

Fulfilling the potential identified in the Government's Life Sciences Vision:

Where are we now - and where next?

January 2023



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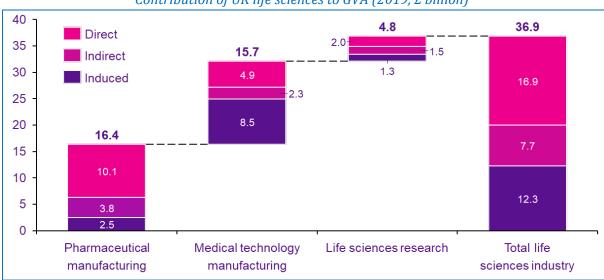
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Introduction

The UK Government's ambition for medicines manufacturing, as set out in the July 2021 Life Sciences Vision (LSV), is to create a globally competitive environment for Life Sciences manufacturing investment, building on the strengths of the UK's manufacturing research and development (R&D), our network of innovation centres, the manufacturing response to COVID-19 and delivery of the Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF)¹.

Medicines and medical technology manufacturing already represent the majority of the Life Sciences Sector's gross value added (GVA) contribution to the UK economy, delivering exports worth around £30bn annually and a combined total of £32.1 billion GVA in 2019, as shown below:



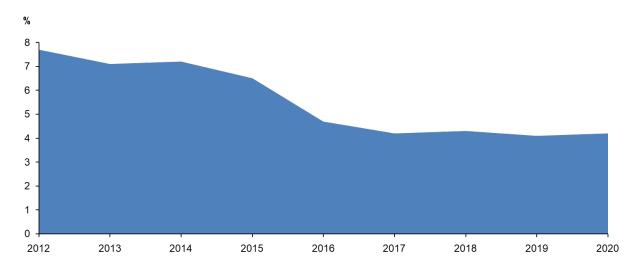
Contribution of UK life sciences to GVA (2019, £ billion)

Source: PwC analysis for the ABPI, FAME, Companies House

While acknowledging the UK's historic strength in Life Sciences innovation and medicines manufacturing, the LSV also recognised the significant reduction in medicines manufacturing capacity over the last 25 years. Since 2009, production volumes have fallen by 29% and over 7,000 jobs have been lost.ⁱⁱ



UK share of global pharmaceutical investment (2012-2020)



Source: PwC analysis of Evaluate Pharma and ONS data

Capital investment in the pharma sector is a critical leading indicator of future capability, capacity, and innovation to drive efficacy or support new manufacturing technologies. Investment in the UK has been in steady decline for a number of years but has fallen markedly over the last 5 years. The loss of these investments in new factories, manufacturing lines or new technologies in existing facilities will feed through in terms of job and export revenue losses for the next 10 to 20 years. Since 2010, the UK has fallen from 4th to 98th place in overall trade balance in pharmaceuticals.ⁱⁱⁱ

Reversing this decline and fulfilling the ambition set out in the LSV is the core focus of the Medicines Manufacturing Industry Partnership (MMIP), which represents the voice of medicines manufacturers in the UK. The MMIP was established jointly by the Government and the biopharmaceutical industry in 2014 to ensure that the UK is recognised by the global medicines industry as a world-class advanced centre for medicines manufacturing. It is now a recognised delivery mechanism for the LSV, working through the Life Science Council to maximise the UK impact of this critical component of the sector.

To fulfil the potential identified in the LSV, the MMIP has produced this white paper to report on progress towards delivery of the Government's ambition and to set out areas of focus over the coming months to build evidence-based recommendations for future growth, underpinned by clear objectives and defined success criteria.

Section 1. Where are we now?

The 2021 LSV set out specific focus areas for medicines manufacturing, all of which have seen progress:



'Build on the UK's Pandemic Manufacturing Infrastructure and deliver the Medicines and Diagnostics Transformation Fund (MDMTF)'

The benefit of having a UK-based, highly flexible medicines manufacturing capability was highlighted early in the Covid pandemic, not only through the contribution of Government-funded organisations such as the Vaccines Manufacturing Innovation Centre (VMIC), but also by companies such as Cobra (now CRL), OXB and Fujifilm.

To build on the foundation of next-generation infrastructure, the government announced a pilot medicines manufacturing capital grant facility – <u>the Medicines and Diagnostics Manufacturing Transformation Fund (MDMTF)</u> – during the 2020 single-year spending review.

The £20m investment was welcomed by the MMIP and attracted a volume of applications and cumulative potential investments far greater than could be matched by the grant facility. The pilot also highlighted opportunities to enhance the impact of future tranches of the fund by enlarging the funding window, starting the interaction with applicants earlier and increasing the scale of the investment opportunities. However, the size and duration of the single-year settlement presented challenges: a short application window; a lack of clarity over criteria for applications; and the overall scale of the fund limiting support to small-to-medium investment opportunities.

The subsequent £60m <u>Life Sciences Innovative Manufacturing Fund</u> (LSIMF), announced by Government in the March 2022 Budget, covers a 3-year spending period and has been designed to address many of the challenges inherent in the pilot. Early indicators show a highly positive response from prospective investors. The LSIMF was announced within an overall investment of £354m for life sciences manufacturing, and it will be important to understand how and when the remaining £294m will be allocated.

'Continue to support the UK's manufacturing innovation ecosystem'

The LSV also called for continued investment in medicines manufacturing innovation, using UK innovation infrastructure to drive industry growth. This builds on a strong base: over the last five-year funding period, Government has invested £374m in medicines and vaccines manufacturing innovation across industry and academia, which has also leveraged co-investment from industry, alongside other funders such as Scottish Government.

The <u>Industrial Strategy Challenge Fund (ISCF) Medicines Manufacturing Challenge</u> has been an important pillar of manufacturing innovation support. Aligning with the MMIP's <u>Technology and Innovation Roadmap</u> strategy, the ISCF has invested in innovative technologies with flexible, agile and scalable characteristics to transform manufacturing across medicines, vaccines and advanced therapies.

Many UK advanced medicine manufacturing centres are recognised as world-leading, including several within the <u>Catapult network</u>, which brings together nine leading technology and innovation centres spanning over 40 locations across the UK. Nearly £200m has been dedicated to the Cell and Gene Therapy Catapult Manufacturing Innovation Centres, collaborating with companies to help them accelerate delivery of life-changing advanced therapies to patients. CPI, part of the UK's High Value Manufacturing (HVM) Catapult, is a leading innovation centre supporting medicines manufacturing innovation for multiple modalities including small



molecules, biopharmaceuticals, and nucleic acid therapies (e.g., oligonucleotides, RNA) and nanotherapeutic drug delivery systems (e.g., LNP) for intracellular delivery. With over £175m innovation facilities in the Northeast of England and Scotland, CPI supports innovative SMEs and large corporates in accelerating transformative and disruptive innovations, through fee-for-service and grand challenge models. In 2022, CPI has established the UK's RNA Centre of Excellence and an RNA Training Academy. Through the HVM Catapult, CPI plays a key role in addressing supply chain and health resilience challenges in the UK. (See also Case Study 2 below)

The potential of the sector to generate global impact also continues to be an objective in the <u>UK</u> Research and Innovation (UKRI) 2022-2027 strategy.

'Support the formation and expansion of Manufacturing Clusters'

Innovative manufacturing centres support the formation of economic clusters, supporting the Government's levelling up agenda as well as creating skills hotspots within which companies can develop. Cluster development is being stimulated by investment in:

- the Cell and Gene Therapy Catapult Manufacturing Innovation Centres in Braintree, Edinburgh, and Stevenage (see also Case Study 1 below)
- the CPI National Biologics Manufacturing Centre and RNA Centre of Excellence in Darlington
- the CPI Medicines Manufacturing Innovation Centre in Renfrewshire
- the CPI National Formulation Centre in Sedgefield
- the former Vaccines Manufacturing Innovation Centre in Oxfordshire, now owned by Catalent Biotherapeutics
- a network of viral vector manufacturing hubs in Bristol, London, and Sheffield, funded by LifeArc, a self-financing medical research charity, and the Medical Research Council (MRC)

Case study 1: The Cell and Gene Therapy Manufacturing Cluster, Stevenage

Of notable success, and a potential playbook for other cluster areas to follow, is the cell and gene therapy manufacturing cluster centred in Stevenage, Hertfordshire, formed following the opening of the Cell and Gene Therapy Catapult Stevenage Manufacturing Innovation Centre (CGTC S-MIC). Approximately £70m has been invested in the facility, subsequently leveraged into over £1.3bn of direct investment in companies based there (eighteen times leverage). The success of the CGTC S-MIC has triggered coordinated investment by property developers, Herts Local Enterprise Partnership, therapy developers and supporting supply chain and logistics companies in the Stevenage area, based on the rapidly growing manufacturing innovation cluster.

'The UK's competitive tax environment'



The decision to increase the UK's headline corporation tax rate to 25% in April 2023 does put the UK at a competitive disadvantage in attracting medicines manufacturing when set against countries like Ireland offering a rate of 12.5% and Switzerland a rate of between 12%-21%. This decision enhances the need for the Government to utilise alternative and targeted fiscal levers which incentivise investment in high growth high productivity activities.

Optimising the competitiveness of the UK's R&D tax relief offer, as well as capital allowances environment will be key to delivering on the UK's medicines manufacturing ambitions. There have already been positive reforms in recent years to the RDEC scheme, though recent announcements to downgrade the SME Tax Credit represents a major blow to the ecosystem, which will harm the UK's ability to maintain its position at the forefront of biomedical innovation and capture future medicines manufacturing investment opportunities.

The introduction of the MDMTF and LSIMF have been welcome contributions to attracting medicines manufacturing investment to the UK. Whilst it is a positive start, the schemes are small in scale compared with similar schemes internationally meaning there is limited ability to influence major, multibillion pound investment decisions. Similarly, the attractiveness of total capital grant funding of £60m over three years within the LSIMF needs to be considered in the context of typical costs of a single new facility exceeding £100m.

Opportunities to enhance the fiscal environment are explored further in section 3 of this paper.

'Enhance the Manufacturing Skills Base'

Talent is critical for UK medicines manufacturing to drive innovation, attract investment, build health resilience, and boost productivity and competitiveness.

Whilst the long-term trend for UK medicines manufacturing and associated jobs is a downward one, recent data suggests improvement across a number of areas. The latest data show that 239,800 people are now employed in the core technical elements of the UK Life Sciences sector – an increase of 16,400 in two years. Latest Office for Life Sciences (OLS) analysis of the scale of UK Life Sciences manufacturing now shows 111,200 people employed across 2,010 sites across the UK in the manufacture of Life Science products, an increase of 16,400 in just two years. The MMIP has contributed to this success in the key areas of People, Modalities and Skills:

- New People: Seeded with £2m Business, Energy and Industrial Strategy (BEIS) investment over four years through the UKRI Medicines Manufacturing Challenge, the ongoing Advanced Therapies Apprenticeship Community (ATAC) has generated 232 apprentices, employed across 48 companies (>50% SME's) on 15 core advanced therapies programmes. The project has leveraged £15.1m additional industry investment and injected new and diverse talent into the sector, with a 92% retention rate against the national average of 52%. Current apprenticeships range from Science and Engineering through to Senior Leadership pathways. The demand for new apprentices this year is expected to exceed 150.
- *New modalities:* The MMIP was essential in driving the funding to support the Advanced Therapies Skills Training Network (ATSTN). Both on-line and in-person training is available with virtual reality training being particularly popular during Covid lockdown. The network has proved to be a huge success with the latest data indicating over 1,209 users across 177 organisations accessing 615 live content items from 30 industry recommended providers.



1,084 courses have been completed to date and 408 delegates have been through three National Training Centres.

• New skills: The 2021 Skills Demand Survey from the Cell and Gene Therapy Catapult shows significant workforce growth prospects for the sector. By 2026, cell and gene roles are predicted to increase by 117% over 2021, with bioprocessing roles set to rise by 151%. However, the same survey showed concerns about the attraction of quality, supply chain, logistics and process development roles. To address this, industry is identifying and developing new workforce skills from declining areas of life sciences manufacture such as process, chemical, and small molecule manufacturing, and from other industries where manufacturing is falling, such as food and drink, automotive, wholesale and retail. The Advanced Therapies Skills Training Network (ATSTN) is critical to supporting experienced people to develop and apply skills in new and different ways. Over recent years, the MMIP has been the conduit for sharing information between industry leaders on how to implement the apprenticeship levy to support skills growth. The Partnership welcomes the Government's commitment as part of the ongoing tax review to explore whether the operation of the apprenticeship levy is doing enough to incentivise businesses to invest in the right kinds of training, and this is considered further in Section 3 of this paper.

'Support the Transition to Net Zero'

Many current life sciences manufacturing processes have been developed to address historical priorities of safety, reliability, cost-effectiveness, and speed. The MMIP is working across the sector to make sustainability an equally fundamental consideration in six key areas:

- Metrics To create harmonised, transparent processes for measuring the carbon footprint of
 individual products, MMIP has launched a webinar series to share best practice on carbon
 reporting and life cycle analysis tools
- *Energy* The MMIP advocates for and showcases the adoption of sustainable, clean energy for our value stream, such as the Energize scheme. MMIP uses its networks to amplify UK UKRI green funding, and to encourage the development of a greener National Grid to aid 'Scope 3' (supplier) greenhouse gas emissions
- Sustainable Manufacturing Through its Technology & Innovation workstream, the MMIP showcases and advocates for the lowest feasible carbon footprint for manufacture through improved and novel industrial techniques
- Safe and Sustainable by design The MMIP vision is to improve the underpinning sustainability in all aspects of and is working to provide industry guidance on raw material sourcing best practices, starting with commonly used excipients. The Partnership is also supporting designers in identifying and selecting the most sustainable manufacturing solutions, with significant progress already being made for raw materials for new and existing products
- *Circular economy and optimized supply* The MMIP and trade associations are together engaging with stakeholders, including regulators, to solve two important challenges: the



provision of electronic patient information; and a viable nationwide recycling and take-back scheme for medicine packaging. Both schemes have the potential to reduce reliance on finite resources with their associated environmental footprints while maintaining patient safety

 Transport and Logistics The MMIP advocates across the sector for electric vehicle and lower energy consumption solutions to all aspects of the manufacturing supply chain, storage, and logistics processes



Case study 2: CPI Medicines Manufacturing Innovation Centre (MMIC), Glasgow

The Medicines Manufacturing Innovation Centre (MMIC) is a partnership between industry, academia, and government, led by deep tech innovation organisation CPI in the UK. The new centre, funded by Innovate UK through the Industrial Strategy Challenge Fund (ISCF), Scottish Enterprise, founding industry partners GSK & AZ, the University of Strathclyde and CPI, has set out a plan to demonstrate a productive and sustainable future for the industry by delivering:

- a facility that exemplifies best-in-class technology to be Net Zero in operation
- Grand Challenge programmes that have a positive environmental benefit
- thought leadership to drive net-zero awareness and adoption of innovative sustainable technology

The MMIC facility will operate a state-of-the-art, low carbon heating network, supplying heat and hot water 90% greener than a gas boiler, Photovoltaic Panels, offsetting 15K Kg of CO2 per annum, and an Intelligent Cleanroom Control System predicted to reduce energy consumption by up to 70% per year.

Each of the of three Grand Challenges currently being executed at MMIC has a substantial focus on process efficiency and elimination of waste:

- Grand Challenge 1 is focussed on the optimisation of tablet manufacture through continuous direct compression. It will result in less API waste in development through in-silico experimentation using the digital twin to reduce reliance on physical experimentation; a smaller manufacturing footprint requiring less infrastructure; and less material waste due to lower surface area of processing equipment and greater proportional batch size.
- Grand Challenge 2 is focussed on Clinical Trials Supply Efficiency. Currently around 50% of all clinical trial stock goes directly to waste (before it leaves the manufacturer).
 This programme will halve this waste and eventually remove it through a make-to-order approach reducing stock and waste.
- Grand Challenge 3 is focussed on optimisation of oligonucleotide manufacture. It will result in: 70% less solvent usage, significantly lowering the environmental impact; the elimination of single-use process support and reduction of reagent excesses, leading to 3-fold reduction in process mass intensity (in combination with reduced solvent use); the elimination or simplification of purification, realising significant saving in energy and buffer use; and, by introducing biocatalysis, will eliminate solvent requirement and improve atom efficiency through use of less complex raw materials.

The centre's strategic goal is to demonstrate a commitment to sustainability through all of its activities and behaviours. In this way, it will proactively support pharmaceutical industry environmental sustainability goals.

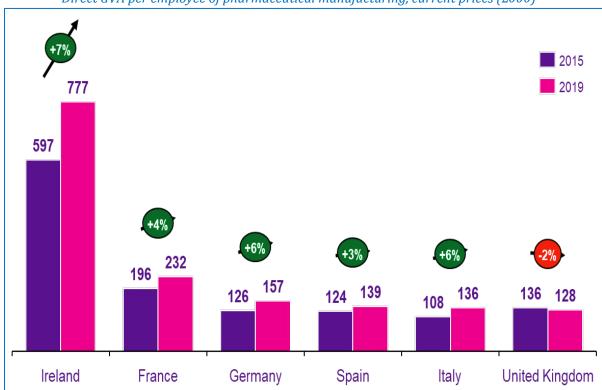


Section 2. Raising the level of ambition

While current progress is encouraging, the UK is far from the only nation to hold ambitions to grow its medicines and vaccines manufacturing sector. International competition to attract medicines and vaccines manufacturing has been growing in intensity for decades and has intensified further as a result of the Covid pandemic.

The University of Cambridge found that between 2009 and 2017, the GVA of the average UK pharmaceutical sector employee fell by 12.3%. This could be due to the faltering attractiveness of the UK for manufacturing which has seen a 31% fall in production volume since 2008. The interest of the UK for manufacturing which has seen a 31% fall in production volume since 2008.

Meanwhile, other countries in Europe have increased their productivity, as illustrated below. In 2015, the UK's pharmaceutical manufacturing sector had a higher GVA per employee than that of Germany, Spain, and Italy. In the subsequent years through to 2019, however, UK productivity has not kept pace with these other countries. Ireland has performed particularly strongly, linked to its investment environment.



Direct GVA per employee of pharmaceutical manufacturing, current prices (£000)vii

Source: PwC analysis for ABPI of data from BvD FAME database, ONS, Eurostat and CSO. Ireland's direct GVA per employee extrapolated from 2014 data based on GVA and employment growth rates, as 2014 is the last available year for which this indicator has data.



Further detail on the factors impacting the successes of Ireland and France is shown below:

Case Study 3: Ireland - a leading pharmaceutical manufacturing hub

Ireland is one of the leading locations for pharmaceutical production in Europe. As indicated by the Irish Pharmaceutical and Healthcare Agency (IPHA):

- Ireland's Life Sciences sector accounts for 39% of national exports (~€60 billion, CSO 2020), is the largest net exporter of pharmaceuticals in the European Union and the third largest exporter of pharmaceuticals globally
- Around 120 overseas companies have a manufacturing presence in the country, including nine of the largest ten pharmaceuticals companies globally
- Over the past decade, Ireland has seen around €10 billion invested in new biopharmaceutical production facilities thanks to its strong talent pool, regulatory environment, government support, and track record in clinical and academic R&D (particularly in nanotechnology and immunology).

The country also has a historically low corporation tax rate of <u>12.5%</u>.

Ireland's ability to attract foreign direct investment is supported by various initiatives that help promote the growth of its knowledge economy, such as the national network of technical training institutes developed in the 1970's.

Originally, Ireland's Life Sciences sector was largely limited to producing active ingredients for export for final processing and refinement.

Since the 1960s, however, it has grown to support more processing of final products and companies have now started to set up R&D centres and joint research projects with academic institutions.

Notable recent developments include:

- <u>Pfizer's</u> 2020 announcement of a €300m investment in Irish manufacturing sites
- <u>AstraZeneca's</u> 2021 announcement of plans to establish a \$360 million nextgeneration active pharmaceutical ingredient (API) manufacturing facility for small molecules
- Expansion of the National Institute of Bioprocessing Research and Training (NIBRT) facility in Dublin including two new training suites and additional training staff focused on cell and gene therapy funded by capital investment from the Industrial Development Agency (IDA) Ireland and the Government of Ireland, opening in first half of 2023



Case study 4: France's Healthcare Innovation 2030

France's <u>Healthcare Innovation 2030</u> strategy aims to shape the country into 'the leading European nation in innovation and sovereignty in healthcare'.

The plan calls for collaboration between academic institutions, R&D hubs, hospitals, healthcare workers, and Life Sciences manufacturers to 'innovate, invent, produce and sell' healthcare solutions. The strategy involves a significant funding target of €7 billion which will be used to:

- Strengthen France's biomedical research capacity and accelerate the innovation that will ultimately benefit patients.
- Enhance strategies for biotherapies and biomanufacturing, digital health, and emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats.
- Support France's role as the leading European country for clinical research by increasing the number of clinical trials and enrolled patients.
- Create a more predictable operating environment by supporting R&D and production investments, while improving budgetary objectives and regulation within the public health insurance system.
- Build out France's healthcare manufacturing footprint, including 123 supported projects as part of the Covid-19 Recovery Plan.

To realise its ambitions, France is changing its market access process, creating a system similar to that used in Germany. This involves providing market access immediately after approval by the French National Health Authority (the Haute Autorité de Santé) for all products assessed to have an 'improvement in actual medical benefit'.

Additionally, the 2030 strategy outlines plans to establish an Agency for Healthcare Innovation, which will be responsible for coordinating healthcare innovation in France and 'guaranteeing the vision and the roadmap of the state'.

France may have already started to see the fruits of its strategy, with Pfizer recently announcing plans to make a €520 million investment in the country over the next five years to scale the production of its antiviral COVID-19 pill. This decision was informed by continued dialogue between Government and industry, who have worked collaboratively for several years on conditions to improve the attractiveness of the French life sciences sector.

Overall, however, the success of Healthcare Innovation 2030 will rest on numerous Life Sciences stakeholders working together to deliver a sustainable and inclusive ecosystem.



Against this intensively competitive international backdrop, the level of UK ambition needs to be raised in the following areas to maximise the opportunities for UK-based smaller companies and drive inward investment from multinationals:

A culture of integrated commitment: Making the UK the favoured place to do business requires competing in all areas, creating, and demonstrating a culture of integrated commitment to leading in the medicines manufacturing landscape. This will include building understanding across Government departments that gaining strength in medicines manufacturing is a long-term ambition for any country and requires consistency in policy over time to maintain flexibility and resilience.

Attraction of talent: The rapid expansion of the medicines manufacturing sector and the evolving skillset required to support future medicines manufacturing will require targeted commitment to attract key talent into the sector. This includes:

- A change of dialogue with our education system around the breadth of skills required to support a growing and successful sector, with a focus not only on science, technology, engineering, and mathematics (STEM) but on digital, core business and leadership skills
- A pathway to leverage transferrable skillsets and move talent from declining sectors much more rapidly to avoid loss of expertise and potential
- A commitment to increasing diversity and inclusion, through attracting talent from outside of the UK and positive reinforcement of UK medicines manufacturing as an area where people can have a long and varied career path

Customer experience: A recent MMIP survey of current and potential life sciences manufacturing investors returned a consistent view from companies of all sizes that, while individual UK Government departments are effective and welcoming, there is no holistic approach to growing indigenous companies or attracting multinationals. Significant waste is incurred by companies looking to manage this aspect of conducting UK operations, which in a globally competitive environment puts the UK at a disadvantage. The clear remits within OLS and the Department for Industry and Trade (DIT) to engage companies through strategic liaison contacts are helpful. However, these would benefit further from the development of joint processes, a single 'shop window' point of contact for companies to deal with across all government departments, and active targeting and pursuit of opportunities for inward investment by multinationals.

Regulatory environment: The UK Medicines and Healthcare Regulatory Agency (MHRA) led much of the world in vaccines' approval during the Covid pandemic. This outstanding performance now needs to be built on with world-class innovation in working with industry engaging in the development of innovative therapies, whilst at the same time driving competitiveness with other global regulators to meet existing market needs. As the MHRA develops its structure, new capabilities and requirements will be needed to continue to drive innovation in the UK.

In a global environment, the Regulator and its alignment to global standards are of critical importance. How the body acts and deals with both routine and new innovations has significant impact on the level of resources required by companies to engage in a manufacturing ecosystem. The recent, welcome acceptance of the MHRA as a member of the International Committee of Harmonisation represents an important step in balancing local innovation with global alignment.



Section 3. Where next?

Over the next six months, the MMIP will gather further evidence to build on progress to create detailed recommendations to Government on a 10-year ambitious, unified UK medicines and vaccines manufacturing strategy, complete with clearly defined desired outcomes and success metrics. This will aim to close the current gaps in delivery of the manufacturing focus areas identified in the Life Sciences Vision, and to secure the UK's future medicines manufacturing resilience, innovation, and competitiveness. Recommendations will be developed with the ambition of working with Government to deliver the following components of a world-leading medicines manufacturing ecosystem:

1. A globally competitive fiscal environment for Life Sciences investment

While there are many factors that influence investment decisions in Life Sciences manufacturing, the tax and fiscal environment of a country is often a key factor in determining where to locate internationally mobile investments. The MMIP has conducted early analysis on the areas which would have the greatest impact in enhancing the UK's attractiveness to inward investors and companies looking to scale up. These will build on the following proposals:

Optimising Research and Development tax reliefs: The announced increase to the RDEC rate from 13% to 20% during the 2022 Autumn Statement represents an extremely positive step which brings the generosity of the scheme in line with other international competitors. However, the simultaneous reduction to the SME relief rate, effectively halving the value for loss-making SMEs, is extremely counterproductive. Emerging biopharma companies (without larger company involvement) are responsible for growing share of molecules in the R&D pipelineviii. By cutting the incentives and support for SMEs to base themselves in the UK, the Government is severely reducing the opportunity to secure future manufacturing investments. The UK's unique Life Sciences ecosystem relies on the strength and interplay of large and small companies, including support for scaleup and manufacturing. Regressive measures within one scheme could therefore dampen potential gains which could be achieved from progressive changes to the other. We recognise that the Government is currently consulting on its review of R&D tax reliefs.

Including capital as eligible expenditure as part of research and development tax credits: Industry considers that recognition of capital within the R&D tax system should be a key priority as the government explores further changes to the RDEC and SME Credit schemes. Across the economy, capital investment accounts for 8.3% (roughly £2.1bn) of all business R&D expenditure in 2019, up from 5.5% in 2010½. In Life Sciences specifically, capital investment is key to a broad range of R&D activity, for example supporting the manufacture of clinical trial medicines, supporting process innovation and the development of efficient and climate-friendly manufacturing practices. The inclusion of capital expenditure would also address a significant flaw in the current fiscal offer, where tax benefits create inconsistent treatment between loss-making firms and profit-making firms, ultimately disincentivising R&D capital expenditure and R&D projects more generally. As a major Life Sciences hub, the UK attracts major R&D investment from companies of all sizes, with many operating as loss-making in the UK but profit-making globally, or as young companies which are not yet profitable. If the UK wants to attract significant capital investment, and the associated job creation and economic output, it must address this current shortcoming in the system.

Apprenticeship Levy: The Levy has had a significant effect in addressing the gaps demonstrated by the latest ABPI Skills Survey, which identified significant concerns about the availability of



digital, data and engineering skills. Industry considers that this impact can be enhanced by making the Levy more flexible to incorporate more of the roles which are needed to enable a future-focused, end-to-end manufacturing and supply chain in the UK, including consideration of a new funding model for higher education.

A competitive Capital Allowances regime: The Super-Deduction, announced by the Government to stimulate investment during the pandemic, represented a highly competitive and internationally unique capital allowances offer. Although recent analysis has shown limited impact so far, it is worth reiterating that major capital investments in Life Sciences manufacturing require significant lead-in time, and as such the potential stimulus effect of such a scheme is unlikely to have translated into tangible investment decisions yet. The MMIP is working across the sector to develop proposals on what an attractive capital allowances regime would look like in future following the conclusion of the Super-Deduction. As capital allowances are only applicable to profit-making in the UK, it is critical that any future regime is accompanied by the inclusion of capital as eligible expenditure as part of R&D tax credits.

Building on the success of the MDMTF and LSIMF: Recognising the long lead-in times and decision-making processes required for internationally mobile investments, MMIP members will build the case for a commitment in principle from Government to continue capital support for Life Sciences manufacturing beyond the current spending review period, coupling an effective grant facility with an attractive fiscal operating environment to further enhance UK attractiveness.

2. A holistic approach to growing the manufacturing skills base

The evolving and growing skills base required to make the UK Life Sciences manufacturing sector successful requires a more organised approach to attract diverse talent in areas of current and future demand. MMIP stakeholders also consistently ask how the Partnership can support them in growing both the specialist and non-specialist workforce needed to make the whole system work. To address these points, the MMIP will bring forward points for discussion with government in the following areas:

Encouraging and enabling transferrable skills from outside the sector for individuals in mid-late stage of career to increase diversity in the current workforce. This will enable the faster build of a sustainable skills development ecosystem and talent pools to minimise capability-related barriers to growth ensuring we attract key elements of the supply chain in the UK

Funding and incentivisation to support skills development across our education landscape, from pupils and staff within schools through to academic institutions, in areas that have been identified as a gap for now and in the future such as digital and engineering, as well as broader business and leadership skills

The implementation of skills hubs in potential cluster localities to support skills and talent development collaboration across medicines manufacturing organisations and the education landscape, with the aim of increasing diversity in the future workforce

Ensuring the sector has access to the tools and information it needs to recruit, reskill, and develop employees in specialist and non-specialist roles

The MMIP will also continue to explore and champion innovative approaches to skills development that sustainably build the necessary infrastructure to support the attraction, development, and deployment of talent into the sector.



3. A resilient and stable manufacturing base to supply UK and global needs

Medicines manufacturing processes depend on a complex global network of suppliers competing for raw materials and equipment. Trade bottlenecks such as export restrictions, regulatory barriers, tariffs, and customs red tape add uncertainty, cost and delay to both manufacturing and patient access. Current geopolitical instability presents supply chain risks that will lead companies to want to re-shore investments in 'safe,' trade-networked and legally secure countries such as the UK.

To create competitive advantage for the UK in this environment, MMIP members will bring forward policy recommendations to Government to:

- Reduce export restrictions
- Strengthen regulatory cooperation, mutual recognition, and capacity building
- Improve trade facilitation and eliminate tariffs
- Develop a global reputation for providing the best governmental support to potential inward investors

4. Global leadership in medicines manufacturing sustainability goals and metrics

There is currently an opportunity for the UK to lead global development and metrics of medicines manufacturing sustainability goals for both the NHS and companies. The MMIP will identify areas where current processes could be improved to deliver this advantage, for example as the NHS works towards implementing its supplier roadmap, and through greater alignment across countries and global company operations.

The UK has the potential to develop sustainable medicines design tools to deliver new medicines, and to use these tools to direct innovative technology and supply chain solutions to address areas of highest environmental impact. MMIP will evidence the areas of highest potential and explore the policy interventions needed to enable the NHS primary care network to develop more robust and integrated medicines' disposal and recycling networks, such as, for example, a national inhaler recycling program to address $\sim 4\%$ of the NHS's greenhouse gas emissions.

5. Transformed medicines manufacturing through innovation

As indicated in Section 1 of this paper, with the support of the MMIP the Industrial Strategy Challenge Fund Medicines Manufacturing Challenge has already made significant progress in establishing UK medicines manufacturing innovation as a foundation for economic growth and health resilience, as demonstrated during the Covid-19 pandemic. Aligning with MMIP's Technology and Innovation Roadmap and strategy, the MMIP believes that continued investment in technology and innovation is a critical pillar of this vision. MMIP is very supportive of the proposal for further support for technologies that will transform manufacturing across medicines, vaccines and advanced therapies, through flexible, agile and scalable approaches.



Reflecting the priorities embedded in the MMIP Technology and Innovation Roadmap, this type of support would provide the UK with a competitive advantage in medicines manufacturing, maximise economic impact and underpin healthcare resilience:

- Driving economic growth to enable SME scale-up especially for SME's developing novel therapies and manufacturing platforms
- Strengthening UK healthcare resilience for future pandemic response and delivering disruptive innovation to improve routine patient care in drug delivery
- Return on Investment leverage the maximum future industry co-investment possible and maximise the UK USP by utilising existing innovation infrastructure across the UK

Transforming Medicines Manufacturing will be developed to concentrate investment in three areas:

- Dramatically improving the speed of development and productivity of medicines manufacturing processes, in particular innovative technologies for manufacturing nucleic acid-based medicines, such as automation and predictive sciences
- Establishing robust, agile, and sustainable medicines supply chains
- Innovative, patient-centric formulation and delivery technologies, with specific support for advanced vaccine formulation and next generation intracellular drug delivery formulations

6. Growth across the end-to-end medicine supply chain and the broader medicines manufacturing ecosystem

As described above, medicines manufacturing processes depend on a complex global network of suppliers for raw materials and equipment, such as fine chemical, equipment, and supplies. To address this, the MMIP will set out requirements to grow a vibrant UK network for vendors, offering a wide range of contracted manufacturing capacity to address specific UK and global supply limitations. Complicating the landscape is the fact that no single body or organisation represents the whole end-to-end process between manufacturing and supply chains, with the result that these elements of the ecosystem remain largely segregated.

The MMIP will therefore also explore how the Partnership could become a catalyst to bring together different sections of the end-to-end medicines supply chain to drive growth, developing a collective vision from a much wider stakeholder group which could include biopharmaceutical companies of all sizes, generic manufacturers, contract manufacturing organisations and medical device manufacturers.

Conclusion

Building on the progress made since the publication of the LSV, the MMIP believes that now is the time to expand the UK's ambition to grow this key sector and develop a long-term vision to deliver a stable, flexible, resilient medicines manufacturing environment fit for the future needs.

Action on the six themes outlined will enable the UK to consolidate recent significant advances in development of innovative new treatments, such as cell and gene therapies, oligonucleotides, and



viral vectors, and to become a global centre of excellence for technology development and innovation to UK patients.

Delivering these benefits will require a multi-dimensional effort that will need to be sustained over the long term. The costs and complexities of moving operations mean that capital investments in manufacturing facilities are significant multi-year commitments, often lasting a decade or more.

The MMIP looks forward to working with Government to bring forward further detail on the themes set out in this white paper to deliver the potential identified for the economy, industry, and patients, both at home and across the world.



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