

September 2017

Response submitted by:

Philippa Brice
philippa.brice@phgfoundation.org

Johan Ordish
johan.ordish@phgfoundation.org

Alison Hall
alison.hall@phgfoundation.org

Inquiry on Life Sciences and the Industrial Strategy: evidence from the PHG Foundation

The PHG Foundation is non-profit health policy think tank. We work to achieve the prompt, effective and responsible application of biomedical and digital technologies within health systems

A vibrant UK Life Sciences sector is highly desirable to underpin better health and wealth for the population; recognition that these two aims are not incompatible is welcome. To maximise the benefits to UK citizens, the Industrial Strategy should aim to realise the value of the NHS as a test bed for (and potential source of) useful innovations, and to help deliver these to NHS professionals and patients promptly, subject to proportionate regulation and careful financial and clinical appraisal. Brexit poses serious threats to the UK's current global pre-eminence in the Life Sciences and care must be taken to mitigate these threats, including steps to ensure appropriate implementation of the EU General Data Protection Regulation and In Vitro Diagnostic Devices Regulation and to maintain close working relations with the European Medicines Agency.

One potential barrier to global pre-eminence in the life sciences is the divergent structures, working practices and objectives of the different contributors: industry, academia, the NHS and the third sector

Science and innovation

How can investors be encouraged to invest in turning basic life science research into new innovations in treatment? Why has investment been lacking in this sector? Does the research base have the necessary infrastructure to be world-leading?

Investment in academic translational research in the UK from charitable and government sources is generally good; provided that this funding is maintained - bearing in mind the expected loss of research funding from the EU- this will remain an important source of clinical innovation. All efforts to maximise opportunities for appropriate private sector collaboration with and investment in university and hospital research are clearly also important, arguably more so if the UK is to be seen as an attractive base for commercial development of innovative treatments. For potential investors, the advantage of operating in the UK should include opportunities to test innovations in patients (subject to a responsible and proportionate regulatory regime) and generate evidence of cost-effective health benefits within the NHS, as has already been widely recognised.

One potential barrier to global pre-eminence in the life sciences is the divergent structures, working practices and objectives of the different contributors: industry, academia, the NHS and the third sector. Efforts to encourage not only cross-sector collaboration via flexible funding models (not merely based on academic-commercial partnering), but also the increased potential for movement of skilled staff between these different sectors are likely to benefit all.

What can be done to ensure the UK has the necessary skills and manpower to build a world class life sciences sector, both within the research base and the NHS?

A world-class life sciences industry necessitates a workforce skilled in maths, science, engineering and technology at all levels. Education and training must therefore be supported from primary schools upwards, including provision of teachers with appropriate skills in these areas. Given that such teachers are already in critically short supply in secondary schools, and even rarer in primary schools, a cross-cutting educational policy that supports home-grown talent needs urgent consideration. This should include measures to provide appropriate training for the support scientists and technicians of the future, as well as research scientists.

At the same time, careful consideration must be given to the urgent necessity to attract and retain skilled life scientists and innovators from around the world to live and work in the UK. Scientific excellence is very much a global endeavour, and Brexit poses a serious risk to the normal international movement of these experts; without the capacity to attract international experts in the life sciences to live and work in the UK, whether in the commercial, third or academic sector, ambitions for a world class life sciences industry will inevitably be curtailed. Of note, this is a problem requiring immediate action, since any efforts to boost the 'home-grown' supply of science talent and skills through education will necessarily take years to bear fruit.

NHS procurement and collaboration

How can the recommendations of the Accelerated Access Review be taken forward alongside the strategy? Will the recent changes to the NHS England approval process for drugs have a positive or negative effect on the availability of new and innovative treatments in the NHS? How can quick access to new treatments and the need to provide value for money be reconciled?

An accelerated process for drug approvals is likely to have a positive effect on the availability of innovative treatments in the NHS, provided that the trial status of innovative treatments is carefully maintained along with rational standards of evidence (with respect to safety, clinical efficacy, and cost) and timescales within which they must be met for a treatment to receive approval for routine use in the NHS. Accelerated access should provide faster access to potentially beneficial innovations for consenting patients, and a cost-effective test-bed for developers. However, the system will require careful and ongoing oversight to ensure that the best interests of all UK citizens and tax-payers (as well as patients) continue to be met. It therefore will be important that the new processes are robust and there is sufficient oversight to prevent the commissioning of treatments that do not sufficiently improve outcomes in a cost-effective manner (irrespective of local or national demand) and commits the NHS to paying for poor value products.

Whilst we support trials of innovative treatments and other products (such as diagnostics) within the NHS and a swifter process for evaluation, favourable conclusions that an innovation is beneficial for patients and the health service (in both clinical and financial terms) must be followed up by appropriate mechanisms for comprehensive roll-out across the NHS, ensuring equity of access for patients across the country.

To ensure that the recommendations of the Accelerated Access Review are reasonably met, the Life Sciences Industrial Strategy should make appropriate provision for industry to engage more closely with the NHS, including (but not only) via NHS England, NHS Improvement and the Academic Health Science Networks (AHSNs). This should involve measures to engage with the NHS and understand fully the practical and cultural barriers that have hitherto hampered efforts to work more closely together.

Explicit recognition is also needed that successful adoption of innovations by health professionals requires a more holistic approach than merely educating them in their use. The Pathway Transformation Fund will be a crucial first step towards this by supporting some elements of integration into clinical practice. Whilst some measures to achieve broad adoption will rest with the NHS, the Life Sciences Industrial Strategy could make specific provision in support of efforts to inform and work with frontline health professionals, commissioners and patients on how innovations can be most effectively put to use in the NHS, and to develop supporting health service strategy and national guidance. Consideration could also be given to discussion on the wider issues pertinent to the uptake of innovations, such as the imperatives for responsible data sharing within the NHS.

...favourable conclusions that an innovation is beneficial for patients and the health service (in both clinical and financial terms) must be followed up by appropriate mechanisms for comprehensive roll-out across the NHS, ensuring equity of access for patients across the country

Reshaping of the AHSNs to enhance their ability to act as brokers and leaders in cross-sector connection and in nurturing, launching and spreading innovations is highly desirable.

Support for NHS staff to work within industry and vice versa should be an important component within the Life Sciences Industrial Strategy, ideally via a variety of mechanisms such as formal secondment programmes or other incentives to employ staff with experience in one sector in the others, encouraging greater movement between the two and enhanced understanding of the needs and drivers of each. Involvement of academia and the third sector would add further benefit.

The AHSNs themselves are one area where multidisciplinary and cross-sector working is highly desirable. Reshaping of the AHSNs to enhance their ability to act as brokers and leaders in cross-sector connection and in nurturing, launching and spreading innovations is highly desirable. Measures to assess the efficacy of AHSNs in not only nurturing innovations, but also in supporting their availability and uptake across the NHS should be built into their evaluation processes.

The Life Sciences Industrial Strategy should make appropriate provision to support the development and wider uptake of NHS 'home-grown' innovations, as well as those that originate in the commercial sector. The NHS Innovation Accelerator and NHS Clinical Entrepreneur Programme are positive developments in this area, especially the latter scheme which is expanding to include healthcare scientists and allied health professionals, and the following year perhaps even to patients and the public. Similarly, inclusion of methods to scope and evaluate ideas originating from patients, charities and the public for potential commercial development would be a desirable addition to the Strategy to maximise creativity, as would explicit support for early commercial co-design with patients, carers and charities.

Responsibility and accountability

Who should take responsibility for the implementation of the Life Sciences Industrial Strategy and to whom should they be accountable? What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

Ideally, implementation of the Life Sciences Industrial Strategy should be the responsibility of a new Life Sciences Minister accountable directly to the government (see response to following question below). Coordination between the Department of Business, Energy and Industrial Strategy and the Department of Health will be essential to ensure that the opportunities presented by the NHS are maximised for the sector, whilst the interests of UK taxpayers and patients remain paramount. Close partnerships between industry, the NHS, academic institutions and charities are desirable for maximal benefit, and all these groups ought to have appropriate involvement in national policy development.

Brexit poses three main risks to the UK Life Sciences sector. Firstly, Brexit is likely to impact access to EU science funding. Secondly, flow of science talent from the EU to the UK is likely to be disrupted. Thirdly, the UK's Life Science sector's success requires continued trade with the EU. If the UK is to continue trade with the EU, it must comply with certain pieces of EU legislation

Does the Government have the right structures in place to support the life science sector? Is the Office of Life Sciences effective? Should the Government appoint a dedicated Life Sciences Minister? If so, should that Minister have UK-wide or England-only responsibilities?

It is the opinion of the PHG Foundation that to have a dedicated Life Sciences Minister supported by the Office of Life Sciences and working between both the Department of Health and the Department of Business, Energy and Industrial Strategy (or future equivalent with oversight of the commercial sector) would have a strongly beneficial effect on the sector. Not only would it signal the UK's ongoing ambitions for a globally competitive position to the world, but also help to ensure constructive and cooperative health and industrial policy in the future, and underpin porosity between life sciences careers and structures – which by creating wider and more varied employment opportunities could itself further incentivise younger people to train for and enter the sector. Whilst the first Life Sciences Minister George Freeman MP was particularly well qualified for the role, this should not be a barrier to the appointment of successors with less experience.

On balance, it would be likely to be of the most benefit to the country as a whole should the role holder have UK-wide responsibilities, rather than being restricted to England, though devolved decision-making and operation may create some complexities and limitations.

Brexit

What impact will Brexit have on the Life Science sector? Will the strategy help the sector to mitigate the risks and take advantage of the opportunities of Brexit?

Brexit poses three main risks to the UK Life Sciences sector. Firstly, Brexit is likely to impact access to EU science funding. The nature of any future relationship is yet to be settled, although the government has recently expressed that research links are indeed 'negotiable'. It is imperative that access to funding programmes such as Horizon 2020 is maintained or replaced with domestic funding schemes. These schemes foster collaborations between researchers, industry, and European labs. Consequently, loss of programmes like Horizon 2020 would likely stifle the flourishing of life science clusters in Cambridge, Oxford, and London. Despite this, the Life Sciences Industry Strategy calls for additional fiscal support of SMEs, investment in infrastructure for Life Science clusters, and further collaboration with the NHS. The PHG Foundation believes that it is vital to secure a robust funding strategy for the UK Life Sciences sector that takes account of all these elements.

Secondly, flow of science talent from the EU to the UK is likely to be disrupted. Free movement of persons has facilitated the exchange of science talent throughout the EU and enabled collaboration on major scientific projects. It is imperative that the UK remain attractive to science talent both in the EU and further abroad. The Strategy again offers pragmatic downstream solutions to this problem. In this regard, the PHG Foundation supports a streamlining of the Tier 2 visa process and the creation of a high-level science recruitment fund.

Despite a narrowed scope for regulatory improvement, the UK does possess an opportunity to foster the life sciences sector. Overall, the UK has a history of arguing for pragmatic, sensible changes to EU legislation. Specifically, the UK has advocated for proportionate and responsible regulation of genetic testing in the EU *In Vitro* Diagnostic Devices Regulation,

Thirdly, the UK's Life Science sector's success requires continued trade with the EU. If the UK is to continue trade with the EU, it must comply with certain pieces of EU legislation. These risks are explored in relation to question 16 below.

How should the regulatory framework be changed or improved after Brexit to support the sector?

The scope for creativity in regards to the regulatory framework may be somewhat limited. Brexit (at least hard Brexit) entails that the legislative supremacy of the EU will no longer apply in the UK. Nevertheless, the UK may still have to comply with some EU standards if trade is to continue unimpeded. For example, the General Data Protection Regulation (GDPR) applies not on the basis of territory but on the basis of destination. No matter where the data is processed, so long as the data is related to goods and services offered to individuals in the EEA, the Regulation applies. The PHG Foundation therefore urges caution, for if improvements to regulation come at the cost to trade, the UK as a whole may lose out.

Despite a narrowed scope for regulatory improvement, the UK does possess an opportunity to foster the life sciences sector. Overall, the UK has a history of arguing for pragmatic, sensible changes to EU legislation. Specifically, the UK has advocated for proportionate and responsible regulation of genetic testing in the EU *In Vitro* Diagnostic Devices Regulation, allowing development of 'in house tests' where justified by public health needs, and opposing mandatory genetic counselling where this seems inconsistent with existing professional practice: thus protecting the interests of both patients and industry. While the UK may no longer directly influence the Commission, the UK now has an opportunity to make its own rules. It is suggested that the UK continue with its pragmatic approach to legislation in the life sciences, stressing feasibility and collaboration between the NHS and industry.

There may be limited scope to improve upon current regulation, since much trade will depend upon the UK being compliant with key pieces of EU legislation. Nevertheless, the UK should continue to advocate for proportionate and responsible implementation of the GDPR and IVDR

To what extent should the UK remain involved with and contribute to agencies such as the EMA post Brexit?

The PHG Foundation notes four major risks that decoupling the Medicines and Healthcare Products Regulatory Agency (MHRA) from the European Medicines Agency (EMA) would imply. Firstly, the EMA is currently located in Canary Wharf, London. Given the agency's location, it draws substantial talent and expertise to the city. There is little the UK can do to stop this but a shift in location of the EMA is likely to dull the UK and London's place as a hub for pharmaceutical development.

It is imperative that the UK retain access to the EMA's data and manpower. Given this, the UK should negotiate a position that will closely mirror the current relationship between UK regulatory agencies and the EMA

Secondly, a complete separation of the MHRA from the EMA is likely to result in delays and added costs for pharmaceutical manufacturers. The EMA – not just the MHRA – has considerable experience in appraising post-licensing safety and efficacy data. To lose the EMA is to lose both its expertise and manpower. The loss of both of elements is likely to result in longer and more expensive licensing regimes. This loss is expected to be particularly onerous on those medicines that have small target markets. As an organisation, the PHG Foundation believes that medicine is, and is becoming, more personalised. If this belief is correct, the loss of the EMA will likely impact not only the development of treatments for orphan diseases but also -increasingly - upon medicines in general.

Thirdly, there is a risk of decreased capability to detect safety signals in new medicines. If the MHRA is to no longer have access to the resources of the EMA and the data it collects, the UK's ability to detect adverse events in the pre-market and post-market phases is set to be diminished. Again, this is likely to have a particularly detrimental impact on 'niche' medicines whose sample sizes are small to begin with.

Following these key risks, the PHG Foundation recommends that the UK attempt to preserve a close working relationship with the EMA. While there is little the UK can do to stop the EMA's move (the intention to move having been announced), it is imperative that the UK retains access to the data and expertise of the EMA. Therefore, it is further recommended that controlling EU legislation like the European Medicines Directive and the General Products Safety directive continue to be enshrined in UK law.

If the UK's regulatory structure becomes increasingly divergent from the EU's in the future, it seems likely that the licensing of new pharmaceuticals and investigational medicinal products will be delayed pending licensing in bigger markets. This process will be exacerbated if the UK fails to maintain a close working relationship with the EMA: this relationship will be difficult if there is lack of regulatory parity between the UK and the EU.

It is imperative that the UK retain access to the EMA's data and manpower. Given this, the UK should negotiate a position that will closely mirror the current relationship between UK regulatory agencies and the EMA.