Life Sciences Recovery Roadmap

3rd June 2020

A joint report to the Life Sciences COVID-19 Response Group

Executive Summary

- The Life Sciences COVID-19 Response Group was established in March 2020 and is co-Chaired by Lord Bethell and Nadhim Zahawi MP. This paper has been jointly developed by the Association of British HealthTech Industries (ABHI); the Association of the British Pharmaceutical Industry (ABPI); the Association of Medical Research Charities (AMRC); the British Generic Manufacturers Association (BGMA); the BioIndustry Association (BIA); the British In Vitro Diagnostic Association (BIVDA) and the Proprietary Association of Great Britain (PAGB) to provide this group with an overview of the key issues for the sector as we look towards recovery and building a new partnership between the Life Sciences sector, Government and NHS.

- The UK's Life Science sector is playing a central role in tackling the COVID-19 outbreak. Industry and charities have created new partnerships with the Government and NHS to scale up rapidly UK diagnostic capacity; supported the NHS to deliver care in a period of exceptional patient demand; and are leading the search for vaccinations and treatments to tackle the pandemic. At the same time, industry has responded to unprecedented demands for the supply of certain medicines and medical products in very challenging conditions.

- To capitalise on this progress, industry and charity partners who have contributed to this paper recommend:

  - **Transforming our partnership with the NHS to support delivery of the Long Term Plan.** Building on and learning from the COVID-19 response, Government and NHS leadership should develop strategic processes to involve industry and charities in work to support NHS transformation and healthcare provision. The sector will work across NHS and social care to identify ways to retain and action positive changes in adoption of innovation and digital solutions, embed new ways of working, harness the potential of data, promote self-care, bring healthcare to patients and diagnose and act faster. Industry and charities are keen to work with the Government's dedicated team examining how the NHS and health infrastructure can be supported during the COVID-19 recovery process and thereafter[i]. Industry and charities also seek longer-term recognition from NHS England/Improvement (NHSE-I) of the Life Sciences sector as a strategic partner in improving health outcomes, facilitated through high-level collaboration to deliver NHS Long Term Plan objectives.

  - **Developing a comprehensive strategy to improve UK manufacturing capability and supply chain resilience in medicines, medical devices and diagnostics.** While supply chains have responded well in the crisis, additional resilience could be provided through improved demand forecasts and transparency along the supply chain, support for supply diversification, international inventory management and development of a strategic reserve of essential medicines. In parallel, there should also be a focus on targeted support for UK manufacturing, particularly advanced medicines, medical technology and diagnostics manufacturing. This should be delivered through a new group that is equipped to focus on supply resilience across the life sciences industry or through expanded sub-groups of the Life Sciences Council groups, including the Health Technology Partnership (HTP) and Medicines Manufacturing Innovation Partnership (MMIP). A focus on exporting and capital grants should be generated to support manufacturing facilities being built in the UK and innovation funding made available for collaborative R&D for manufacturing and skill support. A specific Life Sciences Council workstream to support growth in the Small and Medium Enterprise (SME) base would also ensure that UK manufacturing capability is broadened.

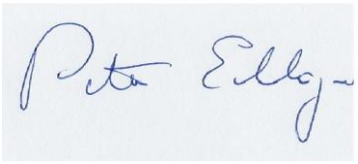
  - **Powering up the benefits of public and charity spending on medical research and delivering bold policies to incentivise research investment.** The doubling of R&D investment announced in the Budget sent a bold signal that the UK aims to be a science-based economy with world-leading research. This should be matched with an aspiration for the UK's R&D incentives to be globally competitive to encourage investment and help the UK lengthen its lead in Foreign Direct Investment in Europe, supported by a skills policy that meets the future demands of the sector and the placing of Life Sciences at the heart of future trade negotiations. The Government and industry should jointly evaluate the competitiveness of the UK's research and manufacturing investment incentives with a view to generating proposals for the autumn Comprehensive Spending Review. Funding and delivery of critical health data infrastructure for research should be continued, as should the 'find and recruit' clinical trial service. Funding should also be targeted to enable the continuity of charity-funded

research, recognising that the strength of the UK life sciences sector lies in its unique diversity, which comprises of funding from public bodies, medical research charities, industry and the NHS.

- **Transforming the UK's clinical research processes**. This will allow for rapid approval, set-up, recruitment and delivery of research across the NHS, powered by new technologies, data and approaches. This in turn will ensure that UK patients are amongst the first in the world to benefit from breakthrough treatments and technologies, with the added benefit of cost savings and investments for the NHS. The Life Science Council's Clinical Research Working Group (CRWG) should play a central role in evaluating lessons learnt and advising on the development, implementation and monitoring of the recovery plan for clinical research. This should be supported by the work of the Medical Research Council / National Institute for Health Research (MRC-NIHR) Trials Methodology Research Partnership.

- **Taking an innovative approach to regulation.** The Medicines and Medical Devices Bill should be reviewed to reflect innovative regulatory approaches introduced by the Medicines and Healthcare products Regulatory Agency (MHRA). Recent learning, in particular the work underway to accelerate access to promising treatments, should be reviewed to see what processes could have a more permanent place in speeding up the approval of licences and variations for existing medicines, and should link into work underway to create more agile and sustained regulatory and Health Technology Assessment (HTA) systems and support patients getting fast access to new treatments. Mutual Recognition Agreements should be leveraged to extend the UK's global reputation and influence through international networks and partnerships. As the UK steps into a new global role, it has the potential to lead new work needed on regulatory frameworks and pathways for emerging innovation, such as cell and gene therapies as well as generic and biosimilar medicines.

- **Accelerating deployment of new and existing treatments and technologies where there are system and patient benefits.** The COVID-19 response has shown that rapid scale-up of existing treatments and devices, coupled with new medicines, medical technology and diagnostics can significantly improve patient outcomes while making more effective use of NHS resources. There is an opportunity for decisive action to build on this to help the NHS address the backlog of care for non-COVID patients. The UK needs a fit-for-purpose medicines assessment process that positions it as a priority market for the launch of innovation, with broader measures of value that reflect the changing nature of treatments. Alongside this, the NHS and MHRA should support the re-purposing of existing medicines if there is compelling evidence of clinical effectiveness and the licensing of the indication will widen access. The learning from the COVID-19 response should be factored into a rapid evolution of NICE methods to support patients getting fast access to new treatments and technologies. The full potential of the Voluntary Pricing and Access Scheme (VPAS) should be exploited to unlock improvements in the valuation of and uptake of new innovative medicines, and reforms paused due to COVID-19 should urgently continue or restart. A practical assessment of opportunities and challenges in the health technology procurement system should be carried out with the support of the Health Technology Partnership. System partners should recognise the case for changing NICE's appraisal methods so they can better consider the value of new medicines. Senior level support is required now to drive the establishment of a shared vision across DHSC, OLS, NHSE, NICE and industry to set out the level of ambition that can be supported to allow NICE to make the changes that are necessary. This is needed in the short term, before NICE progresses further work over the Summer, ahead of the first NICE Methods Review consultation in October. A working group should be established across industry, charities and government to explore the long-term future of health technology regulation and the opportunities that lie with the International Medical Devices Forum and implementation of ethical business processes.



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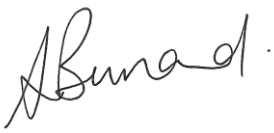

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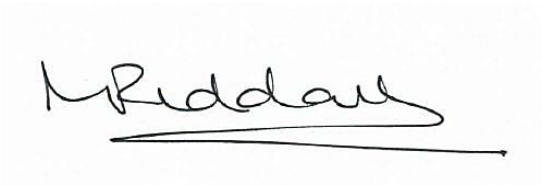

Michelle Riddalls
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Introduction

- The UK's Life Science sector is playing a central role in tackling the COVID-19 outbreak. Industry and charities have created new partnerships with the Government and NHS to scale up rapidly UK diagnostic capacity; supported the NHS to deliver care in a period of exceptional patient demand; and is leading the search for vaccinations and treatments, which will put an end to this epidemic. At the same time, industry has responded to unprecedented demands for the supply of certain medicines and medical products in very challenging conditions.
- We have also seen in action the future of healthcare, with the scientific and technological revolution of the Life Sciences sector – from the use of AI and machine learning in R&D to novel manufacturing technologies and new treatment paradigms – bringing real value to solving health challenges through new therapies and vaccines, and the UK well-placed to play a leading global role.
- The COVID-19 crisis has powerfully demonstrated the strategic importance of the Life Science sector to the UK's health and security, as well as its economy. The UK Life Sciences sector is more than simply a supplier to the NHS. It is also a partner in improving health outcomes and the economic and health security of the UK. This approach to partnership and collaboration has been a constant commitment of the sector in recent years as was set out in the Life Science Industrial Strategy and subsequent Sector Deals.
- Life Sciences are a core strength for the UK economy. It is a critical stabilising sector in a recession-hit economy and remains central to any long-term economic recovery centred on innovation, productivity and high-skilled, quality jobs.

- The Government's COVID-19 recovery strategy states that protecting the UK's economic competitiveness means supporting *"the UK's world leading pharmaceutical and medical-device manufacturing sectors."* This is an ambition that we stand ready to deliver with you in partnership.

- COVID-19 has proven that in order to have a thriving and successful Life Sciences industry, which can be mobilised for such pandemics, as well as other public health emergency scenarios, the groundwork must be laid in normal day-to-day policymaking and operations within UK healthcare and the NHS. To strengthen this approach, the following key policy areas are addressed in this paper:

    1. **Supporting delivery of the NHS Long Term Plan**
    2. **Supply Chain Resilience and Manufacturing**
    3. **Life Sciences Research**
    4. **Innovative approach to regulation**
    5. **Patient access to COVID-19 vaccines, treatments and diagnostics**
    6. **Workforce**
    7. **Global Trade and Supporting UK Exports**

1. Supporting delivery of the NHS Long Term Plan

Objectives:

- **Restart:** Restarting priority Long Term Plan diagnosis and treatment pathways paused due to COVID-19, restoring standards of care where these have been modified to address infection risk.

- **Renew:** Retaining and enhancing positive changes in clinical practice, improving system resilience to meet future pandemic surges without compromising other disease outcomes or impacting delivery of the Long Term Plan.

The response to COVID-19

- **Industry support for 'locking in' positive changes to clinical practice.** 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 with NHS England that we must take this opportunity to 'lock in' the beneficial changes that have been made[ii]. 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"*.

- **Use of digital health technologies.** Digital technologies have shown great value in enabling new care solutions to relieve system pressures and have accelerated the adoption of a digital-first approach to healthcare. Technologies broadly fall into four interlinked areas: population management; triage and clinical decision-making systems; digital diagnostics; and remote services. Examples of the above have been implemented rapidly during the Coronavirus pandemic, More patients have been offered virtual health appointments and are using home monitoring. Electronic prescribing has been much more widely utilised and may be contributing to improved adherence.

- **Self-care.** The shift towards homecare and home monitoring has increased patients' ability to manage their own conditions with their healthcare teams, has reduced the need for hospital attendance and may be preferable to patients in the future. Prior to the coronavirus outbreak there were 18m GP appointments and 3.7m A&E appointments for conditions suitable for self-care[iii]. Pandemic restrictions have meant people have not been able to visit a healthcare professional with these conditions and have therefore practiced self-care. Furthermore, people with coronavirus symptoms have been directed to stay at home and self-care. Online symptom checkers and triaging tools and the NHS 111 online assessment tool have been configured to directly assess people for coronavirus symptoms, appropriately referring people to self-care advice. There has been a significant increase in the demand for over the counter (OTC) products, including demand from patients with milder cases of COVID-19 and other self-treatable conditions. As the crisis phase ends, there is an unprecendented opportunity to embed this self-care behaviour in a sustainable way.

- **The role of health charities.** Throughout the pandemic, many health charities have worked tirelessly to provide information, advice and support to patients through their websites, forums, online support groups and online learning. There are also examples of charities working with the NHS to design and pilot new service. This has demonstrated the important partnerships between patients, their care and treatment from the NHS and support and advice from medical research charities during this time of crisis. Charities have also contributed to the national research effort with funding and infrastructure and supported the secondment of clinical research staff to the NHS front line.

What changes do we need to address?

- **Reducing the backlog.** Recent studies 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[iv]. 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. NHSE-I and the Royal College of Surgeons have published priorities for non-urgent surgery highlighting that some

surgery could be delayed for 3+ months, on top of existing waiting list delays. In the case of orthopaedic patients, a 3-month pause will add around 48,000 joint replacement patients to the waiting list and may also lead to deterioration and reduced outcomes. There will be particular issues with some interventions, such as dentistry, where the aerosol risk is high. Access to appropriate PPE and guidance on working procedures will be critical and the appropriate royal colleges and professional societies should take a lead role in establishing protocols. In some areas there may be a need for capital investment into equipment and treatment rooms, such as air filtration, extraction and pressure management technologies. Government support should be made available to enable this. The need to safeguard NHS capacity has demonstrated the importance of Ambulatory Surgical Centres (ASCs) and pre and post operation care to reduce the need for acute care. A shift to ASCs could have a larger impact on reducing the waiting list quickly.

- **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.

- **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.

- **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.

- **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. There is also an opportunity to improve tools that provide information about self-treatable conditions, advice on treating symptoms and red flags, to support people to self-care. Dedicated self-care information on NHS digital assets (apps and websites), including symptom checkers, and the expansion of the Community Pharmacy Consultation Service to accept online referrals can also support this. NHS funding and a regulatory pathway should be established to trial the re-purposing or licensing of existing medicines for new indications where compelling evidence demonstrates that they could be deployed more widely as successful treatments. Consideration should be given to moving incentives away from productivity-based targets towards system performance and outcomes-based targets. This may help to drive integration of pathways and optimize the patient journey. This evaluation

represents a considerable task for an already stretched system, and an area where industry can provide extensive support, working with the Health Data Research UK Hubs and the Academic Health Science Networks (AHSNs).

Next steps

- **Strategic Partnership.** The Life Sciences sector should be viewed as a key partner working with Government and NHS leadership to restore services, develop system resilience and support delivery of the NHS Long Term Plan. NHSE-I guidance recently issued to NHS organisations to proceed at their own pace in reintroducing services paused due to COVID-19 demonstrates sensitivity to the varying current capabilities across the NHS, but may inadvertently worsen health inequalities already exacerbated by the pandemic.[v] To ensure consistency of approach across the system, a central framework should be created to help local NHS organisations evaluate their approach. Industry can provide expertise to support NHSE-I in establishing this process, and we propose the creation of a strategic forum between industry and NHS leaders to address this and other clearly defined goals.

- **Prevention Green Paper.** Momentum to deliver the Prevention Green Paper must be maintained, with an explicit partnership role for the Life Sciences sector.

- **Self-care** must be fully embedded in the primary care pathway, with appropriate policies to support delivery of the NHS Long Term Plan.

- **Antimicrobial Resistance (AMR).** There needs to be a renewed focus on the Antimicrobial Resistance strategy and collaboration to ensure this is delivered, with particular focus on the impact of COVID-19. In addition to increased demand for antibiotics, COVID-19 may have indirectly caused a temporary loosening of stewardship practice as NHS resources are redirected. Industry is keen to support NHS efforts to maintain AMR stewardship and continue to explore new models to encourage antimicrobial research.

- **Renewed focus on delivering high uptake of routine vaccination coverage.** It will be critical to improve vaccination coverage across the UK to manage the risk of a rise in preventable disease. This is particularly important in managing a second wave of COVID-19, given that individuals particularly at risk of infection are those at most risk from flu, including the over 65s. The annual flu vaccination programme should also be used as an opportunity to offer other adult vaccinations. There will also be additional pressure on school immunisation teams who will need to deliver catch-up programmes for the adolescent (year 8/9) vaccinations that have been suspended. School immunisation teams will need to be given the capacity to deliver the routine programme and to reduce the backlog.

- **Risk stratification of multi-morbid patients.** A study of almost 17,000 people hospitalised with COVID-19 found more than half had at least one comorbidity, the most common of which were chronic cardiac disease (29%), non-asthmatic chronic pulmonary disease (19%) and asthma (14%).[vi] Almost a third of COVID-19 deaths in England have been associated with diabetes, and deaths in people with diabetes in England have more than doubled during the pandemic[vii]. Industry is keen to work with the NHS to support risk stratification of multi-morbid patients and optimise the use of medicines and vaccines in improving their outcomes.

- **Re-purposing.** NHS and wider Government should support the current initiative to provide funding and regulatory support to trial the re-purposing of existing medicines, to ensure that we are maximising their utility to treat new indications where compelling evidence supports their extended use.

- **Specific industry recommendations for cross-sector collaboration to address NHS Long Term Plan priority disease areas are also the subject of separate paper for discussion with NHSE-I leadership and are summarised in draft in Appendix 1 of this document.**

2. Supply Chain Resilience and Manufacturing

Objectives:

- **Restart:** Sourcing of medical and healthcare products aligned with demand.
- **Renew:** Improve UK manufacturing capacity as part of a broader strategy to build supply chain diversification and resilience.

The response to COVID-19

- **Cross-sector collaboration.** Dialogue and collaboration between the Department of Health and Social Care (DHSC), the Medicines and Healthcare products Regulatory Agency (MHRA), the NHS, the Department of International Trade and the Life Sciences industry has been critical in meeting the unprecedented demand for medicines, medical devices, diagnostics and medical technology.
- **Global sourcing of products.** Companies have moved at unprecedented speed to source products from across the globe where shortages have been identified, working to navigate challenges, particularly where there has been disruption in supply chains, including in India and China.
- **Regulatory flexibility**. Flexibilities introduced by the MHRA to support Qualified Persons, extend audits, expedite assessments, consider over-labelling of foreign language packs and the use of alternatives to wet signatures to approve documents, have been particularly useful.
- **Balancing the risk.** To meet the unprecedented demand for ICU medicines, which in some cases has been tenfold of normal usage, NHSE-I put in place measures to help suppliers cope with the huge rise in ordering and to bring in additional stock. For these medicines, NHSE-I asked hospital trusts not to impose non-supply penalties for contracted suppliers and provided letters of intent to wholesalers and suppliers to confirm that any additional stock they had been asked to provide would be used and paid for.
- **Supply management framework.** Co-ordination between Government and industry has been vital in managing continuity of supply of medicines, diagnostics and medical devices. For example, the introduction of restrictions in parallel exporting[viii] has increased the security of medicines intended for the UK and supported the ability of Government and industry to manage pressures on supply.
- **Diplomatic response.** Equally, the Government has used a range of diplomatic channels, including the resource of the Department of International Trade and the Foreign and Commonwealth Office, to support the lifting of export bans where they have arisen to enable the sourcing of additional medical products, active pharmaceutical ingredients and other raw materials.
- **Resilient and flexible global supply chains.** There has been a significant response from UK industry to the supply chain challenges presented by COVID-19. Combining expertise from the life science sector with wider manufacturing capability has prevented collapse of the supply chain in some critical areas and rapidly brought on new capacity, utilising the skills and knowledge within the Life Sciences sector combined with industry's manufacturing capacity.
- **Matching supply with demand.** Industry has provided an increased level of short and medium-term supply projections to enable DHSC and NHSE-I to review demand against supply. With short term easing of pressures for ICU medicines and attention turning to the second half of 2020, we appreciate DHSC's signal that it will attempt to forecast and make available estimated NHS demand for the second half of 2020 for COVID-19 and non-COVID-19 medicines and medical supplies.

What changes do we need to maintain and establish?

- **Enhancing supply chain resilience.** The Government's COVID-19 recovery strategy aims to ensure the UK has robust supply chains across medicines and healthcare products. The Life Sciences sector should be closely involved in the development of this strategy to ensure proposals are practical and

implementable. Strengthening supply chain resilience is critical: the UK cannot produce thousands of medicines; and where UK-based manufacturing is in operation, it will remain reliant on raw materials and components from across the globe. The strategy should aim to support increasing diversity of supply and flexibility in capacity, enabling manufacturers to manage international inventories, particularly after the EU exit transition.

- **Accurate demand forecasting and transparency**. Supply management can only be achieved by a balanced focus on both supply and demand factors. Supply reliance will be greatly supported by more accurate and timely NHS demand forecasts and stronger communication to prescribers to avoid putting unnecessary pressure on supply through extended prescriptions. This can be achieved through collective dialogue as to which medicines, devices and consumables need to be produced and in which capacity, with improved transparency along the entire supply chain. A joint NHS/NHSSC and Industry taskforce should be established to review and action workforce development, processes and systems as the NHS restarts elective procedures. Industry needs to be engaged early about future supply needs, particularly in light of potential supply issues that may occur at the end of the EU exit transition period.

- **Procurement.** Future procurement strategy for critical devices/medicines should not be based on lowest cost alone, but should also consider value, secure plurality of supply and a multi-vendor approach in critical areas. The drive by the NHS to purchase the lowest price product and single supplier contracts has resulted in manufacturing being driven to low cost labour markets, weakening the resilience of UK supply. While price will of course continue to be a major factor in procurement, additional considerations need to be introduced to improve robust, ethical and sustainable UK supply chains. Procurement systems for secondary care should be rebalanced to include a commitment from the NHS to purchase as well as a commitment from industry to supply, at least for critical supplies. This, together with procurement award criteria that promote supply performance, sustainability and resilience, will provide greater incentives for suppliers to invest in strengthening their supply chains.

- **Reinforcing UK manufacturing**. There is a significant opportunity for the UK to improve the attractiveness of medical and medical device manufacturing to enhance future supply chain resilience and generate economic growth. The Life Sciences Industrial Strategy set the ambition to attract ten large and ten smaller manufacturing facilities to the UK. However, “on-shoring” of manufacturing should not be viewed as a way of securing complete UK self-sufficiency for the management of future health emergencies, as supply chains will remain global. The answer is likely to be a targeted approach to strengthen supply chains and could be focused on critical medicines / active pharmaceutical ingredients, or where there is current weakness in supply chain resilience, procurement and /or strategic reserve-holding. Additionally, expanding aseptic secondary manufacturing and fill-finish facilities could be co-located with other manufacturing assets to reduce costs and ensure regular usage, which could be converted for emergency provisions. With many countries now looking towards their own individual resilience plans and capacity, the Government should consider:
    - the core manufacturing competencies and capabilities it requires to support the NHS during any future pandemics
    - flexible and expert capacity in the UK that can be repurposed at pace if required. This capacity must have a formal trigger mechanism and must meet international medical certification standards
    - key supply chains and jurisdiction where international cooperation is required to ensure a robust flow of raw materials and components
- The economics of establishing and continuing to run flexible, pandemic-ready manufacturing while not hampering the normal successful operation of the competitive market will be a challenge that will need to be understood. If significant investments are made, and innovative medicines and manufacturing are achieved, the willingness for the NHS to purchase the resulting product also needs to be better understood, related to the procurement point above. Skills, costs, regulation and technology are central to the attractiveness of a manufacturing location, alongside the terms of trading, including the unfettered ability for companies to export to global markets. The Government should also be aware of the actions and manufacturing incentives provided in other global locations and provide a competitive offering to retain and build on the current base.

- **Strategic safety stocks**. Reserve or strategic safety stocks of medicines, diagnostics and medical devices are essential to support the continuity of supply in times of emergency and as a contingency for other unexpected events. This approach allows for flexibility in terms of manufacturing location and business model. A Government strategy for appropriate UK stockpiling should be put in place, based

on an agreed list of critical medicines and devices. Vaccine stockpiles could be updated every year to match circulating strains. Additionally, stockpiles could be developed or extended for adjuvants as well as medicine and manufacturing components such as Active Pharmaceutical Ingredients (APIs), vials, and syringes. Pharmacy and GSL products should also be included, and the strategy also needs to take into account the potential impact of exiting the EU at the end of the transition period.

- **Supply data management**. Covid-19 has highlighted inadequacies in data management for devices leading to poor planning and therefore shortfalls in essential products, such as respirators, PPE and IVDs. The establishment of a national product registry with a stronger role for existing standards would support better analysis of device status. The speed and affordability to establish registries could be greatly helped by use of common data standards to promote interoperability between suppliers and customers and support a more efficient, responsive and flexible supply chain.

- **Support for Small to Medium Enterprise (SME) Life Sciences base.** The experience during COVID-19 has shown that combining specific medical device experience with manufacturing capacity from wider industry has been a successful combination. Creating stronger networks and clusters across the wider Life Sciences industry can create flexible capacity and response mechanisms for any future crisis and would create an attractive investment environment. The majority of the device and digital health sectors are comprised of SMEs, and, in a recent survey of SMEs by MedCity, 36% of correspondents identified 'key operations' such as manufacturing as a key challenge facing their business.[ix] Supporting SMEs should therefore be a key component in the development of future manufacturing strategy. A suggestion to enable this would be Government loans to SMEs over a 10-year period in which repayment does not start until year 3 to allow manufacturing scale up and purchase of cap-ex equipment. This practical solution would allow companies to invest in UK manufacturing offering innovative technologies to the NHS within short time frames.

- **Expansion of the UK-RTC.** The UK Rapid Test Consortium (UK-RTC) was established to harness the UK's capability for development and manufacture of high-quality rapid diagnostic technologies in response to concerns about the poor quality of similar technology purchased overseas. Future consortia of a similar nature should be formed to allow "home grown" innovative technology to be produced when faced with future unmet needs. The effectiveness of the UK-RTC has proven this is possible and the UK diagnostic industry needs further investment and scaling to ensure it is well positioned to provide this expertise to the UK Government in future. There is great potential for collaboration between Innovate UK and industry to create national projects that focus on key unmet needs. Currently this approach in the UK is fragmented. Harnessing the UK-RTC approach to bring together academia, innovation, manufacturing and commercial parties would allow rapid development and manufacturing of innovative technologies, with the potential to attract investment from venture capital.

- **UK as a voice for global trade.** Measures such as eliminating tariffs on medicines, diagnostics medical and protective equipment, as well as elements of their supply chains, can facilitate free trade in medicines and should be actively supported by the UK Government, along with opposing countries imposition of export restrictions that disrupt global supply chains. International cooperation and mutual recognition on medicines regulation, particularly for quality checks, are also essential for movement of medical goods as the UK leaves the EU single market.

Next steps

- Recent experiences from EU exit preparedness and management of Covid-19 should encourage Government, NHS and the whole industry to collaboratively develop robust, parallel strategies for supply resilience and for medicine and medical technology manufacturing. This should be delivered through a new group that can fully represent the medicines, diagnostics and medical devices supply chain, or by adding to the HTP sub-groups of the Life Sciences Council and MMIP so that they are representative of the sector as a whole, including companies producing GSL and pharmacy medicines.

- Establishment of a procurement methodology within NHS E-I for essential medicines, devices and technologies that looks beyond lowest possible price to consider areas such as system and patient outcomes, resilience, evidence, ethics and quality.

- Government should also consider changes to capital investment allowances and tax credits to support inward investment from Life Sciences manufacturing.

3. Life Sciences Research

Objectives:

- **Restart:** Resumption of paused research, including clinical trials, carried out by charity, academic and industry partners.

- **Renew:** Evaluate innovative approaches taken to research during the pandemic to improve the UK's attractiveness for inward research investment and deliver Government goals for Life Sciences research.

The response to COVID-19

- **Unprecedented research collaboration.** The scientific and research community in the UK has partnered at unprecedented speed and scale to research and develop new treatments, vaccines and medical technologies against COVID-19. This response has shown how NHS, industry, academia, charities and the Government can deliver high quality research at pace and scale. Maintaining the UK's world-leading research excellence and mitigating the impacts of COVID-19 on university-based research will be vital if the UK's is to continue to build its skills base, research capacity and attract global scientific talent.

- **Impact on non-COVID-19 research.** The necessary focus on COVID-19 research, along with the impact of the virus itself, has had a significant impact on non-COVID-19 research, with 55% of ongoing commercial clinical trials paused[x] and an estimated 148,000 patients currently unable to participate in charity-funded clinical studies. The Government has set out an ambition to invest unprecedented levels in R&D and for the UK to be the global hub for Life Sciences. The impact of COVID-19 on the UK's research base is significant and has put this ambition at risk.

- **Innovative regulatory approaches.** The MHRA and HRA have shown significant flexibility in supporting both COVID-19 and non-COVID-19 research. Examples include expedited scientific advice, rapid review of clinical trial applications and remote auditing and monitoring. This approach has improved speed and efficiency of clinical research as well as ensuring patient safety and safety of research staff.

- **Animal research.** Social distancing measures and disruption to supply routes have had an impact on the continuity of animal research in the UK. Regulatory flexibilities in areas such as data requirements have supported the continuance of research and rapid set up of COVID-19 research.

- **Large, multi-centre clinical trials.** We have seen large multi-centre innovative trials take place, including through the ACCORD platform, supported by UKRI, and the RECOVERY trial integrating clinical research into routine care for COVID-19 patients. A joint NIHR-UKRI rapid response call awarded £24.6m across 27 projects including for testing a vaccine, developing therapies and improving understanding of how to treat COVID-19.

- **Collection and sharing of data.** Trial sponsors have been able to access COVID-19 data from registries and HDR-UK Research Hubs to support clinical research. New approaches to epidemiological research using very large datasets contained in the NHS electronic health records have demonstrated they can rapidly yield key clinical insights. There is an opportunity to explore how we can continue to expedite secure access to health data for on-going COVID-19 research as well as new clinical research in other areas.

- **Establishment of Vaccine and Therapeutic Taskforces.** The UK Government has established a Vaccine Taskforce and a Therapeutic Taskforce to coordinate the research into new vaccines and therapeutics, as well as to look at the role existing medicines may be able to play in providing treatment for COVID-19. True partnership is fuelling progress in these taskforces and should be locked in as a model for the future.

What changes do we need to maintain and establish?

- **Evaluation of adaptations applied during the COVID-19 pandemic.** Several innovative and flexible approaches to conducting trials have emerged during the pandemic, including direct-to-home shipments for patients in addition to streamlined regulatory and NHS approval processes. These should be assessed to understand which changes should become permanent, in parallel to the resumption of clinical trials. Evaluation should include how such changes would interact with international clinical trial platforms post-pandemic and post-EU exit, with patient safety, robust ethics and governance procedures and future UK competitiveness in attracting research as key components.

- **Strategy to restart clinical research.** There should be a clear plan to restart clinical research paused during the pandemic, with the goal of radically improving the way that trials are conducted to enhance the UK's existing scientific strength. We welcome the NIHR's framework to guide the restarting of NIHR research activities, which will provide important support in overcoming some of the restart challenges. However, it is vital that there is transparency on when all trials can restart; how trials will be prioritised; steps being taken to speed up approvals, flexibility in the regulatory framework for trials and managing the uncertainty that COVID-19 brings with regard to future waves of infection. This plan must also articulate to clinical trial sponsors that the UK is open for clinical research and demonstrate that the UK has the necessary resilience to manage future waves of the pandemic. It should include research into and acceleration of digital data tools for care pathways to enable remote COVID-19 monitoring, staff testing and monitoring and remote patient communications to maximise safety, productivity and efficiency. This work can be structured across the following pillars:

    - Maintaining and maximizing COVID-19 Clinical Trials
    - Resuming paused non-COVID-19 clinical research activity
    - Resuming feasibility and start up of new clinical trials for new non-COVID-19 and COVID-19 research

- **Patient and public engagement in research.** The HRA has confirmed that only 20% of COVID-19 studies planned to conduct patient and public involvement and engagement activities. The HRA and NIHR should establish mechanisms to ensure that patients are engaged in future clinical research, COVID and non-COVID. NIHR's Centre for Engagement is well placed to take on this coordination role. Action also needs to be taken to ensure that study participants and researchers are protected from exposure to COVID-19 and appropriate monitoring and surveillance regimes are in place. Maintaining and expanding recruitment into COVID-19 trials, potentially in collaboration with the Government's Test and Trace programme, is also required.

- **Application of data and real-world evidence (RWE**). Use of the COVID-19 app and other digital health technologies, has generated real world evidence directly from patients and the public on a sustained basis to support the response to the pandemic. The utilisation of this technology and self-reported outcomes can provide data to support new indications, advice or claims for treatments and should continue to be adopted and advanced more widely. In parallel, Government and the NHS will need to assure the public that their data are being used appropriately.

- **Funding mechanisms.** Agile funding mechanisms can support highly innovative and collaborative research and could enhance the attractiveness of the UK as a destination for Life Sciences. The demand for research into COVID-19 in parallel with other disease areas suggests a need for additional resource across the system. Increasing university QR funding will also be necessary to maintain the UK as a world-leader in science and research. UKRI should co-ordinate the creation of a coherent strategy to stimulate cross-sector collaboration between the Research Councils, academia, charities and industry.

- **Life Sciences-Charity Partnerships Fund.** Medical research charities constitute a vibrant component of the UK's world leading R&D base, supporting science from basic research through to clinical trials and translation. In 2019, AMRC's members collectively invested £1.9 billion in UK R&D. It is estimated that charity sector research investment faces a shortfall of between £252m - £368m in 2020/21. This is the result of a collapse in charity fundraising income and the increased costs of paused/delayed research. To preserve the distinct contributions of charities to the UK's research base

and to harness their role in supporting the UK's post-COVID-19 economic and social recovery, we propose a government-charity co-investment scheme that provides a level of match funding from Government for future charity research over the next three years via a Life Sciences-Charity Partnerships Fund.

Next steps

- The Clinical Research Working Group (CRWG) under the Life Sciences Council structure, has the necessary expertise to play a central role in evaluating lessons learnt and advising the development, implementation and monitoring of the recovery plan for clinical research. This should be supported by the work of the MRC-NIHR Trials Methodology Research Partnership. Life Sciences Industrial Strategy recommendations for R&D should continue to be prioritised for implementation.

- The Government should commit to prioritise Life Sciences in future trade negotiations to maintain the UK as a global hub for Life Sciences innovation and should develop trade deals that allow this innovation, as well as the UK's exporting potential, the greatest possible global reach.

- The Government should engage with the medical research charity sector on the Life Sciences-Charity Partnerships Fund, recognising the unique contribution of charity-funded research to UK life sciences.

4. Innovative approach to regulation

Objectives:

- **Restart:** Evaluate and retain positive regulatory flexibilities introduced during the COVID-19 pandemic.

- **Renew:** Develop a strategy to introduce additional regulatory flexibilities that increase efficiency, remove avoidable burdens and support Life Sciences investment after the EU exit transition period.

The response to COVID-19

- The rapid introduction of regulatory flexibilities has been critical to supporting the response to the COVID-19 pandemic. The MHRA has been swift to adopt a collaborative approach with industry during this iterative process. The use of real-time safety data by regulators and industry has helped to identify opportunities and to put them rapidly in place while retaining a strong focus on patient safety.

- **Temporary regulatory flexibilities introduced.** Temporary regulatory flexibilities have been put in place to support the Life Sciences sector to respond at speed to the COVID-19 pandemic.

- **Global regulatory cooperation.** The COVID-19 pandemic has seen global regulatory authorities collaborate via the International Coalition of Medicines Regulatory Authorities (ICMRA) on a set of common principles to ease the introduction of therapies to treat the disease whilst a vaccine is being researched and developed. A clear, coordinated, scientific assessment as these treatments are developed has been critical, whilst preserving national sovereignty for decision-making and approval.

What changes do we need to maintain and establish?

- **Evaluation and retention of beneficial regulatory flexibilities.** A range of regulatory flexibilities has been introduced, such as speeding up processes for submitting supply-related variations, providing commitments rather than data to support certain variation changes, the use of electronic signatures, remote inspections, ability to "dual source" API / materials and swift addition of alternative suppliers of raw materials and APIs to MAs to support industry to respond to short term peak demands. All could have significant long-term benefits to patients and, following evaluation, should be prioritised and maintained in the longer term. Further regulatory flexibilities may be needed to support the Life Sciences sector in continuing to respond to future waves of COVID-19, and these should be explored in dialogue with industry and other global regulatory bodies. For precision medicines and accompanying diagnostics, it will be important to ensure that new regulatory approaches remain sufficiently harmonised with those of other regulatory authorities and that uncompetitive UK trial requirements are removed to attract further investment.

- **Regulation to support growth and faster access to innovation.** Agile regulatory systems can support flexibility in UK development and manufacturing, whether for domestic use or export. The possibility of linking the Early Access to Medicines Scheme to conditional reimbursement should be explored in this regard. Enabling companies to rapidly iterate products and supply global markets is crucial to this goal, as is the ability to simplify to import products where licensed variants exist in markets with "trusted" regulatory systems. Combining international standards and best practice can give the UK a significant advantage in a global marketplace and attract inward investment. It will be important to take learnings from the International Medical Device Regulators Forum (IMDRF) principles in developing this approach. It will also be important for regulators to work collaboratively with industry to provide accelerated UK pathways for regulation of digital technologies to promote the UK as a global tech innovation hub/accelerator. The medical technology sector would also benefit from Government providing legal certainty of the recognition of EU Medical Device Regulation (MDR) in the UK from January 2021.

- **Renewed focus on regulatory science.** There is a need for the UK to refocus on regulatory science and, where appropriate, to develop new tools, standards and approaches to evaluate new medical products and therapies including Artificial Intelligence (AI), cell and gene therapies and digital technologies. Attention should also be given to addressing the shortage of regulatory professionals in the industry workforce. New regulatory approaches should be centered on Mutual Recognition

Agreements with other global regulators to assess benefit-risk, facilitate sound and transparent decision-making and avoid creating overlapping processes or requirements. A regulatory framework that rapidly makes medicines and medical technologies available to UK patients will also improve the attractiveness of the UK to Life Sciences companies.

- **New regulatory responses for emerging threats.** Building on the collaboration across global regulatory authorities, the UK can benefit from work-sharing opportunities across national competent authorities (NCAs) in line with sovereignty of decision-making. This could produce an interactive, fast but rigorous system. This mechanism should be maintained beyond management of the current pandemic and can become an established collaborative pathway to address new emerging threats (such as anti-microbial resistance), future pandemics or common unmet clinical needs.

- **The Government's Medicines and Medical Devices Bill.** The Bill is welcomed as it gives the UK power to update/revise regulatory directives as needed. Following its passing, the Bill should reflect the innovative regulatory approaches introduced by the MHRA in in secondary legislation.

Next steps

- The Health Technologies and Pharmaceuticals (HTP) Programme, the Life Sciences Council Clinical Research Working Group (CRWG) and the MHRA Industry Liaison Group should take forward an analysis of the above recommendations.

5. Patient access to COVID-19 vaccines, treatments and diagnostics

Objectives:

- **Restart:** Closer engagement and alignment between DHSC, NIHR, MHRA, HRA, NICE, NHSE and the Life Sciences sector to capitalise on new opportunities identified across regulation, manufacturing, health technology assessment and commissioning.

- **Renew:** Develop a multi-agency, cross-sector strategy to maximise patient access to future COVID-19 treatments, vaccines and diagnostics.

The response to COVID-19

- **Development of vaccines and treatments.** A key focus of the UK Life Sciences sector during the pandemic has been participation in the global effort to develop vaccines, treatments and diagnostics for COVID-19. One treatment and several antibody tests have now been approved for use in the UK, and investigations into further repurposing of existing medicines and developing new treatments are continuing at pace. Phase three of the Government's COVID-19 Recovery Strategy includes a focus on 'reliable treatment' and *"will do all it can to develop and roll out both treatments and vaccines at the fastest possible rate".* It will be critical that access to medicines, treatments and diagnostics is considered with a view to the maximum possible global coordination.

- **Collaboration to scale UK manufacturing.** Partnerships have been developed to rapidly advance manufacturing facilities for any new vaccine that is discovered and to understand the capacity that exists in academic and industrial settings alongside the UK's national centres. Analysis is ongoing to understand where the UK can repurpose existing sites and where new capacity can be created.

- **Collaboration to prepare Nightingale hospitals.** Unprecedented speed and partnership between a range of public and private organisations and companies was demonstrated when rolling out the Nightingale field hospitals to extend ICU capacity.

- **Vaccines Manufacturing and Innovation Centre.** The timetable for expanding the capacity of the VMIC has been brought forward so that it becomes operational earlier than planned and can manufacture population-level doses at scale.

What changes do we need to maintain and establish?

- **Develop a clear national strategy for the rollout of COVID-19 vaccines, treatments and diagnostics.** The Life Sciences sector will be critical in the manufacture and distribution of any COVID-19 vaccine that is developed. The Government acknowledges this will be a major logistical undertaking and is seeking advice from the Joint Committee on Vaccination and Immunisation (JCVI) on deployment. It is critical that plans are developed in partnership with the world's leading vaccine manufacturers. Regulators, including the MHRA, will also have a critical role to play. Digital platforms may be able to support clinical surveillance and vaccine management, particularly if a vaccination programme is staggered, and maximising the impact could be achieved through this approach. Much greater focus is also required on the role of diagnostics in core laboratory and point of care settings, including more transparent funding streams to support the availability of the vaccine when available.

- **Repurposing.** In parallel with investigations into new treatments, research is being conducted on how existing treatments might be repurposed, as these therapies have the benefit that supply chains are already developed and can more easily be extended or enhanced. For such repurposed existing treatments, it will be important to have a regulatory approach in place, as well as incentives for manufacturers, should trials prove positive.

- **Development of an integrated vaccination programme**. Building a COVID-19 vaccination programme should be on the Government's strategic agenda in parallel with vaccine development, trials, manufacturing and logistics. The programme also needs to look at enabling wider, and faster, access to diagnostic tests by increasing their availability at Urgent Treatment Centres and community pharmacies. It also need to consider building public trust and confidence in the vaccination process.

- **Rapid evolution of NICE methods.** The production of rapid NICE guidance offers a powerful route to deliver rapid re-start of clinical procedures as the height of the COVID-19 pandemic passes, enabling consistency in delivery of care across the country and reducing inequalities. The learning from the COVID-19 response should be factored into a rapid evolution of NICE methods to support patients getting faster access to new treatments. This is an opportunity to be ambitious in what NICE seeks to achieve through the methods review, to truly future-proof HTA in England for COVID-19 and non-COVID-19 medicines. NICE has de-prioritised some engagement processes in relation to non-COVID-19, non-cancer treatments and it will be important for evaluations to restart alongside the continuation of the NICE Methods Review. A more flexible approach to technology assessment enabling new forms of real world evidence and wider definition of value needs to be developed in conjunction with industry. When developed, NICE guidance on COVID-19 must be accompanied by a clear implementation strategy supported by mechanisms such as existing NICE resource templates to support and ensure consistent implementation.

- **Vaccines evaluation**. There are also specific engagements required on vaccines evaluation speed and agility with the JCVI. Due to the number of COVID-19 vaccines in development and to support rapid assessment, an understanding of JCVI's assessment criteria re efficacy in specific populations is required. This includes an understanding of the data sources and assumptions underpinning the health economic methodology. This is an opportunity to ensure that JCVI is fully resourced to manage increasing demand and that its processes and methods are fit for the future. Increasing transparency of processes and methods is needed, along with increased interaction with industry, to ensure rapid access to vaccines and immunisations in the UK. The JCVI and its Secretariat should be resourced to manage its growing workload in a timely manner and to allow it to adopt best-practice, transparent approaches for process and methods, inclusive stakeholder engagement and consultation to match international and UK best practice seen elsewhere within the system.

- **Delivery of more flexible commercial and managed access arrangements.** COVID-19 has demonstrated the need for even greater agility and flexibility in securing robust commercial arrangements for supply of technologies. The necessity of introducing greater centralised contracting has facilitated swifter introduction of vital new technologies and should be reviewed to see how its benefits could be maintained. Commissioning policies may in future need to incorporate more transparent criteria identifying the sequence in which patients will be prioritised for treatment. Value-based healthcare and reimbursement based on patient outcomes and system efficiencies need to be introduced.

- **Monitoring and reporting of uptake of diagnostics, treatments and vaccines.** Investment in tracking uptake of treatments, technologies and diagnostics at a national, regional and local level with transparent and regular reporting will be more important than ever to ensure health inequalities generated because of COVID-19 can be eliminated as quickly as possible. Mechanisms need to be introduced to support localities that are shown to be poor at adopting innovations and / or realising the benefits of competition when multi-source markets form. These mechanisms could be developed in partnership between industry and the NHS. Efforts must also be made to understand and build public confidence so that any potential barriers to people coming forward for vaccination can be addressed proactively and optimum levels of uptake in target populations can be achieved.

- **Preservation of Intellectual Property (IP).** Existing IP protections have enabled the biopharmaceutical industry's rapid response to COVID-19 and are facilitating the collaborations and partnerships needed to defeat the virus and end the pandemic. The UK Government should ensure that maintenance of this system of IP is at the heart of its future trade policy.

Next steps

- Development of multi-agency dialogue between industry, DHSC/NHSE/NICE/PHE/JVCI to progress Life Sciences strategies for regulation, manufacturing, evaluation, access and commissioning of future COVID-19 diagnostics, vaccines and treatments.

- Development of a pandemic surveillance scheme on a national and international level, linking early detection, contact tracings, scientific understanding and vaccine development in a coordinated way. Such an approach could also be used to minimize deaths due to seasonal flu, as in Finland, and could build on the UK's world-leading expertise in running large-scale biobank approaches.

Workforce

Objectives:

- **Restart:** Supporting the NHS and Life Sciences workforce to return to work safely.

- **Renew:** Develop and resource skills development programmes to meet NHS and life science sector workforce priorities, together with a renewed focus on the Science Industry Partnership (SIP) 2030 Skills Strategy to support 'build back better' transformation of UK economy.

The response to COVID-19

- **Sharing of expertise.** The skills and experience of the Life Sciences sector workforce have been essential in supporting the NHS and Government to respond to the COVID-19 pandemic. From scientific and manufacturing expertise, to medical and clinical staff, employees in the Life Sciences sector have worked in partnership to support the national effort to combat COVID-19.

- **Maintaining manufacturing and research capabilities.** The Life Sciences sector has continued to operate manufacturing and research facilities throughout the period of the pandemic, operating social distancing measures and implementing new practices to protect the health of staff. This has been critical to the ability of companies to continue to operate manufacturing and research facilities and ensure supply continuity to the NHS.

- **Volunteer support for the NHS, public health and research.** A huge number of volunteers from the Life Sciences workforce volunteered to support the NHS on the front line as well as volunteering as part of the public health response. Over 1000 charity-supported clinical research staff from the Association of Medical Research Charities' (AMRC)'s membership have been seconded to support frontline patient care. Similarly, a significant proportion of the research workforce has been redeployed in the NHS, delivering frontline care and nationally prioritised COVID-19 studies.

- **Key worker identification.** The Government included Life Sciences workers as 'essential workers' when announcing the closure of schools at the start of the lockdown. This enabled companies to make good decisions about how best to continue to operate manufacturing and research facilities. This status should continue to be the default arrangements during COVID-9 and for any future pandemics

- **Remote working embedded.** The Life Sciences sector has rapidly established new remote working practices and interfaces with regulators and the NHS, which have been critical in maintaining collaboration and dialogue.

- **Engagement with frontline NHS staff.** Many companies reduced and stopped face-to-face interactions with frontline NHS staff, in recognition of the significant capacity challenges they faced. This has included technicians and educational/training staff who are no longer supporting the NHS in these areas. However industry has continued to support urgent (eg trauma) interventions with expert technical advice on procedures such as heart valve replacements, orthopaedic surgery and endoscopic procedure and service teams have been at NHS sites maintaining vital equipment.

What changes do we need to maintain and establish?

- **NHS People Plan.** The NHS People Plan should recognise the breadth of roles where upskilling is needed within the NHS to support the longer-term resilience of the healthcare system and resumption of clinical research. These include immunologists, clinical research nurses and those with digital skills. The Life Sciences sector can play a key role in supplementing NHS skills and providing expert support in use of their technologies, in addition to freeing up time for direct patient care by use of digital health technologies. This could further reduce the recruitment burden. These specialists can help embed new ways of working using digital technology to improve patient outcomes, which could reduce the NHS' recruitment burden.

- **Resumption of industry and NHS partnership working.** The Life Sciences sector can play a significant role in supporting the NHS to address some of the backlog in patient care arising from the pandemic. To do so, it will need to be clear how industry staff can re-engage directly with frontline NHS organisations and staff safely. A plan for the resumption of this activity should be created jointly between the NHS and the Life Sciences sector, sensitive to local needs but with a consistent framework for exploring new ways of working such as online tools and programmes for support and education.

- **Resourcing scientific expertise.** Research and development and regulatory science expertise is developing new tools, standards and approaches to evaluate the efficacy, safety, quality and performance of medical products. This work is being internationally harmonised to allow new treatment and vaccines to be available as quickly as possible across the globe. This expertise needs to be supported and made possible through the UK's skills and immigration policies. As COVID-19 research activity is likely to be maintained, an increase in resource and workforce, including in Government agencies, will be needed to re-establish the levels of clinical research activity in the UK from before the pandemic to ensure the UK remains an attractive place for researchers and regulatory scientist to want to work. Furthermore, it is critical that the UK continues to maintain early stage career researchers and others to enable us to capitalise on our ambition to be a world-leading R&D destination.

- **Migrating staff back from the NHS.** Clarity is needed on how the salaries of clinical researchers seconded back to the NHS front line during the crisis will be recovered, particularly the over 1000 charity-supported clinical research staff who have been seconded to frontline patient care. Researchers will need to be supported in order to return to clinical research, and may need to retrain and recalibrate away from frontline care to a research setting.

- **Safe return to work.** Safe return to work is another critical factor to consider in planning the resumption of clinical research activity. Building on the Government's *Safe Return to Work* guidance, it is critical that Life Science sector staff have access to the necessary PPE and testing in order to resume key activities.

- **Continuing support for those individuals in the UK actively producing, manufacturing, supplying and distributing medicines and devices.** Such workers accessed testing following healthcare workers, aiding the continued supply of key product to the NHS. We suggest that this precedent continues for any future antibody testing or vaccine.

Next steps

- Joint development by the NHS and the Life Sciences sector of guidance on how and when industry employees can safely interact with NHS frontline staff and support the delivery of patient care.

- Convening of a Life Sciences Skills Strategic Advisory Group, comprising industry, NHS, academia, learned societies and Government Departments, to horizon-scan workforce needs that will support Government's desire to seek new economic opportunities for the UK's world leading pharmaceutical and medical-device manufacturing sectors.

- A renewed focus between Government and industry on delivering the SIP 2030 Skills Strategy as part of the Life Sciences Industrial Strategy Implementation Board, including refreshing the plan for developing scientific expertise in the UK and identifying immediate opportunities for reskilling from other sectors.

6. Global Trade and Supporting UK Exports

Objectives:

- **Restart:** the global sales pitch for the UK as a prime location for life science investment into research, development and manufacturing.

- **Renew:** Commitment by the Government to Life Sciences and biomedical innovation at the heart of the UK's trade agenda as a future engine of economic growth.

The response to COVID-19

- **Tariff liberalisation for COVID-19 related technologies.** To help facilitate trade, many countries have eliminated tariffs on medicines and medical and protective equipment used to detect or in the treatment of COVID-19.

- **Continuation of Trade negotiations.** Despite initial delays, the UK Government has adapted quickly to continue and initiate key trade negotiations which industry hopes will help to remove trade barriers in partner countries for UK Life Science exports.

What changes do we need to maintain and establish?

- **Increased Government support for Life Sciences exports.** The Trade Access Programme (TAP) has been critical in supporting Life Sciences companies with global exports. These grants have allowed small companies to attend international trade shows and overseas missions. Funding for this programme amongst others has fallen, and should be restated alongside evaluating other initiatives to help kick-start Life Sciences exports. In the short-term it will be challenging for UK Life Science companies to travel to international trade shows due to travel restrictions and the inevitable reduction in numbers of healthcare professionals attending these meetings. Therefore, on-line initiatives need to be developed and supported to showcase the best of UK SME life science.

- **Tariff liberalisation for UK exports.** Following the recent G20 trade ministers' statement, we would also call for the UK to build on this by supporting emerging international trade liberalisation initiatives for medical goods (e.g. tariff reductions, customs facilitation, expansion of the WTO Pharmaceutical Tariff Elimination Agreement).

- **A UK trade agenda that put Life Sciences at its heart.** Ensuring that trade partners work with the UK to promote global regulatory convergence for medicines and medical technologies is critical, particularly as the end of the EU exit transition period approaches. So too is a renewed commitment to strong intellectual property protection which encourages and supports innovation and provides transparent and predictable market access conditions while balancing fair and effective competition.

Next steps

- Ongoing refinement of business consultation mechanisms for trade discussions to ensure that UK trade negotiators receive real-time feedback from businesses about the impact of potential measures on business and are well-equipped to negotiate outcomes that best support the stated aims for the Life Sciences industry in the UK.

- Utilisation of existing forums e.g. EURG for innovative sectors, with its remit expanded to non-EU trade, to ensure that issues with potential impact on the EU, US and other negotiations can be considered in full. There should also be a clearly defined mode of interaction between the EURG and DIT's Expert Trade Advisory Groups, including on Life Sciences and customs. To enable due representation from the off-patent sector, there should be parallel groups for innovative and off-patent sectors, or there should be more balanced representation on existing groups, such as the ETAGs.

Appendix 1: Supporting delivery of the NHS Long Term Plan

Summary of draft recommendations by NHS Long Term Plan Priority Disease Area

Note: A separate paper detailing these recommendations is in draft for discussion with NHSE-I Leadership

- **Cancer:**
    - Rapidly restoring and expanding diagnostic services
    - Rolling back quickly interim cancer treatment regimens of lower proven efficacy which have temporarily used to reduce risk of COVID-19 in some cancer patients
    - Restoration of diagnostic testing capacity within the national Genomic Medicine Service
    - Development of the DATA-CAN Health Data Research Hub to evaluate the impact of alternative delivery models of consultation, care and support
    - A concerted initiative by NHSEI to scale the benefits of new approaches consistently across the system to reduce backlogs and avoid exacerbating health inequalities
    - Development of strategies to increase resilience of the cancer service workforce in order to maintain crucial functions during a future wave of the pandemic
    - New collaborations with professional groups, cancer alliances, AHSNs and Primary Care Networks (PCNs) to advance medical education at pace

- **Diabetes:**
    - A clear focus on the importance of secondary prevention of complications in diabetes, including appropriate utilisation of innovative medicines where this remains slow, inconsistent and often unaligned to NICE guidelines
    - Systematic risk stratification of people with diabetes, enabling the most vulnerable to be prioritised for pro-active support
    - Formal evaluation of the impact of changes to diabetes care made during COVID-19 and collaboration to develop and deliver a shared vision of diabetes care
    - Continued collaboration to provide relevant education for clinicians, enhanced by greater alignment across industry to avoid duplication and increase consistency
    - Cross-sector collaboration to support the interaction and interdependency between medicines and diagnostics in improving the lives of people with diabetes
    - More integrated messaging to patients through collaboration to support improved patient education and self-management
    - Clear timelines for delivery of NICE's review of diabetes guidelines

Cardiovascular disease (CVD):

- Strong PHE leadership to encourage patients to improve their levels of self-care
- Greater direction from NHSE Clinical Leadership to ensure that holistic care is emphasised
- Implementation as planned this summer of the national CVD prevention audit for primary care, 'CVDPrevent', to help clinicians improve care for patients at risk of CVD events
- Development and implementation of planned Direct Enhanced Services (DES) Contract for Primary Care Networks
- Increased working with patient groups, homecare services and nurse support programmes to meet the demand from patients for education and support
- Placing industry within the "key stakeholder groups" that are designing community-based care models so that they can lend expertise to risk stratification and pathways
- Prioritisation by NHSE-I of the collection of the CVD data and its analysis to drive rapid improvements in local care
- System incentives to support the uptake of 'CVDPrevent' and to drive improvements in local care
- A renewed focus on improving secondary prevention through tackling inappropriate variation in use of innovative treatments and the health inequalities that this exacerbates
- Improved visibility of the NHSE-I Long Term Plan delivery structure for CVD, involving industry as a full delivery partner
- Cross-sector collaboration to support new technologies to track symptoms and monitor outcomes in the community

Respiratory Disease:

- Development of enhanced patient education tools to reduce cultural and health literacy challenges in collaboration with NHSE-I and patient organisations
- Industry and patient organisations routinely integrated into working groups developing self-care guidelines and patient support programmes
- Reinstatement of quality improvement programmes and incentives for respiratory care, such as the Quality Outcomes Framework (QOF) and Enhanced Service
- Evaluating the impact on respiratory data collection during the first wave of the pandemic and assessing whether and where variation has increased
- Development of direction to healthcare professionals to pro-actively check any diagnoses that were made remotely during the first wave of COVID-19
- Assessment of the skill set required for virtual multi-disciplinary team assessments and incorporation in NHS workforce training, utilising respiratory reviews and technology enablers
- Development of standardised tools to support workforce capability and risk-stratify patients to the most appropriate care pathway
- Evaluation of the discharge guidelines used during COVID-19 and adoption of best practice – including support and guidance for care homes - to reduce winter pressure bed-blocking
- Evaluation of options to support patients with self-care at home, through provision of homecare services and high-quality patient support programmes
- Improvements in data sharing to create world-class disease registers and enable industry to develop tailored solutions
- Sharing of expertise in online training and web-based platforms, building on successful implementation of initiatives such as the PRIMIS/ GRASP COPD tool (a medicines optimisation risk stratification tool); Project management and implementation support at ICS level; patient awareness and activation schemes; and homecare patient support programmes

Mental Health:

- Systematic risk stratification of mental health patients, enabling the most vulnerable to be prioritised for pro-active support and avoid admission to hospital
- Prioritisation of structured medicines reviews for individual patients and proactive transition from short to long-acting medicines where appropriate
- Formal evaluation of changes to mental health care made in response to COVID-19 and their impact in order to inform future delivery
- Scaling of the Nottingham, Northamptonshire and Surrey ICSs' approach to mental health care provision, with the support of the AHSN Network
- Accelerated and consistent roll-out of electronic prescribing
- Industry-NHS collaboration to develop and implement new service models and consistently implement NICE guidelines on treatment and prescribing pathways
- Collaboration between NHS, industry and patient organisations to explore the potential for more integrated, systematic collection of mental health data via a mental health data hub

Immunisation:

- Public-facing campaigns and work with patient groups to communicate the importance of all immunisations
- Development of national guidance to support reintroduction of immunisation services impacted by COVID-19, including catch-up campaigns for specific age or at-risk groups
- Development and consistent use of existing data infrastructure (such as SystmOne live data collection) to support recovery of all NIPs
- Efforts to increase flu VCRs this winter, with PHE using learning from the southern hemisphere and publishing a mitigation strategy for risks identified
- Continued close liaison with industry on vaccine supply and stock management.
- Making every contact count by highlighting eligibility for other vaccinations when people receive flu vaccination
- Expansion of school immunisation workforce capacity
- Implementation of the vaccination and immunisation reforms to the GP contract should move forward as planned
- Development and publication of the DHSC Vaccine Strategy as a priority
- Consideration of the opportunity for a wider range of providers to offer immunisations to increase capacity in the system

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