Written Evidence Submitted by The Association of the British Pharmaceutical Industry (ABPI)

(C190098)

Inquiry: UK Science, Research and Technology Capability and Influence in Global Disease Outbreaks

Key points

Research and Development of therapeutics and vaccines:

- The global R&D response to COVID-19 is unprecedented in scale and speed. In order to ensure R&D efforts in the UK complement global activity and avoid unnecessary duplication, the UK Government must coordinate with other governments and with the global industry to ensure government funded research is not duplicative and resources are applied in a targeted way.
- Given the risk and uncertainty in the R&D process, it is critical that the UK continues to take multiple 'shots on goal' and supports a range of vaccine and therapeutic candidates. For therapeutics specifically, government should ensure that Urgent Public Health studies give adequate prioritisation to promising novel therapies – the vast majority of which are being developed by the innovative pharmaceutical industry – alongside the large clinical studies focused on repurposed medicines.

Capacity to manufacture, scale-up and distribute therapeutics and vaccines:

- Industry is already taking steps to increase manufacturing capacity in anticipation of successful vaccine candidates, at significant organisational risk given it is unclear what candidates will be successful.
- To respond to COVID-19 and future pandemics Government should aim to attract medicines manufacturing facilities to the UK that bring innovative, high value platforms and technologies which are flexible, agile, and scalable.
- Introducing capital grants to incentivise advanced medicines manufacturing investment as part of the upcoming CSR and Autumn budget will support this objective.

The flexibility and agility of institutions, Government departments and public bodies, and processes to respond appropriately during the crisis

- The MHRA (Medicines and Healthcare products Regulatory Agency) and HRA (Health Research Authority) have worked closely with industry to identify regulatory flexibilities or process improvements which can support the response to COVID-19. Government should look to lock in these positive changes and, where appropriate, implement them on a permanent basis.
- New structures such as the Vaccines Taskforce, Therapeutics Taskforce, and the NIHR Restart Advisory Group have been set up by Government to support the response to

COVID-19. A blueprint for establishing such taskforces/groups, which clearly outlines how they link into permanent government structures should be produced. This would help to support: 1) quick and effective establishment in future; 2) appropriate engagement with the right industry groups when required; 3) good governance and transparency; 4) effective communication with stakeholders.

- The UK's focus on COVID-19 R&D and the decision by the NIHR Clinical Research Network to pause the set-up of new and ongoing studies that were not nationally prioritised COVID-19 studies has impacted clinical research activity in the UK for non-COVID-19 research. A process for which such research can be universally recognised as a national priority should be established, to ensure patients with life-threatening diseases are supported throughout any future COVID-19 waves and future pandemics.

The capturing during the crisis of data of the quantity and quality needed to inform decisions made during the crisis and maximise the learnings afterwards

- Richer data (enabled by the expansion of the testing capability and the test and trace programme) can be used to ensure we identify local hotspots where clinical trials could be feasible, rather than requiring a high national prevalence to test efficacy.
- Similarly, improved local and regional data about COVID-19 prevalence can be used to inform decisions about the resumption of treatment or clinical trials for non-COVID patients which may have been put on hold during the pandemic.

The UK's readiness for future pandemics:

- Government should urgently review the resourcing of the NIHR (National Institute for Health Research), and where required increase funding to ensure that there is enough resilience and capacity within the system to continue non-pandemic clinical research in the event of future waves or other pandemics.
- The pharmaceutical industry is committed to supporting the NHS return to full strength and help support preparations for further waves of COVID-19 or future pandemics. This response outlines actions in the following areas which can support these objectives:
    - Reducing the backlog of treatments and services,
    - Delivering high uptake of routine vaccinations throughout future pandemic waves,
    - Improving early diagnosis, primary and secondary prevention,
    - Supporting appropriate self-care,
    - Incentivising community-based healthcare,
    - Evaluating and embedding innovative changes in practice

Life Sciences Recovery Roadmap:

Alongside this submission, ABPI would like to draw the Committee's attention to the "Life Sciences Recovery Roadmap", which was recently produced by ABPI and seven other Life Sciences Trade Associations and the Association of Medical Research Charities.

The Roadmap reflects the views of hundreds of members from across 8 different trade associations and represents a sector-wide consensus on how the Life Sciences sector can

work with Government and the NHS to help drive the UK's economic recovery, and support the NHS to return to full strength.

About ABPI

The Association of the British Pharmaceutical Industry (ABPI) exists to make the UK the best place in the world to research, develop and use new medicines. We represent companies of all sizes who invest in discovering the medicines of the future. Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Our members are playing a leading role within the UK and globally in responding to COVID-19.

Our priorities in responding to the current COVID-19 outbreak in the UK

1. Research and develop new treatments and vaccines, at pace, for COVID-19.
2. Support the NHS in responding to the crisis, by drawing on our companies' breadth of expertise.
3. Focus on securing the supply of medicines for patients.

The capacity and capability of the UK research base in providing a response to the outbreak and capacity to manufacture and distribute testing, diagnostics, therapeutics, and vaccines

Research and development (R&D) of therapeutics & vaccines

1.1 The global R&D effort in response to the COVID-19 pandemic is unprecedented in terms of scale and speed. There are multiple companies and partnerships globally looking at the development and manufacturing of potential COVID-19 vaccines and therapies, as detailed by the International Federation of Pharmaceutical Manufacturers and Associations (1).

1.2 For commercial R&D, as of 21st July 2020, WHO's COVID-19 vaccine database states there are 24 candidate COVID-19 vaccines in clinical evaluation and a further 142 candidate vaccines in pre-clinical evaluation globally (2). Furthermore, the global industry had 487 potential therapies to treat and/or prevent COVID-19 in development (84 in clinical development), with over 2,600 clinical trials being conducted globally (3).

1.3 In the UK, the Government have set-up a process for nationally prioritising and approving Urgent Public Health studies for COVID-19 research, with 50 studies identified to date and over 120,000 participants recruited (4). This includes 8 commercial studies, sponsored by companies Roche, Gilead, Novartis, GSK, Synairgen and RevImmune, focused on developing treatments for COVID-19. These commercial studies are exploring the use of monoclonal antibodies in Phase II (Otilimab) and Phase III (Toclizumab and Canakinumab), broad-spectrum anti-virals (Remdesivir) in Phase III and immunological agents (including kinase inhibitor Ruxolitinib) in Phase II and III.

1.4 The COVID-19 R&D effort needs to work towards having the right selection of treatments for this new disease, so that we have the right medicine, at the right dose, at the right time for patients, ensuring we address the range of health issues associated with COVID-19. **To achieve this, government should ensure that Urgent Public Health studies give adequate prioritisation to promising novel therapies** – the vast majority of which are being developed by the innovative pharmaceutical industry. Whilst novel therapies are high risk and will take longer to research and develop, they have the potential to offer higher rewards through a tailored and targeted approach, which could provide our most significant step forward in the battle against COVID-19.

1.5 The UK will need a clear strategy for the continued research, development, manufacturing and distribution of COVID-19 research. With over 2600 trials worldwide and a changing patient population in each location as the virus spreads and is suppressed, the UK cannot do this alone.

1.6 **Given the scale of the global R&D response to COVID-19, it is essential that the UK Government coordinates with other governments and with the global industry to ensure government funded research is not duplicative at a time where maximising speed, safety and efficiency is key.**

1.7 **The UK Government, and new structures such as the Vaccine and Therapeutics Taskforces should continue to engage directly with Industry and draw from industry's considerable expertise in taking products from basic research to patient delivery at large scale.**

Capacity to manufacture, scale-up and distribute therapeutics and vaccines

2 Across this vast R&D portfolio, the pharmaceutical industry is preparing for the large-scale manufacturing and distribution of potential COVID-19 therapeutics and vaccines.

2.1 The vaccines in research and development for COVID-19 use a range of technologies that require different manufacturing approaches together with specific skill sets. **Investing in manufacturing capacity now is essential, so that the UK is able and prepared to produce at scale once a vaccine is approved**. This investment does however carry financial risk because it is not known which (if any) candidates will be successful.

2.2 Companies are already making significant investments at high risk, to ensure there is sufficient manufacturing capability if/when a successful vaccine(s) are identified. Examples of the industry's preparation include (and are not limited to):

- **AstraZeneca** and the University of Oxford are collaborating on the scale-up production of their potential COVID-19 vaccine, AZD1222 (5). AstraZeneca has reached agreements with European countries (including Germany, France, Italy and the Netherlands) to supply 400 million doses of the vaccine (6). Furthermore, AstraZeneca has reached a licensing agreement with the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance and the Serum Institute of India to supply low and middle-income countries with the vaccine also (7).
- **GSK** confirmed in May 2020, its aim to manufacture 1 billion doses of its pandemic vaccine adjuvant system, which can reduce the amount of protein require for vaccine

dose. The manufacture of these adjuvant systems for COVID-19 vaccines will be carried out at sites in the UK, USA, Canada and Europe (8).

- **Pfizer** are working to develop, test and manufacture an mRNA-based vaccine for COVID-19, using their 40 Pfizer-owned sites and over 200 global suppliers. Pfizer estimates they have a capacity to manufacture over 500 million doses of medicines and vaccines (9).

Supply resilience:

3. Covid-19 has highlighted potential medicines supply shortages that might occur in an emergency, when there is extraordinary and simultaneous demand globally – for example in Intensive Care Unit medicines. Industry has gone to extraordinary lengths to minimise the impact of this – and in the UK has worked closely with the DHSC and the NHS to source alternative supplies or where necessary issue advice on the management of affected patients.

3.1 Government should aim to attract medicines manufacturing facilities to the UK that bring innovative, high value platforms and technologies which are flexible, agile, and scalable. Attracting such facilities will carry both economic benefits including high value job creation and anchoring R&D in the UK, in addition to improving supply chain resilience and adaptability in the event of future emergencies.

3.2 **To support this ambition, the UK should introduce globally competitive incentives for advanced manufacturing by introducing capital grants (in line with other competitive nations) or through further modernisation and expansion of the scope of R&D tax credits so that capital expenditure falls within scope.**

3.3 Such incentives are already available in other countries around the world, including Ireland, Singapore, Germany and the USA. It is also reported that incentives to entice medicine manufacturers to relocate to the EU will be a key objective of the EU's upcoming pharmaceutical strategy. In order to maintain a globally competitive offer and avoid missing out on the opportunity to attract advanced manufacturing to the UK, the **UK should introduce these incentives as part of the recently confirmed Comprehensive Spending Review.**

3.4 To increase future resilience, we will need a system which combines some UK manufacturing of selected medicines and/or technologies, with a diversity of global supply options, as well as targeted stockpiling measures. A combination of all will be needed to ensure medicines are manufactured at the highest quality, the required scale, and deliver resilient supply at an acceptable cost for the NHS. **Self-sufficiency should not be the aim of such policies, but rather how the UK can play a more proactive and strategic part in the sustainable supply chains of the future.**

The flexibility and agility of institutions, Government departments and public bodies, and processes to respond appropriately during the crisis

Regulatory and ethical processes for research during COVID-19

4. In order to respond to the COVID-19 pandemic and mobilise COVID-19 research in the UK, the Government established a central process for Urgent Public Health studies. This involved triaging across Government institutes, regulators and the National Institute for Health Research (NIHR) to prioritise, approve and set-up COVID-19 research studies. Through this central process, regulatory and ethical approvals have occurred at an unprecedented rate.

4.1 For commercially sponsored Urgent Public Health studies, the average time for the Health Research Authority (HRA), ethics approval was between 5 and 11 days, and for the Medicines Regulatory Authority (MHRA), regulatory approval was between 2 and 8 days [data provided by NIHR].

4.2 The HRA and MHRA were also quick to announce guidance and flexibilities to support COVID-19 research and ongoing non-COVID-19 research. This included guidance such as remote monitoring of clinical trial sites, electronic consent, and flexibilities around the requirement for HRA approval and R&D agreement for non-substantial amendments.

4.3 Furthermore, the HRA provided strong leadership and new services to support the involvement and engagement of patients and the public in COVID-19 research. This included establishing a new link-up service to connect researchers to public contributors. This complements the current NIHR service and was welcomed by the research community.

4.4 **The pharmaceutical industry welcomes the flexible, agile and speedy response of both the MHRA and HRA during the COVID-19 pandemic.** ABPI and our members will be reviewing uptake and usage of these flexibilities, to inform recommendations for the HRA and MHRA on how these new ways of working could be adopted as business-as-usual.

4.5 **Secondary Legislation enabled by the Medicines and Medical Devices Bill (currently in the House of Lords) can be used to lock-in positive changes which have supported accelerated research and development into COVID-19 Vaccines and Therapeutics** so that the UK can support more efficient development of medicines across a range of disease areas. Consultation with Industry will be essential to identify which changes and flexibilities can have the maximum impact whilst maintaining the highest standards of patient safety.

Other Government processes for research during COVID-19

4.6 Early in the COVID-19 pandemic, the DHSC issued a statement that the NIHR Clinical Research Network was pausing the site set-up of any new or ongoing studies at NHS and social care sites that were not nationally prioritised COVID-19 studies. This resulted in only a proportion of studies being able to continue, to varying degrees across non-commercial and commercial portfolios. This had an immediate impact on clinical research activity in the UK for non-COVID-19 disease areas, meaning many patients were/are unable to access opportunities to participate in trials which provide access to experimental treatments and medicines.

4.7 As the UK COVID-19 burden has declined and clinical research activity in other disease areas has begun to restart, it has become evident that restarting the UK's vast portfolio of

research is a complex process, with many operational challenges remaining which prevent a full restart of clinical research in non-COVID disease areas in the UK. **According to statistics published by Medidata, the number of new patients entering trials in the UK in May 2020, has decreased by 98% compared with May 2019 (10).**

4.8 **Research which includes urgent treatment or intervention, without which patient health and wellbeing is jeopardised, must be prioritised and supported alongside COVID-19 research as the pandemic response progresses. A process for which such research can be universally recognised as a national priority should be established**, to ensure patients with life-threatening diseases are supported throughout any future COVID-19 waves and future pandemics.

New structures

4.9 A number of new structures have been developed by Government to support the response to COVID-19. Notably, the Vaccines Taskforce, Therapeutics Taskforce, and the NIHR Clinical Research Advisory Group. **Having a blueprint for such taskforces/groups, which clearly outlines how they link into permanent structures should be produced, so that necessary structures can be established quickly and effectively in future. Government should review the effectiveness of these structures, including their terms of reference, and resourcing to decide if they should be replicated, or adapted in future pandemics.**

The Life Sciences workforce and responding to COVID-19

4.10 The Life Sciences sector workforce have played a key role in supporting the NHS and Government to respond to the COVID-19 pandemic. This has included employees returning from companies to the NHS frontline to support efforts, ongoing efforts from employees to maximise manufacturing output and ensure supply of medicines meets demand, and the work of scientific, medical and clinical staff to accelerate or maintain essential research and development activity.

4.11 **Following the introduction of lockdown measures, Life Sciences workers were designated 'key worker' status which enabled critical employees involved in medicine manufacture and supply, or research and development to continue working. This status should be maintained for Life Sciences employees in the event of further waves of COVID-19 or in future pandemics.**

4.12 Throughout the pandemic response, Government actively involved the pharmaceutical industry in the development of safer working guidance, and specifically developed guidance for laboratory environments following feedback. **We would strongly encourage government to replicate this process of engagement in the event of future pandemics.**

The capturing during the crisis of data of the quantity and quality needed to inform decisions made during the crisis and maximise the learnings afterwards

5. Reliable and timely data on infection rates and disease burden, is essential for national and international decision-making during a pandemic. This data is acquired through national testing programmes and the evolving global understanding of the disease as the infection spreads.

5.1 On a national level, the data available on confirmed COVID-19 cases has impacted decision-making around workforce, research and healthcare delivery. In terms of the impact on research and healthcare delivery, the decision to redeploy NHS staff to frontline care in order to manage the expected COVID-19 burden, led to a reduction in capacity to deliver clinical services and non-COVID-19 research. Consequently, in March 2020, the NIHR Clinical Research Network decided to temporarily pause site set-up of all new or ongoing studies other than nationally prioritised urgent public health research into COVID-19. This has had implications for patients who have no longer been able to enter trials.

5.2 As testing capacity has expanded, and the new Test and Trace programme rolled out, this has provided the means with which to make more informed choices about resourcing, workforce, and other necessary interventions. For example:

5.2.1 A number of Urgent Public Health studies for COVID-19 were approved and set-up when infection rates were low and lockdown measures were in full force. In some instances, studies have struggled to recruit patients. **Improved data collection now can be used to ensure we identify where patients are (e.g. in local hotspots) and aim to recruit patients in areas where the number of cases are acute, rather than requiring national prevalence to be high.**

5.2.2 Similarly, **improved local and regional data can be used to inform decisions about the resumption of treatment or clinical trials for non-COVID patients where they have been impacted during the crisis**.

The mechanisms for communication of scientific evidence internationally, within national governments and with the public

6. **ABPI were supportive of the HRA's work to put in place mechanisms early on in the pandemic, to share lay summaries of approved COVID-19 research which are freely available and accessible online via their research summary portal** (12).

6.1 In addition to the rapid publication of research summaries, findings from ongoing clinical trials have also been made available, with rapid data analysis and publication of results. For example, the UK's RECOVERY trial, which aims to identify treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19, have published their results for Dexamethasone, Hydroxychloroquine and Lopinavir-Ritonavir via their website (13), med-archive (14) and journals (15). **This approach should be encouraged and supported across all COVID-19 research, to ensure rapid**

dissemination of research findings nationally and internationally which can help inform healthcare delivery and research prioritisation decision-making.

6.2 **Rapid data analysis and publication of results, must not however, come at the expense of scientific robustness.**

6.3 International cooperation has also been seen across the research landscape, with research initiatives established to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines (e.g. the COVID-19 Therapeutics Accelerator (16) and Access to COVID-19 Tools (ACT) Accelerator (17)). Alongside this the International Coalition of Medicines Regulatory Authorities (ICMRA) have supported strategic coordination and international cooperation among global medicine regulatory authorities (18). **COVID-19 is a global problem which requires a global solution and international collaboration and communication are key to developing a robust evidence base and informing a coordinated global R&D strategy.**

The UK's readiness for future outbreaks

7. The continuity of non-COVID clinical research has been severely hampered by the pandemic, with many sites lacking the resources and personnel needed to continue or start new studies – particularly with many staff being redirected to the NHS frontline. **Government should urgently review the resourcing of NIHR, and where required increase funding to ensure that there is enough resilience and capacity within the system to continue non-pandemic research in the event of future waves or other pandemics.** Such a review should also ensure that staff that support clinical research within trusts (e.g. R&D teams, research nurses and PIs, pharmacists) receive the support and resources they need.

7.1 The Life Sciences Council's Clinical Research Working Group was tasked by the Department of Health and Social Care to lead on a recovery and resilience workstream to review lessons learnt and identify new ways of working following COVID-19. The findings and recommendations will be fed-up to the Department of Health and Social Care and other relevant stakeholders to help planning for future COVID-19 waves, future public health emergencies and long-term transformation of the clinical research environment.

7.2 In addition to unprecedented collaboration to develop vaccines, diagnostics and treatments for COVID-19, the Life Sciences sector has supported the NHS in repurposing acute services and addressing staffing and capacity. The sector strongly agrees (19) with NHS England that we must take this opportunity to 'lock in' the beneficial changes that have been made. The Government's COVID-19 recovery strategy also focuses on the need to seek "innovative operating models for the UK's health and care settings". The Pharmaceutical Industry are committed to supporting the NHS return to full strength and prepare for the possibility of future waves of COVID-19 or other pandemics. To do this, ABPI recommends focus on the following areas:

7.2.1 **Reducing the backlog:** Recent studies (20) have illustrated the challenge that the NHS will face in restoring standards of care, including a recent study which estimated the UK could face as many as 18,000 additional cancer deaths this year due to

pauses in screening and treatment. The need to build COVID-19 testing capacity has impacted on lab capacity available for treatment of cancers, including those that rely on a genomic test, increasing the complexity of embedding new genomics pathways and potentially reducing access to certain medicines. It is crucial that diagnostic processes are restored quickly. Patients are also missing out on routine vaccinations; for example, school-based vaccination for HPV, tetanus, diphtheria and polio has been completely suspended. **A renewed focus on delivering high uptake of routine vaccination coverage is needed.**

7.2.2 **Improving early diagnosis, primary and secondary prevention:** Given the impact of co-morbidities, this will be critical to prevent elongation of the current pandemic, reduce the impact of future waves, and improve population health outcomes longer term. Pursuing a sustained prevention strategy for conditions such as diabetes and heart disease will be essential, and should focus on primary prevention - including ambitious vaccination and smoking cessation strategies – together with secondary prevention, driving appropriately **high and consistent use of new medicines and medical technologies to prevent disease progression where there is clear evidence of benefit over existing treatments**. **Embedding self-care and expanding the role of community pharmacy in the core primary care team can also support this approach**. Actions should include **giving pharmacists 'write access' to medical records and empowering pharmacists to refer people to other healthcare professionals,** fast-tracked if necessary. **NHS data showing new patient initiations on treatments used for secondary prevention should be monitored closely as a leading indicator of improving health and resilience**

7.2.3 **Supporting appropriate self-care:** The potential for a second wave of COVID-19 means the NHS needs to provide alternative solutions to ensure continuity of care for patients with ongoing healthcare needs, especially those which currently require multiple visits to secondary care. **An increased emphasis on self-care and education about when and how to interact with healthcare professionals will be key to building system resilience.** Patients should be supported to self-care in a way that ensures routes into help when needed. **Progress on telemedicine must be maintained and enhanced where appropriate to reduce pressure on acute care, support patient self-management improve choice and address health inequalities.** However, **further research is required to assess where telemedicine is suitable for vulnerable people, such as those with learning difficulties.** In is also important that telemedicine is not allowed to create new demand or provide an alternative route for people with self-treatable conditions to access a GP consultation when they should be practicing self-care with support, if required, from a pharmacist.

7.2.4 **Incentivising community-based healthcare:** Funding mechanisms, incentives and tariffs should be aligned to incentivise a community care approach, treating patients outside hospital where appropriate. In line with this, **special consideration should be given to innovations that can help patients be triaged at home or monitored outside secondary care**. Consideration also needs to be given to more flexible arrangements in the Drug Tariff to enable provision of a wider range of products,

including Apps, and the ability to prescribe reusable products. **This reimbursement mechanism needs to be supported through greater use of electronic prescribing, community pharmacy and dispensing appliance contractors.**

7.2.5 **Evaluating and embedding innovative changes in practice:** Examples emerging during COVID-19 have included moving patients requiring anti-coagulation away from warfarin, which necessitates extensive hospital monitoring, and towards modern, direct anti-coagulants (DOACs) which can be managed in primary care. There are further examples where new technologies can support greater remote monitoring of conditions for example in diabetes and heart failure. **Such changes to clinical pathways should be rapidly evaluated and positive changes should be confirmed across the health system.** Consideration should be given to moving incentives away from productivity-based targets towards system performance and outcomes-based targets.

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