The fiscal benefits of establishing and retaining medicine manufacture in the UK

Introduction

This paper highlights the factors which combine to make the UK one of the most competitive tax and fiscal frameworks globally for medicines manufacture and in the top tier of the G20. This is not widely recognised here in the UK or overseas and the purpose of this paper is to start to address this lack of awareness by setting out the UK proposition in a simple summary.

While the UK demonstrates its commitment to remaining internationally competitive through the tax environment for innovation, it is important that additional steps are taken to remain competitive. This includes implementing fiscal policies to secure new medicines manufacturing growth sectors such as cell and gene therapies.

This guide is relevant to all companies, UK or international, involved in the development and manufacture of medicinal products including pharma, biotech and CDMO (Contract Development & Manufacturing Organisation) service businesses. It covers all stages of development from pre-clinical, through clinical to commercial and all product types from small molecules to biopharmaceuticals and advanced therapies.

In summary, not only should a UK company which develops and manufactures in the UK enjoy a long term effective tax rate of 11%-13% it will receive substantial R&D tax credits along the way of up to 33p/£.

Enterprises undertaking development and manufacture in the UK could achieve an effective tax rate ('ETR') of 11% – 13%. This is delivered through:

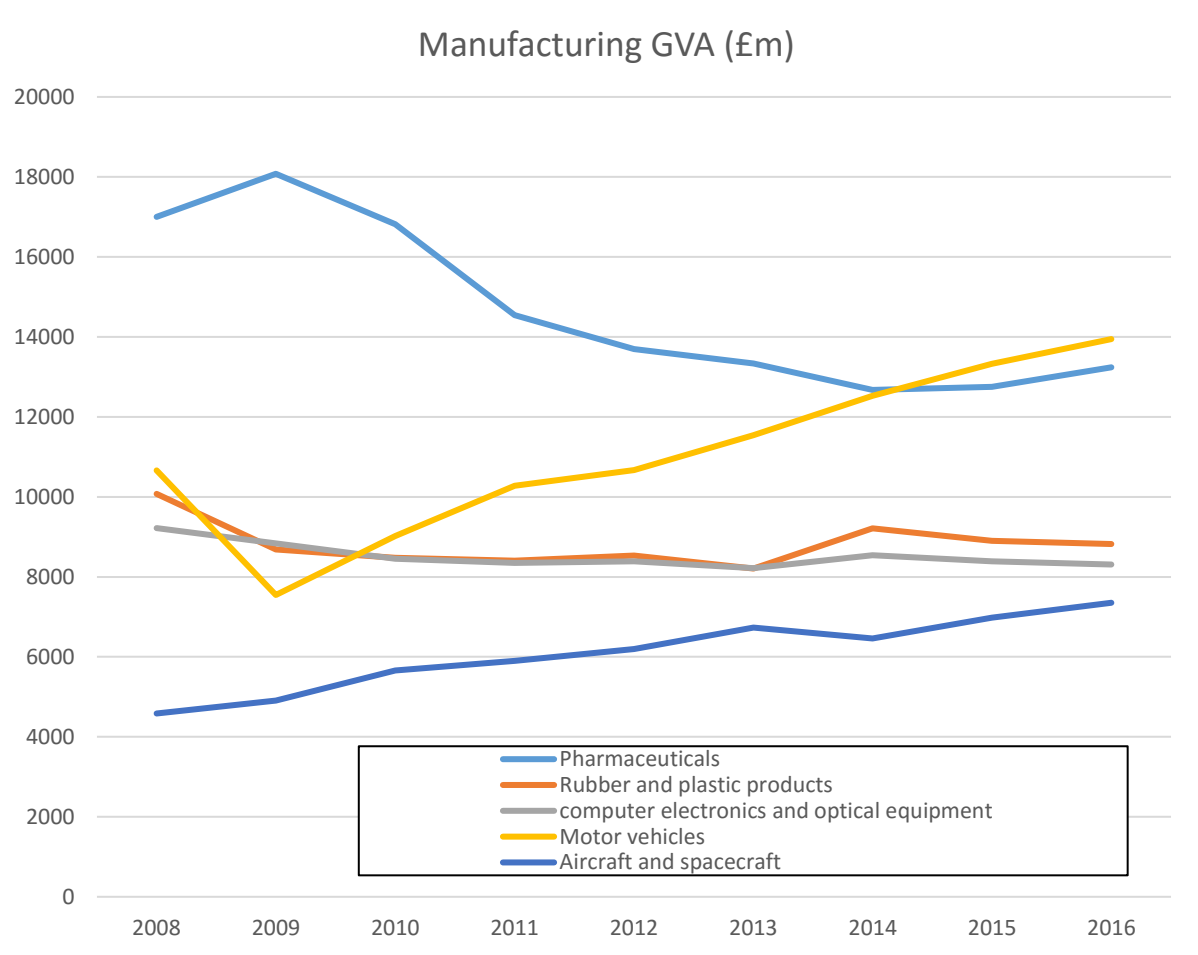
- 17% headline corporation tax rate from 2020
- Patent box tax rate at 10% on profits attributable to patents
- R&D relief 25p-33p/£ for SMEs and 11p/£ for large businesses
- Tax losses- These can be carried forward indefinitely and offset against future profits
- Clinical manufacturing expenditure is normally eligible for the R&D incentive either at 33p/£ or 11p/£

Background

Whilst recognised as a leading centre for medicinal research and development, the UK has been largely overlooked as a medicine manufacturing location. This is illustrated by the situation with biopharmaceuticals which has seen the most growth in the medicines sector in the past 20 years and transformed the pharmaceutical industry. The top ten prescribed biopharmaceuticals globally now have combined annual revenues in excess of £50bn and biopharmaceuticals now represent 7 of the top 10 drugs. This represents a major manufacturing demand and value but despite the UK having been engaged in biopharmaceutical research and development, none of these products are made in the UK. Without action to present the most competitive fiscal offer to globally mobile inward

investors, the UK risks missing out on the potential benefits of manufacturing the next generation of medicines, cell and gene therapies. Countries around the world will implement measures to capture a larger share of a cell and gene therapy market, the value of which is estimated to be of between $14-21bn per year by 2025.

GVA (gross value add) is the measure of the value of goods and services produced in an area, industry or sector measured as output less immediate consumption. The GVA deriving from medicine manufacturing is in decline, a concern which led to the formation of the MMIP (Medicines Manufacturing Industry Partnership) in 2014. The failure of the UK to capture a significant part of the biopharmaceutical manufacturing opportunity is a key factor behind this decline as manufacture of older small molecule drug products has not been replaced by products from this new growth sector. Interviews with industry leaders have confirmed that the lack of a clearly articulated UK fiscal proposition has been a key factor behind this failure.



This graph shows the decline in the contribution of medicines manufacturing to the GVA of the UK economy. In 2009 UK medicines manufacturing provided £16bn GVA to the UK economy. By 2014 this had declined to £11bn GVA, a 30% reduction. This is measured using the Chained Volume Measure approach in constant prices. Source: https://www.ons.gov.uk/economy/grossdomesticproductgdp/datasets/ukgdpolowlevelaggregates accessed 24.02.17

For more information, please visit abpi.org.uk/our-work/MMIP or email MMIP@bioindustry.org.uk.

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The UK has created a very favourable tax environment for innovation and commercialisation. In the past, UK companies would locate elements of the supply chain across two or more territories in order to access more competitive tax rates and incentives.

The UK tax landscape has changed in recent years to present a much more compelling case for retaining the entire supply chain from development through to manufacture in the UK. The tax benefits of this are set out below with further efficiency being made possible through the lower cost of compliance with reduced cross border transactions and product flow.

The UK's R&D tax credit system is highly beneficial at all stages of pre-clinical and clinical development and manufacturing including the manufacturing of clinical materials. This benefit applies whether the work is done by biotech SMEs, larger companies or the CDMO service sector and can include CDMOs working for overseas customers. The wide application of this benefit is not fully recognised yet can profoundly impact the high cost of clinical development. There is also a possibility of extending these tax benefits to other activities in the manufacturing envelope. The Patent Box then offers significant value for commercial manufacturing.

"The UK is a much better place financially for medicine manufacturing than is generally believed and should be recognised as in the top tier globally." – Richard Turner, FTI Consulting

Exploring the medicines manufacturing financial landscape

- **Tax rates** – The current corporation tax rate is 20% regardless of the size of the business and will reduce to 17% by 2020 with the Government committed to maintaining a very competitive rate long term. . This is one of the lowest rates of tax among the developed economies, such as France (33%), Germany (30%-33%), US (35%-40%), Japan (30%), Ireland (12.5% trading income/25% non-trading income), Switzerland (10%-25%).
- **Patent box** – Tax on profits attributable to the use of qualifying patented technologies is reduced to 10%. Enterprises undertaking all development and manufacture in the UK, might therefore expect a long term effective tax rate in the region of 11%-13%.
- **R&D relief** – Available to all companies undertaking qualifying R&D activities including manufacturing for clinical development
    - For SMEs (less than 500 employees and either Annual turnover <€100m or Balance sheet <€86m) the relief ranges between 25p-33p/£ on qualifying expenditure and either reduces the tax liability or is repaid as a credit. Qualifying expenditure includes work contracted out to third parties.
    - Where a group exceeds the SME criteria, it can claim a taxable credit (RDEC) of 11p/£ of qualifying expenditure. For Large Enterprises (non SMEs), qualifying expenditure does not include work contracted to 3rd parties or overseas connected companies.

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- A CDMO engagement in clinical manufacturing services should be eligible for the RDEC which will deliver a saving of 11% on its labour, consumables and a proportion of running costs.

- **Clinical manufacture** – With planning, a significant element of clinical manufacturing expenditure should attract the R&D incentive either at 33p/£ or 11p/£. This would include labour cost, materials and attributable utility costs. If this activity were undertaken in-house but outside the UK, not only would these incentives no longer be available for large enterprises, it could impact the amount of Patent Box relief that is subsequently available.
- **Tax losses** – These can be carried forward indefinitely and offset against future profits and therefore shelter taxable income arising after product launch.

Conclusions

The paper illustrates that the UK has a very competitive tax rate which is a positive benefit for companies considering long-term manufacture of medicinal products. Furthermore the R&D tax credit system offers substantial benefit for large and small UK companies developing and manufacturing medicinal products in pre-clinical and clinical development. When combined, the UKs overall fiscal proposition places the country in the top tier globally for rewarding medicines manufacture.

However, the UK must ensure it remains competitive if the UK economy is to benefit by securing new medicines manufacturing growth sectors such as cell and gene therapies.

The MMIP is committed to working across the sector and with Government, to identify and seek additional changes to the UKs fiscal system that can further encourage companies to establish and/or expand medicine manufacturing.

About this paper

As part of the Medicines Manufacturing Industry Partnership's work on the business environment, it has sought to improve its understanding of the current fiscal proposition in the UK for medicine manufacturing investments and activity. This work was led by Stephen Taylor (SCT Biotech and formerly Fujifilm) and Richard Turner (FTI Consulting). This paper is a headline summary of this tax framework in layman's terms. It illustrates the substantial benefits already available to businesses. This links to the work of the BioIndustry Association Finance and Taxation Advisory Committee (FTAC) which creates policies and initiatives to create a supportive financial environment for UK bioscience companies.

This summary is intended to be disseminated widely so we would welcome your help in sharing within your own organisations. This guide highlights the current financial landscape, but should not be considered as financial advice.