BIA response to Biological Security Strategy call for evidence

1: What are the key biological security opportunities, challenges, threats and vulnerabilities facing the UK:

a. now?

The primary opportunity for the UK is the country's competitive advantage in life sciences, which will be the most strategically important industry globally in the 21st Century in relation to biological security, as well as for the nation's health and prosperity more broadly. As explored throughout this submission, the UK life sciences community (academic and industry) has shown its strength during the pandemic, but weaknesses have also surfaced. Work is already underway to capitalise on the strengths and address the weaknesses. This work represents a major opportunity for the UK to secure global leadership in and resilience to future biological challenges, threats and vulnerabilities.

Key challenges, threats and corresponding opportunities

The COVID-19 pandemic continues to pose a challenge the UK's biological security, especially with the risk of new variants having significant ability to evade the protection offered by current vaccines. The UK also faces threats from other emerging zoonotic diseases, as the relatively recent outbreaks of swine flu, SARS, MERS and Ebola have shown that the potential for such pandemics is ever-present. The threat posed by pandemics is exacerbated by the fact that UK currently only has a small number of established companies and facilities for viral vector, sub-unit protein and whole virus vaccine manufacturing. Moreover, the likely sale of the Vaccine Manufacturing Innovation Centre (VMIC) means that there will be gaps in the UK's manufacturing and research capacity for multiple vaccine candidates. However, there is a significant opportunity for the UK to continue building its onshore capacity to develop and manufacture vaccines at pace, including mRNA vaccines. There is also an opportunity for the UK to capitalise on other lessons learned from COVID-19, including by building its capabilities in the development of antiviral treatments.

Antimicrobial resistance (AMR) poses an enormous threat globally, including in the UK. A recent study published in the Lancet found that 1.27 million deaths globally in 2019 were the direct result of drug-resistant bacterial infections, and without further mitigations this figure is set to rise significantly. The UK has an opportunity to lead the global response to tackling AMR, including through the promotion of stewardship and the development of innovative antimicrobials. A key challenge is that existing reimbursement models for drug development fail to encourage investment in the development of new antimicrobials which would only be used as a last resort for treating infections in order to avoid the emergence of further resistance. New economic models are needed which de-link the price paid for antimicrobials from the volumes sold to incentivise investment. The UK is leading the way in this area, as the National Institute for Health and Care Excellence (NICE) prepares for the final phase its pilot scheme for a subscription-based payment model for antimicrobial drugs. This will be the

world's first subscription-based payment model for antimicrobials and the international AMR community will be watching very closely.

Another significant biological security threat facing the UK is biological and chemical warfare. The 2018 Novichok attack demonstrated how readily certain actors will use chemical warfare to target individuals, with subsequent fall-out for the surrounding population. The proliferation of chemical, biological, radiological and nuclear (CBRN) technologies to State and non-State actors also raises the threat of biological and/or chemical warfare being waged on the civilian population. This threat is also related to the risk posed by AMR, as there is a risk that drug-resistant pathogens, such as anthrax, will be deliberately spread as a weapon. In order to address these threats, there is an opportunity for the UK life sciences sector to build its capabilities in the research and development of medical countermeasures to CBRN technologies. Such countermeasures have the capacity to significantly reduce the risk posed by biological and chemical warfare. The BIA has a number of members in this space, including in the development and manufacture of countermeasures against cyanide, chemical weapons, nerve agents and anthrax. The Government should support this industry to ensure the UK has sufficient stockpiles and manufacturing capacity of these countermeasures and should also play a role in supplying countermeasures to other countries.

Another threat facing the UK is animal and plant disease, which can have far-reaching effects, and can occur naturally or as a form of warfare. Recent experiences of foot and mouth disease and avian flu demonstrate how such diseases can have profound effects upon UK agriculture and the wider economy. It is important that the UK builds and maintains its capability to respond to threat posed by animal and plant diseases, including through the development of animal and plant disease treatments and countermeasures.

Biological security risks could also arise from cyber and physical security breaches at organisations working in the biological sciences sector. It is important that these organisations have policies and practices in place to mitigate this risk. Smaller and earlier-stage companies will be less likely to be prepared for this, so the BIA supports its members to ensure they are informed on this matter, supported by UK agencies. It is important that agencies' outreach to our sector continues.

Enabling platform technologies

The UK's strength in genomics is a key opportunity in our defence against biological threats. Our genomic surveillance of SARS-CoV-2 throughout the pandemic outpaced the rest of the world. The COVID-19 Genomics UK Consortium (COG – UK) was an innovative collaboration that sequenced over a million SARS-CoV-2 genomes, more than any other country. Genomic sequencing capability is also vital in our defence against antimicrobial resistance. Using these genomic epidemiology techniques can track outbreaks to a high level of detail and can be used to monitor a range of environments from farms and sewages to hospitals. The UK should maintain this strength in genomics by prioritising investment in research and innovation, and the necessary infrastructure to support it. The pandemic has shown that existing resource, infrastructure and investments can pivot to address public health threats when needed. In addition, research into new technologies which can faster perform sequencing should be invested in, further bolstering this line of defence. Finally, data about such outbreaks needs to be properly shared, enabling real-time insights and responses.

The field of engineering biology also provides opportunities for the UK to address many of the biological security threats it faces, from AMR to climate change. This rapidly evolving technology uses biology to design and engineer biologically-based parts, devices and

systems, and redesign existing, natural biological systems. It can help to ensure biological security by enabling sustainable and resource-efficient solutions to society's challenges in food, chemicals, materials, water, energy, health and environmental protection. In healthcare, engineering biology can ensure biological security by enabling sustainable and resource-efficient solutions to society's challenges in food, chemicals, materials, water, energy, health and environmental protection. For example, on AMR, researchers are exploring the potential of synthetic biologically engineered antibiotics to monitor the adaptation of bacteria and modify their response accordingly. The UK has significant expertise in engineering biology but faces challenges in fully realising its potential through the translation and commercialisation of this research and technology. A strong skills and talent pipeline and access to scale-up investment is crucial to UK growth of this disruptive technology.

While engineering biology and its far-reaching applications offer sustainable and innovative solutions to many of the challenges faced by society today and in future, there are concerns regarding the potential implications of these complex engineered solutions themselves. These include the engineering of pathogens and microbes to produce harmful biochemicals, both deliberately or accidentally, and the potential release of these biochemicals into the environment. It is important that appropriate risk management systems are in place to manage these risks.

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b. in 5 years?

The threats and challenges posed by AMR will increase over time unless significant action is taken to address it. The threat posed by specific microbes will also change over time, and the pattern of these changes may be difficult to predict. For example, the threat posed by

methicillin-resistant Staphylococcus aureus (MRSA), which caused more that 100,000 deaths in 2019, could become even greater in the next five years. The risk of antimicrobial resistant superbugs being engineered for use as biological weapons may also increase in coming years. The use of genomics surveillance techniques will become even more important in detecting, understanding and responding to these threats.

Over the next five years, the UK has an opportunity to become the global leader in the development of innovative antimicrobials and antifungals. The UK is already recognised as a leader on AMR policy, especially following the publication of the 2016 O'Neill report and the work of Professor Dame Sally Davies, the UK Special Envoy on AMR. During its 2021 G7 Presidency, the UK ensured recognition of AMR as a global health priority. In December 2021, G7 Finance Ministers committed to 'take additional specific and appropriate steps to address the antibiotic market failure', including by strengthening incentives for antimicrobials drug development. The UK should capitalise on the opportunity to maintain this leadership by ensuring that its delivers on this commitment. The UK already has a strong research base in the research and development of novel antimicrobials and antifungals, but changes are needed to incentivise commercial investment. The National Institute for Health and Care Excellence (NICE)'s project to test a new evaluation process and payment model for antimicrobials is the perfect opportunity for this. If the project is a success, then it will help to incentivise the UK life sciences sector to increase investment into innovative antimicrobials, providing a model for other countries to follow.

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c. in 10 years?

The threats and challenges discussed above are likely to remain for the forseeable future, and the UK should continue to take action to address these.

In ten years, the impact of climate change could mean that UK faces an increased threat of disease spread by mosquitoes and ticks. This creates potential for the increased occurrence of tropical diseases, such as malaria, in the UK. The Government should continue its surveillance of this issue, and should take action now to reduce the impact of these diseases, including through the development of vaccines and treatments. The UK life sciences sector has already made signficiant progress in this area, including GSK's RTS,S malaria vaccine, which was approved by the WHO in October 2021. The Government should

support further investment into this area to enhance the biological security both in the UK and globally.

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2: How can the UK capitalise on the identified opportunities?

a. What are the key global, regional and domestic trends affecting UK biological security out to 2030?

The COVID-19 pandemic has shone a spotlight on infectious diseases and the catastrophic global impact of being unprepared for a pandemic. There is now much greater recoginition of the need to monitor and prepare for biosecurity threats.

A major trend which the BIA has observed is the recognition by governments around the world of the importance of onshoring the life sciences supply chain to secure resilience to health emergencies. The supply chain for the manufacture of vaccines and medicines is complex and international. Whilst full onshoring is not realistic, governments globally are creating incentives and putting policies in place to attract and retain life science businesses in their countries.

Engineering biology is increasingly being recognised as a technology that will transform biological security with applications across medicine, agriculture, energy and manufacturing. This technology can be used to develop sustainable and resource-efficient solutions to society's challenges in food, chemicals, materials, water, energy, health and environmental protection. The future of UK biological security is likely to be highly dependent on advances in this field.

b. How should the government prioritise its efforts to identify and respond to these?

The Government should ensure that lessons are learned from the COVID-19 pandemic and that the UK is better prepared for future biosecurity risks. It should continue to work in close collaboration with stakeholders outside government, including the life sciences sector, to build capacity in the UK.

By supporting the life sciences sector to develop innovative solutions to biosecurity threats and onshoring manufacturing and genomic surveillance, the UK can capitalise on the opportunities to lead the global biosecurity response. The Life Sciences Vision, published in July 2021, set out how the UK can regain its status as a science superpower by becoming the leading global hub for life sciences. It recognised the the need to build on news ways of working from COVID-19, including through private-sector engagement. The Government should ensure that its assessment of biological security threats is communicated to industry

to ensure appropriate prioritisation of efforts and investment. Surveillance and health systems should be set up with the appropriate data flows to enable real time monitoring of health threats.

The Government must ensure the UK is internationally competitive for both life sciences R&D and manufacturing. Major policy levers for the former are increasing the budget of Innovate UK to allow it to offer more innovation grants and increasing the generosity of R&D tax credits for both SMEs and large companies. Manufacturing can be incentivised also through grants for capital investment, such as the recnetly launched Life Sciences Innovative Manufacturing Fund (LSIMF) and also by maintaining an attractive fiscal environment (e.g., by offering low corporation tax through the Patent Box). The LSIMF is a welcome new development and if it proves successful, it should be expanded to anchor more life sciences manufacturing in the UK. The Government should also prioritise investment in genomics companies, including through Innovate UK grants. The BIA's *Genomics Nation* report, published in July 2021, found that public investment in genomics has stimulated strong returns on private investment. Investment in national programmes such as Genomics England and the UK Biobank is another way to stimulate the UK genomics sector. To fully benefit from these initiatives SMEs should also be given access to participate in them. Skills are another important element for both R&D and manufacturing and the Government should work closely with industry to identify and address current and future skills shortages.

The Government should ensure that the UK is in a position to fully realise the potential of engineering biology. There is currently a lack of UK investor awarness of this field and thus a lack of sufficient finance to develop companies. The UK also has a more conservative entrepreneurial culture in comparison to the US biotech sector, a smaller skills and talent pool, and fragmented markets. Calculated risks by investors – both private and public - are necessary for the UK to reap the rewards of engineering biology and its products and processes. We welcome the identification of engineering biology as a key technology in the recent Innovation Strategy, significant investment will be needed to capture the full benefits for the UK. The National Engineering Biology Programme (NEBP), announced by UK Research and Innovation (UKRI) in June 2021, could also play a key role in supporting UK capability in engineering biology. The Government should continue to provide leadership and strategic coordination on UK engineering biology, including through the Engineering Biology Leadership Council (EBLC) and Industrial Biotechnology Leadership Forum (IBLF), which bring together industry, government and academic stakeholders.

The Biological Security Strategy should also recognise the importance of strong intellectual property (IP) rights in the UK and internationally to foster innovation in the life sciences sector. The significant investment required for the extensive R&D activities and innovation in this sector is made possible by the commercial incentive provided by patent protection. Robust patent applications are also essential to persuade investors to finance the research and invest in bioscience SMEs. In order to foster innovation, companies in the life sciences sector need a strong IP system to enable them to innovate and access the investment necessary to conduct R&D.

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c. How do new mitigations which emerged through the COVID-19 pandemic (such as mRNA vaccines) alter the risk landscape?

mRNA vaccines, which can be developed very quickly and can produce enhanced immune responses, have the potential to significantly improve the UK's risk landscape with regard COVID-19 and future pandemics. With the acceleration in the understanding and development of mRNA therapies and vaccines, the UK has put in place the foundations for a prosperous and robust mRNA sector. As part of the Vaccines Taskforce investment in May 2020, the UK's medicine Catapult Network saw expansion in terms of facilities and remit. The new Cell and Gene Manufacturing Innovation Centre (CGMIC) in Braintree, which is focussed on advanced therapies, could easily pivot to manufacture and develop mRNA vaccines, thus helping to reduce the risk landscape.

The Centre for Process Innovation (CPI) in Darlington also received investment and has now come online an industry leading mRNA library, which is attracting the attention of international pharmaceutical companies for collaboration opportunities. The CPI has also created an mRNA training academy which will be a key facility to drive industry skills in this area here in the UK and abroad. This strategy has leveraged in further private sector investment from Fujifilm Diosynth Biotechnologies and Pfizer, increasing their UK manufacturing capacity to support the creation of RNA therapies and resulting in high skilled, well-paid jobs being created in Teesside and Swindon, respectively.

The genomics surveillance networks and data flows established during the pandemic illustrate what can be achieved when government, academia, industry and the NHS work together. Learning from the success of these systems, and embedding the capabilities into our defences will go some way to reducing future risk.

d. How might surveillance tools and capabilities enhance our resilience to natural hazards and malicious biological threats?

Surveillance tools can enhance resilience by ensuring appropriate levels of preparedness for specific threats. Surveillance of the threat posed by AMR is particularly important, as the the threat posed by specific drug-resistant infections has the potential to change rapidly. In 2015, the Government initiated the Fleming Fund to improve surveillance of drug-resistant infections in low and middle income countries (LMICs). This work is crucial in tackling AMR as it helps to inform stewardship in prescribing and helps to direct investment to the most pressing areas.

The COVID-19 pandemic has shown that health surveillance on a global scale is critical. The UK should play a leading role globally in the provision and support of activity in this area. As referenced previously, genomics sequencing and surveillance was a key strength of the UK during the pandemic. Understanding the genome of pathogens will not only help us detect

and respond to outbreaks but also to develop new treatments and vaccines. Genomics technologies are therefore vital in our resilience to future threats.

e. Are there successful examples of surveillance and/or wider approaches and capabilities for mitigating biological risks in other countries that we can learn from?

N/A

f. What further steps should the UK take to maximise our resilience to and preparedness for natural hazards, accidental release, malicious biological threats, and emerging zoonotic pathogens?

It is important that the UK continues to onshore its manufacturing and research capacity for vaccines and other medical countermeasures. By simply procuring vaccines supplies now and in the future, the UK risks facing high costs for long term contracts and supply chain failure. It also increases risk of companies succumbing to other countries' legislation, such as the US Defence Act, and companies choosing larger markets such as the US and EU to first launch their products. Continuing to invest in genomics research and innovation will ensure we can capitalise on breakthroughs and maximise resilience.

g. What role would health systems overseas (including in Low and Middle Income Countries) and their resilience play?

Health systems overseas, including in LMICs, have a crucial role to play in addressing global biological security threats, especially the threats posed by infectious diseases and AMR. The Government has made significant contributions in this area, including through the Fleming Fund, which supports 24 countries in Africa and Asia to tackle AMR. The UK should continue this vital work to support the capacity and resilience of overseas health systems.

h. Should research and laboratory standards, safety and security play more of a role (domestic and international), and what else should we be doing?

N/A

3. What lessons can we learn from the UK's biological security delivery since 2018, including but not limited to COVID-19?

a. Which are the key successes we should look to develop and build on, and where are areas for development?

The key success of the UK's biological security delivery since 2018 has been the COVID-19 vaccine programme. This success was built upon historic Innovate UK investment in the UK biotech and life sciences sector and the strategic decisions taken by the Vaccine Taskforce under Dame Kate Bingham to ensure that the UK had a growing and flexible manufacturing base for this pandemic and those in the future.

The COG-UK consortium is another example of a successful initiative born from the pandemic. As well as providing the genome data that informed public health actions and policy decisions, the COG-UK network has now amassed a unique dataset that can be used to study COVID-19. This work was facilitated by existing investment in research and innovation, as well as the rapid research response 'fighting fund'. The model of combining long-term and rapid response funding and investment is something that could be further developed in future.

The COVID-19 pandemic also exposed some weaknesses in the UK's biological security strategy, including pandemic preparedness being focussed too closely on influenza and not coronavirus, despite the recent outbreaks of SARS and MERS in Asian countries. It is important that the UK is prepared for a wide range of threats.

The UK has so far achieved relative success in tackling AMR, including by drawing international attention to the issue, supporting healthcare systems in LMICs, and by supporting the development of innovative antimicrobials. It is important that the UK builds on this success in the coming years.

b. How can the future development and delivery of the strategy be improved by adjustments to UK systems, capabilities and the UK life sciences industry?

As described in previous answers, government should continue to provide support for R&D and manufacturing in the life sciences sector. A dynamic private sector is critical in driving innovation in this sector and the Government should therefore support the growth of the private life sciences sector in the UK as a means to deliver strategic capability on biological security. A cohesive strategy exists in the Life Sciences Vision, but it needs linking with the Biological Security Strategy and cross-government support and coordination, along with substantial investment, to be successful. Key areas in need of focus include:

- increasing access to finance for start-ups and scale-ups to nurture a diverse and vibrant community of innovative companies, from which the innovations to address future challenges will emerge.

- creating incentives for life sciences manufacturing to strengthen UK resilience in the face of future public health threats as well as to capture the economic benefits of increased life sciences R&D investment.

- working collaboratively with industry, as was done through the Vaccines Taskforce, to provide strategic leadership and investment in critical technology areas, such as engineering biology, AMR, cell and gene therapies and other advanced vaccines and therapies manufacturing.

The Government should also consider its purchasing decisions in establishing UK capability in biological security, including increasing the proportion of UK suppliers of medical countermeasures in its national stockpiles. This would support the scale-up of innovative companies by providing them with an anchor customer.

It is also important that the UK has a strong and strategic presence in global fora where scientific standards are established. To build and maintain this presence, the UK should ensure it has sufficient technical and scientific capability in relevant civil service institutions and should closely monitor informal standard setting groups in academia, industry and elsewhere.

c. Should the UK have a single accountable role or body responsible for meeting the full range of biological threats?

N/A

d. What can we learn from other countries' biological security practises and experiences?

N/A

e. How should the UK engage with, support or influence, existing multilateral and other international collaborative efforts towards biological security to improve the impact of our strategy?

N/A

4. How should progress be monitored and evaluated, and how often should the strategy be refreshed?

a. Are there successful approaches in other countries that we can learn from?

N/A

b. How should UK collaborations, investments, and interventions be designed to assure the development and delivery of the strategy?

These should be designed in collaboration with industry and be as transparent as possible in order to enable accountability regarding the development and delivery of the strategy.