share data with other actors. Occasionally, this can involve commercially sensitive data. Platforms supported by artificial intelligence and blockchain technologies could help support such data sharing. For example, in 2019 ten large pharma companies and other partners joined forces to bring together data on small molecules into an Artificial Intelligence-based platform to accelerate drug discovery. The platform, known as MELLODDY (Machine Learning Ledger Orchestration for Drug Discovery), will use a blockchain architecture where the algorithm searches company datasets on annotated chemical libraries with full traceability, without disclosing commercial secrets.³⁵ Such technologies could potentially also support collaboration in the area of COVID-19 innovation and in innovation for other infectious disease threats, given appropriate data quality and interoperability standards. However, if this type of collaboration is to be scaled, there is likely to be a need for

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further consideration of not only technical requirements but also of data standards and the governance of such collaborations in terms of benefit distribution. The need for global-scale action and global-scale data sharing to tackle emerging infectious disease threats also implies a likely need for different pharmaceutical companies (who generally might be competing with each other) to share data with each other, as part of innovation efforts. This challenges the historical – although gradually changing – competitive dynamics and commercial sensitivities within the industry, which are also changing in the context of COVID-19.¹⁰

Beyond data issues, ensuring timely access to the requisite clinical trial infrastructure for industry contributions is also a critical success factor in tackling infectious disease threats. The public sector has a big role to play in this regard – both in relation to resource investment and in relation to coordinating available clinical trial

infrastructure within a particular geography. The availability of good trials infrastructure is an incentive for pharmaceutical companies – not least in relation to the quest for speed and efficiency. To this effect, and in the context of COVID-19, in the United Kingdom the Department of Health and Social Care and UK Research and Innovation have sponsored the ACCORD (Accelerating COVID-19 Research & Development) clinical trial platform to fast-track COVID-related trials. This was enabled by collaborative working between various government agencies and government funded initiatives, including the Government Scientific Office, the National Institute for Health Research’s biomedical research centres and clinical research facilities – as well as centres of expertise in Northern Ireland, Scotland and Wales – and collaboration with the private sector (namely clinical research company IQVIA and the pharmaceutical company AstraZeneca).³⁶ Rapid regulatory approval and a focus on prompt patient enrolment have been central to this effort and to the role it aims to play in accelerating COVID-19 related R&D.

However, questions remain as to the extent to which the public sector and policy actions can sustain attractive and timely support for a coordinated clinical trial infrastructure that can be rapidly mobilised for infectious disease and public health innovation efforts outside of a crisis context. There is also a risk that if some trial needs are pushed to the front of the queue, other areas in need of clinical trials are pushed back. Avoiding this risk requires innovating in how the clinical trials infrastructure is coordinated and in how trials operate across the spectrum. There may be transferrable learning to be gained from how this is happening in the COVID-19 response context.

There is a need to consider success criteria extending beyond the innovation-intensive product development phase alone.

Finally, there is a need to consider success criteria extending beyond the innovation-intensive product development phase alone. Many of these criteria represent important industrial and healthcare policy concerns, and will require coordination between public and private sector actors. This applies to areas such as ensuring an appropriate approval process for innovations that are in the pipeline and carefully considered procurement practices, so that accelerated access does not compromise safe access and bear other unintended, global consequences. Recent RAND research examined the potential unintended consequences of innovation in this space. Amongst other potential unintended impacts, the research identified a need to ensure that appropriate testing is aligned with rapid access to treatments so that products are not inappropriately channelled to those who may not benefit or who may experience undesirable side effects. The research also underlined the need to ensure a sufficient supply of drugs that may be used for multiple clinical indications

when resources are diverted to a pandemic, and to ensure ethical practices when considering supply to populations across the world, including in the world's poorest countries.³⁷ *To tackle some of these issues, policymakers and industry will also need to focus on securing appropriate manufacturing capacity within industry; this too is likely in some instances to require collaboration between different pharmaceutical companies to ensure sufficient production capacity.*¹⁰ Although many pharmaceutical companies have said that they will focus resources on manufacturing a COVID-19 vaccine if and once developed, there will only be some vaccine candidates that achieve success and reach the manufacture stage. It is difficult to predict which these will be and to plan for manufacturing capacity within a specific company or amongst collaborators behind a successful collaboration.³⁸ *Industry and governments will also need to work together to revisit and reform pharmaceutical supply chains to avoid overly relying on a few countries, and to strengthen distribution and delivery systems and delivery capacity for potentially successful products within national health systems.*³⁹

The ultimate impact from pharmaceutical industry innovation efforts will depend on the ability of many actors to work together to address both upstream bottlenecks to the pharmaceutical industry's commitment to innovate, as well as downstream challenges on which effective, equitable and affordable access to innovations depend. The pharmaceutical industry will need to deliver on commitments made in response to any financial and regulatory incentive systems that are put in place. Ensuring such delivery will require industry to engage with society in ways that extend beyond coming up with and manufacturing the pill, test or vaccine and agreeing

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on a price. For example, there is a role for the pharmaceutical industry to play in ensuring fair and equitable distribution of innovative products, in helping support compliance with treatment regimes, in raising awareness and in education efforts geared at healthcare service providers, patients and the public. The patient and public voice and patient and public concerns must not be forgotten in innovation conversations on infectious diseases and public health – not least as public trust and buy-in will determine many of the critical success criteria for innovation development (e.g. access to data) *and for downstream public health impact (e.g. uptake of testing, medicines or vaccines).*

Industry and government actors will also need to reflect on the distribution of benefits from highly collaborative efforts, in which pharmaceutical industry pipelines and development efforts are supported by both academic research and by the breadth of scientific and technological innovation taking place more widely in the biotech and small and medium enterprise sectors, which also need

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incentives for working on emerging infectious disease threats.

The areas in need of policy attention are more straightforward to identify than finding solutions to them. But as we have shown, there is fertile ground from which to learn, and based on which to design solutions in many – if not all – of the areas highlighted in this reflective paper. Innovation in response to the COVID-19 pandemic is showing what can be pursued – and hopefully achieved – when the political will, policy and regulatory momentum,

industry commitment and global collaboration across sectors, professions and disciplines are unleashed. Building on this momentum to ensure sustainable and scalable approaches to pharmaceutical innovation will prepare for other pressing, emerging and re-emerging infectious disease and public health threats of our time – now and in the future.

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About This Perspective

In this Perspective, the authors discuss the need for more sustainable and scalable ways of incentivising pharmaceutical industry innovation in response to infectious disease threats to public health. The authors consider incentives for innovation both in the current context of the COVID-19 crisis, and in the context of preventing other emerging or re-emerging infectious disease threats from becoming crises further down the line. The paper discusses the potential for innovative financial instruments, such as subscription-based models and bond-based approaches, to act as incentives. The authors also highlight the need to tackle a range of critical success factors beyond financial considerations. This includes tackling issues related to data access and the governance of data sharing, securing appropriate clinical trials infrastructure, ensuring suitable approval processes and procurement practices, and planning for manufacturing and supply chain capacity to mitigate against unintended consequences in affordability and access. Finally, the authors observe that the pharmaceutical industry will need to engage with society in ways that extend beyond producing a pill, diagnostic test or vaccine, in order to deliver on commitments made in response to any incentive systems that are put in place.

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