Executive Summary

UK Biopharma - Adapting to a changing landscape to deliver a better global future

1. Background

The UK Referendum decision on EU Membership has opened a new chapter in the future of the UK, both socially and economically. The challenge is that we must now write that chapter with little precedent from which to learn. This means the Government urgently needs to develop a comprehensive industrial strategy for the life sciences to secure opportunities that will benefit healthcare and patients.

This short paper draws from EMIG's full paper ***"UK Biopharma - Adapting to a changing landscape to deliver a better global future",*** which is free to download from the EMIG homepage – www.emig.org.uk. It describes what a pragmatic, constructive implementation of the Referendum result could mean for the UK and EU biopharmaceutical sectors. *A priori*, while recognising the risks of the UK leaving the EU, it proposes ideas for *opportunities* that the UK could exploit to its advantage on a global stage, and critically, to show how the UK remains fully open for biopharmaceutical business. Several of these have already had a long "latent" period and therefore, did not directly need "Brexit" to be realised. What the prospect of Brexit *will* do however, is make it crucial for their potential to be released. Neither would many of them require "new money", rather a change in outlook and collective behavior, that's driven by melding *capability*, *opportunity*, and *motive*.

A core message of the full report is the criticality of addressing the future of healthcare and life sciences research in the UK from a *whole-system* perspective. Accordingly, there is a need for close collaboration between many Government departments to ensure the UK is positioned as a world-leader in healthcare, its application, regulation and research, and thereby attract significant new investment from overseas.

"In the middle of difficulty lies opportunity" (Einstein).

2. About EMIG

EMIG is the biopharmaceutical trade association that is the voice of 250+ companies and organisations, mostly SMEs, based in the UK. It represents a wide range of members from start-ups, whose prime focus is often research and development, to highly developed businesses delivering essential products to patients and the NHS. Indeed, EMIG members provide about 40-50% of all branded medicines, by volume, supplied to the NHS. Importantly, approximately 90% of its biopharma members are represented only by EMIG at trade body level. In addition to biopharmaceutical companies and their associated commercial service providers, EMIG also has patient groups, research charities, and universities in its membership, and their membership is free of charge. This enables EMIG to

represent the views of our pharma members but balance these with views from a wider stakeholder group, including the interests of patients and the NHS. We therefore strive to adopt a more independent and holistic approach to policy matters. This rich blend also facilitates knowledge, understanding and information exchange between a diverse range of organisations involved in the life sciences that, without this as an enabling platform, might not otherwise occur.

3. Summary of Recommendations

As an acknowledged 'jewel in the crown' of the UK economy, the new Government will be anxious to mitigate the impact on the UK life sciences sector and will be open to ideas on how to exploit UK industry and research base strengths in a post-EU world. The life sciences industry, therefore, has a real opportunity to gain a greater share of voice through a concerted lobbying camping to achieve its aims for healthcare and patients. Opportunities include:

Regulation

Guiding fact – the MHRA currently prosecutes over 30% of the EMA's total workload.

- Leveraging fully the large contribution the MHRA makes to the work of the EMA, to ensure that the negotiation of all relevant mutual recognition-type agreements are prioritized.
- Enabling the MHRA and NIBSC to exploit further its existing leadership in regulatory science and policy matters to develop unique, bespoke regulation for a range of advanced product areas that could have future global application.
- Developing strong relationships with other 1) leading global regulators in areas of shared scientific and public health interest e.g. with MHLW and FDA and 2) country regulators e.g. Australia, Canada, India, China, where a streamlined approach to medicines regulation could aid both public health and life sciences investment.

Life Sciences Market Attractiveness

Guiding fact – the swift adoption and efficient diffusion of "value-shown" innovative medicines and health technologies by the NHS is the cornerstone to optimise the success of a new comprehensive life sciences strategy.

- Promoting the UK's leading role with NCEs and speciality medicines, the global influence of NICE determinations and the importance of international reference pricing.
- Working with NICE, the MHRA and Government to leverage internationally UK expertise with real-world evidence and the application of data science.
- Establishing a new ring-fenced medicines fund for the NHS from the rebates paid by the industry to the Government, and also exploring actively a range of new funding models with the biopharmaceutical industry.

- Re-instating the "taper" for small companies to encourage growth and investment.
- Streamlining and promoting the critical role of Academic Health Science Networks as central brokers for the adoption and diffusion of new medicines and health technologies.
- Seeking a significant reduction in corporation tax (i.e. as close to the Republic of Ireland as possible) as an incentive for inward investment.
- Asking the Government further to enhance the Patent Box to the extent possible under the UK's G20 obligations
- Reinforcing the Government's appreciation of the power of effective intellectual property protection and regulatory exclusivities to attract investment
- Seeking the adoption of regulatory and reimbursement regimes designed to encourage rather than deter the use and adoption of new treatments

Research and Development

Guiding fact – the UK has world-class capabilities across the spectrum of life sciences research, but fails to work consistently in a truly collaborative manner for collective advantage.

- Using a proportion of the EU "rebates" to further boost schemes such as the Biomedical Catalyst.
- Incentivising (e.g. via the Research Excellence Framework) better industry-academia, intra-institutional, and *critically*, inter-institutional collaborations.
- Establishing the UK as the world-leader for translational drug development.
- Using the influence of the NIHR to encourage NHS trusts to harmonise their clinical trial performance operations and standards.
- Introducing operating models by which industry can access the research partners it needs quickly and efficiently.

People, skills and training

Guiding fact – without easy access to the appropriately-skilled people, who feel confident living and working in the UK, we will fail.

- Encouraging a positive immigration policy for easy access to the appropriately-skilled people, no matter where in the World they originate, and for them to feel welcomed to long-term life and work in the UK.
- Exploring novel ways to develop skills and talent e.g. via better collaborations between Further/Higher Education providers and businesses to deliver more jobs that are directly linked with educational outcome, or exploiting the latent knowledge and expertise of sector-specific service companies.

Marketing the UK

Guiding fact – there is insufficient awareness in the world's life sciences businesses about the UK's collective capabilities.

- DfIT to partner *holistically* with all parts of the commercial life sciences service sector to market the UK assertively and globally.

Finally, we suggest a vision for the future that pulls together many of the above opportunities into a single, fully integrated, health sciences ecosystem. In effect, this would establish the UK as the world's **"Open Centre for Health Sciences"**. This would feature a truly collaborative network of universities and their associated NHS Trusts working with the life sciences industry across the entire "bench to bedside and back" spectrum for the discovery, development, adoption and diffusion of medicines and medical technologies. The AHSN network in England and their equivalents in the devolved nations, MedCity, and the NHSA would all play a central, pivotal brokerage role, with the MHRA, NICE and HRA additionally involved as critical partners on each medicine's/medtech's journey.

Leslie Galloway, EMIG Chairman – leslie.galloway@emig.org.uk
Dr Mark Edwards, EMIG R&D Director – mark.edwards@emig.org.uk