

# Unlocking growth: the promise held by sustainable medicines manufacturing

### **Position Paper**

Anca Tacu, Policy Adviser and Dr Luís Miguel Lacerda, Policy Adviser



### Introduction

The launch of the new <u>Industrial Strategy Green</u>

Paper presents a unique window of opportunity for the UK to capitalise on the significant potential for economic growth and increased national resilience offered by sustainable medicines manufacturing. This position paper proposes some key considerations and recommendations on how to improve the sustainability of the medicines manufacturing ecosystem in the UK through the new industrial strategy.

The capacity to respond to health-related challenges such as increased risks posed by climate change, and new pandemic threats, is essential to the UK's future national security and resilience.

For the UK to respond effectively to these challenges, we must be able to mobilise stakeholders across academia, industry, the NHS and wider society to deliver innovations at scale – in a way which is, as yet, unprecedented. A starting point for this must be the life sciences sector, given its strategic importance to the UK's health and national resilience.

The development of the Oxford/AstraZeneca vaccine during the Covid-19 pandemic is a prominent example of how integral the life sciences sector can be when the UK is faced with a health emergency.

Life sciences was also identified as one of the sectors with the highest potential for economic growth in the Industrial Strategy Green Paper. With a strong base for R&D and early stages of medicines development, the UK life sciences sector contributed over £43 billion in Gross Value Added (GVA) in 2021<sup>1</sup> to the UK economy. Within the UK life sciences sector, medicines manufacturing is responsible for the largest share of economic activity, providing high quality jobs across the UK, including in less economically prosperous areas<sup>2</sup>.

The potential is clear. However, achieving economic growth and delivering the health and resilience of the nation must be pursued in a way which is mindful of Net Zero – and broader environmental objectives – and not at their expense. Although the pharmaceutical industry is a significant contributor to greenhouse gas

<sup>1</sup> PwC (2023) The UK's life sciences sector contributes £43.3billion in GVA as it enters a new supercharged era of innovation and breakthrough science

 $<sup>^2</sup>$  Medicines Manufacturing Industry Partnership (2023) Follow the green,  $\underline{high\text{-}tech\,road}$ 

emissions (GHG)<sup>3</sup>, this has not been researched to the same extent as in the case of other industries<sup>4</sup>. When compared to other industries, there is also a notable lack of low-carbon pharmaceutical products<sup>5</sup>.

In the UK, medicine manufacturing and freight account for 20% of the overall NHS emissions<sup>6</sup>. The NHS expects its suppliers to help them to tackle these emissions and align with their Net Zero ambition<sup>7</sup>. Given the significant purchasing power of the NHS, this expectation has the potential to shape the market by stimulating demand for medicines manufactured with a lower carbon footprint and potentially reducing their price points.

However, increased demand is not enough on its own. It must be met with improved infrastructure, recognising that transitioning to a future where all medicines are manufactured in a sustainable manner requires the creation of a robust ecosystem which facilitates innovation and enables cross-sectoral collaboration, and is underpinned by consistent funding support at all levels.

An agile regulatory environment will also be needed to enable the adoption of sustainability-related innovations, whilst delivering new standards that can promote best practices across the sector.

## Capitalising on R&D in UK medicine manufacturing

The UK has a strong base for R&D and early stages of medicines development but hasn't always capitalised on this in terms of establishing manufacturing for domestic use and export, which is key to delivering economic growth and increasing national resilience<sup>2</sup>. This means that technologies and products developed in the UK –

for example monoclonal antibodies - have not subsequently been commercialised manufactured in the UK<sup>8</sup>. In the last 25 years, there has been a significant reduction in UK's medicines manufacturing capacity, with production volumes having fallen by 29% and 7,000 jobs lost since 20099. Furthermore, the process of manufacturing new medicines relies on global supply chains and the UK has approximately 25% of its inputs being imported from abroad in the pharmaceutical sector9, making it vulnerable to shocks and production disruptions. At the same time, competing countries including Germany, Ireland Singapore have prioritised manufacturing8; the US has recently announced a biotechnology and biomanufacturing strategy with \$2bn+ funding - setting ambitious goals for and building а harnessing R&D strong biomanufacturing infrastructure to tackle a broad range of societal challenges, including in climate change and human health 10.

Although there has been increased awareness and recognition from policymakers of the importance of manufacturing for the UK economy, significant challenges remain and opportunities continue to be missed. One such challenge is the need for long-term support for scaling up lab-based demonstrations<sup>11</sup>. This requires adequate infrastructure to test how to manufacture a new product complying with Good Manufacturing Practices (GMP), but also a commitment to addressing the gaps in skills required for future medicines manufacturing<sup>2</sup>. An example of the type of infrastructure required is the publicly funded Vaccine Manufacturing Innovation Centre (VMIC). In its original vision, VMIC was supposed to be a not-for-profit innovation hub aiming to accelerate the early-stage clinical development of new vaccines and develop vaccine manufacturing processes, as well as providing training for

<sup>&</sup>lt;sup>3</sup>Belkhir, L., Elmeligi A. (2019) *Carbon footprint of the global pharmaceutical industry and relative impact of its major players*, Journal of Cleaner Production

<sup>&</sup>lt;sup>4</sup> Clinton Health Access Initiative (2023) First-of-its-kind study, shows that big pharma could cut by nearly half, its carbon footprint, if it made some key changes

<sup>&</sup>lt;sup>5</sup><u>Deloitte (2022) Embedding environmental sustainability into pharma's DNA</u>

<sup>&</sup>lt;sup>6</sup> NHS England (2020) *Delivering a 'Net Zero' National Health Service* 

<sup>&</sup>lt;sup>7</sup>NHS England (2023) Net Zero Supplier Roadmap

<sup>8</sup> Cambridge Industrial Innovation Policy (2022) The UK Innovation Report 2022

<sup>&</sup>lt;sup>9</sup>HM Government (2021) *Life Sciences Vision* 

<sup>&</sup>lt;sup>10</sup>The White House Office of Science and Technology Policy (2023) *Bold Goals for U.S. Biotechnology and Biomanufacturing* 

<sup>&</sup>lt;sup>11</sup> Tacu, A. (2024) Unleashing the economic potential of UK manufacturing

developing GMP-level vaccines <sup>12,13</sup>. VMIC has however been sold off, a decision which has been openly criticised by scientists as it has left the UK at risk of losing the ability to enable small-scale vaccine innovation <sup>14,15</sup>.

Recommendation: Develop dedicated infrastructure that will enable accelerated development of new medicines and sustainable medicine manufacturing processes at scale. Initial aims set for VMIC could be used as a blueprint.

New investments around infrastructure should also consider whether there are opportunities to retrofit, modernize or adapt existing infrastructure and technology to promote cross-industry collaborations to deliver economic growth<sup>16</sup>. Leveraging innovation in digital technologies (e.g. digital twins) to predict what type of infrastructure is actually needed, and also to improve the range of available manufacturing capabilities to deliver at point of care, for example, can be explored in the context of the updated Made Smarter Innovation programme.

There are many basic infrastructure blocks across different industries that can be used for multiple applications (e.g. bioreactors across health, food, fuel and waste management). The joint use of infrastructure, such as manufacturing facilities or research laboratories, can therefore support the scale-up activities of early start-ups and promote diffusion better and adoption technologies 17. However these sectors experience distinct regulatory requirements, which makes it challenging to align processes and share resources. Government action becomes essential in fostering knowledge sharing and collaboration across manufacturing industries to address coordination challenges, and can be a decisive factor to enable economic growth.

One particular action that could be taken is to develop policies that facilitate easy access to existing infrastructure in the UK (e.g. CPI,

biofoundaries) and to push for an umbrella/ framework agreement to avoid having multiple contracts in place, reducing administrative burden and expedite production (see recent evaluation of the Industrial Strategy Challenge Fund). In addition, the Government could use new initiatives such as the recently launched design for life road map to advance sustainability in the life sciences sector by ensuring close collaboration with other key industries such as clean energy/green technology and digital and technologies, like artificial intelligence.

Recommendation: UK government to provide a joined-up policy approach which fosters and incentivises knowledge sharing and collaboration across manufacturing industries to support scaling up. This should include exploration of enhanced support for joint use of existing infrastructure through the creation of overarching framework agreements.

### Promoting agile regulation and common metrics and standards

The pharmaceutical industry is highly regulated due the importance of guaranteeing the safety and efficacy of its products. However, when it comes to environmental footprint reducing the medicines, regulatory standards can also act as a barrier. For example, once the manufacturing process for a product has been approved as being compliant with GMP, companies cannot easily change that process 18. The regulatory uncertainty associated with developing a new manufacturing process which could reduce carbon emissions (e.g. continuous manufacturing), combined with the high upfront costs often required for this type of solutions, means that adoption across the pharmaceutical industry remains low<sup>19</sup>. Similarly, in terms of reducing waste, regulatory constraints and the lack of recycling infrastructure makes

<sup>&</sup>lt;sup>12</sup> University of Oxford (2018) New vaccines centre to protect UK from pandemic threats

<sup>&</sup>lt;sup>13</sup> Pharmaceutical Technology (2019) Vaccines Manufacturing Innovation Centre, Oxfordshire

<sup>&</sup>lt;sup>14</sup>Glover R E, Roberts A P, Singer A C, Kirchhelle C. (2022) Sale of UK's Vaccine Manufacturing and Innovation Centre, BMJ

<sup>&</sup>lt;sup>15</sup> The Guardian (2021) Plans to sell off UK vaccine development centre criticised by scientists

<sup>&</sup>lt;sup>16</sup>AstraZeneca (2023) AstraZeneca advances UK clean heat and energy efficiencies with £100m commitment

<sup>&</sup>lt;sup>17</sup> BioBase Europe Pilot Plant, Testimonials and Collaboration Results

<sup>&</sup>lt;sup>18</sup> Firth I., Hitch J., Henderson N., Cookson G. (2022) Supporting the Era of Green Pharmaceuticals in the UK, OHE Consulting Report

<sup>&</sup>lt;sup>19</sup> Zamecnick, A. (2022) Continuous manufacturing builds on hype but adoption remains gradual

adopting innovative solutions particularly complex for medicine manufacturers<sup>20</sup>.

For regulation to enable sustainability-related changes across the pharmaceutical industry, the assessment of medicines by the regulator could include sustainability as a criterion alongside quality, efficacy and safety<sup>21</sup>. However, this would require having an agreed framework which clearly articulates which sustainability-related factors should be measured and what data should be collected and reported; this could also help to facilitate collaboration across the sector<sup>20, 22, 23</sup>. Any such framework would also be dependent on having a common language for bioprocessing, similar to the minimum information standards developed for biosciences.

Recommendation: Encourage regulatory authorities to incentivise innovation in medicine manufacturing geared towards sustainability. The newly announced Regulatory Innovation Office could be well-placed to accelerate such innovations given engineering biology is one of its focus areas.

Recommendation: Establish industry-wide advanced recycling facilities to process recyclable waste. In parallel, map wider waste supply chains and its potential for feedstock across industries.

The role of common standards and metrics in supporting innovation in sustainable medicines manufacturing cannot be understated. There is a lack of unified methods, data systems and metrics for measuring and communicating environmental impact of the manufacturing process for medicines. For example, there is no single agreed global standard approach to measure GHG emissions at a unit or patient level which has led to fragmentation, with many companies and other stakeholders working independently towards their own sustainability targets<sup>2</sup>.

We need to understand what evidence is needed to adopt common standards and more sustainable

solutions, and move from voluntary to mandatory reporting of emissions and environmental impacts without stifling innovation or creating additional bureaucracy.

Building on the NHS supplier roadmap<sup>7</sup>, the UK could become a global leader in standardised sustainability metrics<sup>24</sup>. The UK could bring together expertise from the British Standards Institute, the Office for Life Science and the NHS, and use its global convening power to create an internationally recognised standard for measuring GHG emissions in medicine manufacturing<sup>2,18</sup>. This will be further explored in an upcoming Policy Impact Unit policy brief informed by research conducted within the VaxHubs and the FTHM hub.

Recommendation: UK government to provide leadership and coordination on sustainability measurements and standards, both in medicines manufacturing specifically, and related sectors more broadly.

#### Conclusions

There is an inextricable link between the health, resilience and security of the nation, economic prosperity, and achieving Net Zero and broader environmental objectives. The UK Industrial Strategy Green Paper sets out a vision for a 10-year plan which aims to deliver a more certain and stable policy environment to enable and drive economic growth in a way which is aligned with the country's Net Zero objectives.

We argue that focusing on sustainable medicines manufacturing will stimulate innovation and unlock economic growth in the life sciences sector, at the same time as reducing the environmental impact of the pharmaceutical industry and of the NHS. It will also enable the UK to crowd in investments from and facilitate exports to locations with similar net zero commitments.

We believe that the recommendations presented in this paper can enable the shift towards sustainable medicines manufacturing, whilst offering some key considerations that can be

<sup>&</sup>lt;sup>20</sup> <u>BioPhorum (2022) Environmental Sustainability Roadmap</u>

<sup>&</sup>lt;sup>21</sup> Niklasson, P., Carr, G. (2023) A New Regulatory Approach to Drive Sustainable Medicines

<sup>&</sup>lt;sup>22</sup> Marsh, K., Ganz, M.L., Hsu, J., Strandberg-Larsen, M., Gonzalez, R.P. & N. Lund (2016) Expanding Health Technology Assessments to Include

Effects on the Environment, Value in Health

<sup>&</sup>lt;sup>23</sup> BSI, The Design and Assessment of Sustainable Medicines

<sup>&</sup>lt;sup>24</sup> Medicines Manufacturing Industry Partnership. 2021. Fulfilling the potential identified in the Government's Life Sciences Vision: Where are we now – and where next?

applied to other sectors identified in the Industrial Strategy Green Paper. There is a clear window of opportunity during the development of the industrial strategy to leverage the expertise and momentum in the UK and contribute towards delivering the industrial strategy to its full potential.

### **Authors**

Anca Tacu: Policy Adviser, Policy Impact Unit at UCL STEAPP. Anca is currently working closely with researchers in VaxHub Sustainable and VaxHub Global, leading on policy engagement to facilitate and enhance the policy impact of their work. Anca's background includes a particular emphasis on the Sustainable Development Goals (SDGs) and she was the founding network manager of the Sustainable Development Solutions Network UK.

Dr Luís Lacerda: Policy Adviser, Policy Impact Unit at UCL STEaPP. Luís is currently working with researchers at the Future Targeted Healthcare Manufacturing Hub to facilitate the policy impact of their work, as well as leading PIU's engagement on Health Inequalities, and Science Diplomacy. At PIU Luís has also previously supported researchers developing artificial intelligence (AI) tools to improve surgery. He is now working with other colleagues to design policy engagement strategies that promote action to reduce the transmission of hospital airborne diseases. As a complement to his academic activity, he has led the Portuguese Association of Researchers and Students in the United Kingdom (PARSUK) to create the first Scientific Advisory Board in a Portuguese Embassy worldwide.

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