Life Sciences Sector Report

This report covers Life Sciences, Medical Devices and Pharmaceuticals.

1. This is a report for the House of Commons Committee on Exiting the European Union following the motion passed at the Opposition Day debate on 1 November, which called on the Government to provide the Committee with impact assessments arising from the sectoral analysis it has conducted with regards to the list of 58 sectors referred to in the answer of 26 June 2017 to Question 239.

2. As the government has already made clear, it is not the case that 58 sectoral impact assessments exist. The Government's sectoral analysis is a wide mix of qualitative and quantitative analysis contained in a range of documents developed at different times since the referendum. This report brings together information about the sector in a way that is accessible and informative. Some reports aggregate some sectors in order to avoid repetition of information or because of the strong interlinkages between some of these sectors.

3. This report covers: a description of the sector, the current EU regulatory regime, existing frameworks for how trade is facilitated between countries in this sector, and sector views. It does not contain commercially-, market- or negotiation-sensitive information.

Description of sector

4. This Sectoral Report reflects 3 of the 58 listed sectors; 'Pharmaceuticals', 'Medical Devices' and 'Life Sciences'.

5. Life Sciences refers to the application of biology and technology to health improvement, including biopharmaceuticals, medical technology, genomics, diagnostics and digital health.

5. This report does not cover all health related issues; issues relating to animal and plant health are included in the Sectoral Report 'Agriculture, Animal and Plant Health, Food and Drink Manufacturing (including Catering: Retail and Wholesale)'. Other health related issues are covered in the 'Medical Services and Social Care' Sector Report.

6. ONS data on the pharmaceutical and medical technology (Med Tech) sectors is based on Standard Industry Classification (SIC) codes (specifically SIC 2007). This is the main classification system used for EU industrial statistics, however, the only categories for health Life Science industries within the classification are those for companies whose primary activity is manufacturing (e.g. pharmaceuticals and medical devices) or those whose primary activity is research in biotechnology (which includes non-health biotechnology). The classification system, and therefore ONS data, does not adequately reflect the size and shape of the UK Life Sciences sector as a whole, for example, the following sub-sectors cannot be separately identified and included:

i. Companies offering specialised Life Science Services, such as those involved in drug development and management of clinical trials, to pharmaceutical and medical technology companies (this is a growing area as biopharma and Med Tech companies are increasing outsourcing research and development (R&D) activities);

ii. Companies offering specialist non-Research and Development (R&D) services such as regulatory, supplies and analytical services;

iii. Companies whose primary activity is R&D but not in biotechnology – as biotechnology is only part of medical science, this includes many pharmaceutical research companies as well as those developing medical technology products;

iv. Companies developing products and services in digital health;

v. Companies manufacturing Life Science products that are classified with non-Life Science products e.g. laboratory equipment and reagents; and

vi. Manufacturing companies which have Life Science activities but are classified in other categories due to their other products.

7. To get a richer picture of the Life Sciences sector in the UK and also to identify individual companies, the Office for Life Sciences (OLS) commissions a bespoke database to collect information on UK Health Life Science companies and publishes a summary in the annual 'Strength and Opportunities' (S&O) report.[1]

8. The database uses information in the public domain (e.g. websites) coupled with financial and employment data obtained under licence from commercial sources and so uses a completely different methodology than ONS statistics which are derived from responses to ONS surveys. Therefore, there are some large discrepancies between the two sets of data. For example, ONS estimates[2] that there are 90,000 jobs in pharmaceutical and Med Tech manufacturing companies in 2016, whilst the S&O report estimates that there are 233,000 jobs in the health Life Science sector as a whole. The database only provides figures on numbers of companies, employees and turnover not GVA or exports.

9. The UK has one of the strongest and most productive Life Sciences industries in the world. The Life Sciences industry generated approximately £20.7 billion turnover (2015) with 90,000 jobs (2016).[3]

[1] Bioscience and health technology database: annual report 2016, Gov.uk, April 2016

[2] ONS data from Workforce Jobs (2016) and the Annual Business Survey (2016)
[3] ONS Production and Services Turnover Survey (2016)

Table 1: Life Sciences Data – Headline Figures

	ONS data[2, 4]		Life Science Database[1]
Employment			
Life Sciences	**90,000**	**Life Sciences**	**233,000**
Pharmaceuticals	*40,000*	*Biopharmaceuticals*	*113,000*
Medtech	*50,000*	*Medtech*	*120,000*
Turnover			
Life Sciences	**£20.7bn**	**Life Sciences**	**£63.5bn**
Pharmaceuticals	*£14.0bn*	*Biopharmaceuticals*	*£41.9bn*
Medtech	*£6.7bn*	*Medtech*	*£21.6bn*

GVA[5]	Current Prices	As a percentage of Manufacturing GVA	As a percentage of Total Economy GVA
Life Sciences	**16,697**	**8.9%**	**0.9%**
Pharmaceuticals	*12,813*	*7.7%*	*0.7%*
Medtech	*3,884*	*1.2%*	*0.2%*

[4] ONS Production and Services Turnover Survey (2016)
[5] OLS analysis of ONS National Accounts data (2016) and the ONS Annual Business survey (2016)

Trade	Value of trade (£m)	As a % of UK total	EU exports as % of UK total	Rest of world exports as % of UK total
Exports				
Life Sciences[6]	**30,724**	**5.6%**	**48%**	**52%**
Pharmaceuticals	*25,828*	*4.7%*	*47%*	*53%*
Medtech	*4,869*	*0.9%*	*55%*	*45%*
Imports				
Life Sciences	**35,321**	**6.0%**	**74%**	**26%**
Pharmaceuticals	*28,656*	*4.9%*	*76%*	*24%*
Medtech	*6,662*	*1.1%*	*64%*	*36%*

10. We have provided both ONS and S&O data where possible. As described above S&O data allows a more granular analysis of the broader sector data provided by ONS.[7]

Key features of the sector

11. In 2016, manufacture of basic pharmaceuticals accounted for 74% of total Life Science turnover and 44% of employment.

[6] ONS Balance of Payments data (2016)

[7] ONS data classified by SIC code only captures the output of the Life Science manufacturing sector and not Life Sciences R&D output
When making comparisons between the Life Sciences manufacturing sector and other sectors in the Economy, we use ONS data available under the following Standard Industry Classification (SIC) codes:

i.SIC 21; Manufacture of basic pharmaceutical products
This includes both
I.21.1 Manufacture of Basic Pharmaceuticals
II.21.2 Manufacture of Pharmaceutical Products and Preparations
ii. SIC 26.6; Manufacture of irradiation, electromedical and electrotherapeutic equipment
iii.SIC 32.5; Manufacture of medical and dental instruments and supplies

Table 2: OLS calculations based on ONS data on Turnover and Employment in the Life Science Manufacturing sector by SIC code

	Turnover[3]	Employment[2]
Source	Annual Business Survey	Workforce Jobs
SIC 21: Manufacture of basic pharmaceuticals	£18.4bn	40,000
SIC 26.6: Manufacture of irradiation, electromedical and electrotherapeutic equipment.	£1.3bn	5,000
SIC 32.5: Manufacture of medical and dental instruments and supplies	£5.2bn	45,000
Total Life Sciences	£24.9bn	90,000

12. In 2016, the Life Science sector had 5,142 companies, generating approximately £63.5 billion in turnover with 233,000 jobs. The database shows that the sector is also growing, with 6.2 per cent revenue growth and 2.5 per cent employment growth from 2015 to 2016.

13. The Life Sciences database[6] shows that in 2015, the Life Sciences sector had 5,142 companies generating approx. £63.5 billion turnover. This covers both core Life Sciences companies and the service and supply chain. This breaks down into:

    - biopharmaceutical sector and service and supply chain 1,857 companies, generating £41.9 billion turnover; employing 113,000 workers;
    - The biopharmaceutical sector is largely dominated by large, global companies. There is a diverse size range of core biopharmaceutical companies with a lot of micro companies: 43 per cent have less than 5 employees and 10 per cent have over 250 people;
    - Medical technology sector and service and supply chain 3,463 companies, generating £21 billion turnover; employing 120,000 workers; and
    - 98 per cent of UK Med Tech firms are SME's, 42 per cent are micro- companies with less than 5 employees and only 2 per cent have over 250 employees.

14. From these firms, we can identify that:

    - The digital health sector (a sub-sector of Med Tech) has an estimated turnover of £1bn and employs approximately 10,000 workers.
    - Genomics related activities in Life Science companies generate an estimated turnover of £1bn, and employs 1,800 workers.

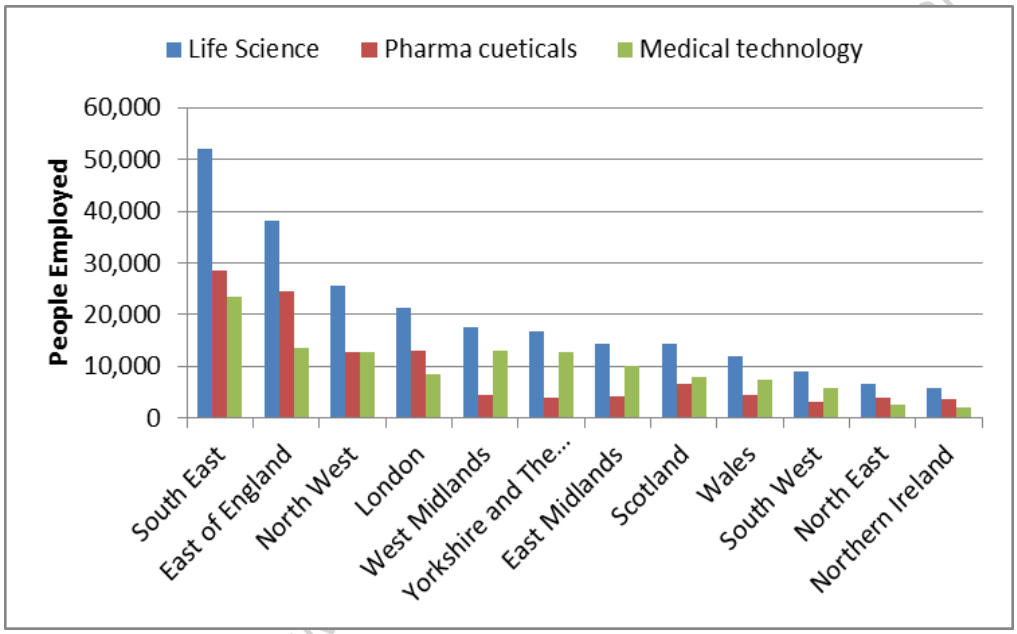
Devolved Administrations and regional breakdown

15. The Life Sciences sector is a significant sector in the devolved administrations. Of the 233,400 employed by the sector across the UK, 6 per cent work in Scotland, 5 per cent in Wales and 2 per cent in Northern Ireland. Turnover from the sector in Scotland in 2016 was £2.8 billion, in Wales it was £1.9 billion and for Northern Ireland it was £812 million.[7]

16. It is not possible to show the ONS Workforce Jobs or National Accounts data by region. However, the Life Science database does allow us to see the geographical split of employment and Turnover in the UK (see Figures 1 and 2).

17. Whilst the biopharmaceutical core is focused in the South East (28,000) and East of England (24,000); the medical technology sectors are more evenly spread throughout the UK.

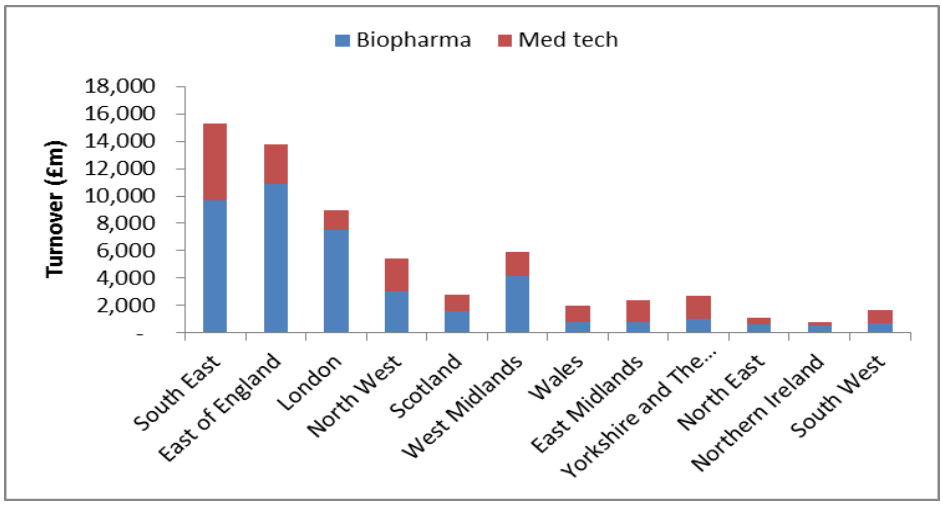
Figure 1: Life Sciences Employment in the UK



Source: Strength and Opportunities Report 2016

18. The split of turnover by region from the Strength and Opportunities report is provided in Figure 2 below. The South East (£15 billion) and East of England (£14 billion) have the highest turnover.

Figure 2: Turnover across UK areas



Source: Strength and opportunity report 2015

19. Combining National Accounts data with more granular data from the Annual Business Survey provides an estimate of the output of the Life Science sector as a whole:

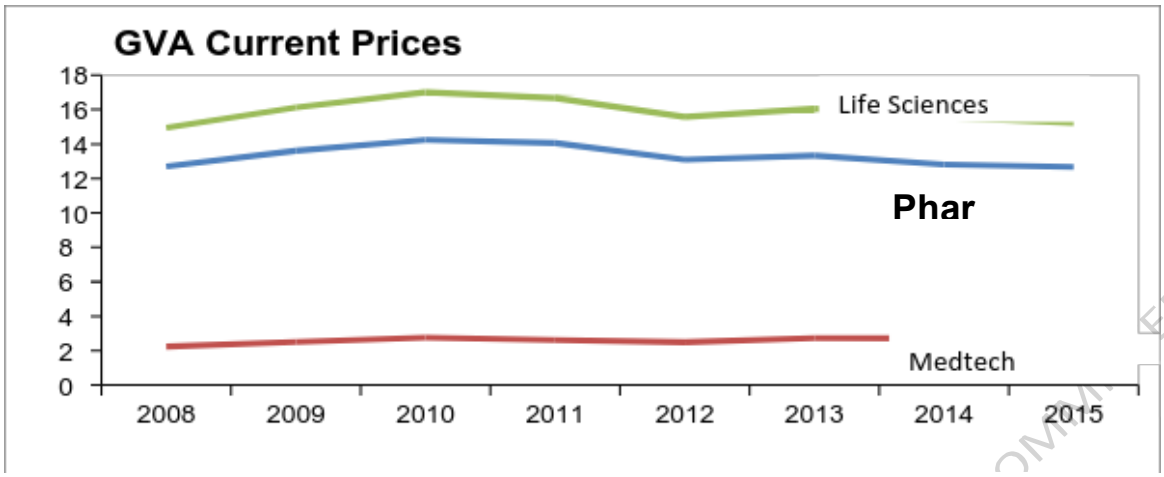
    - Pharmaceutical manufacturing currently accounts for about 7.7 per cent of total UK manufacturing GVA;
    - Total Life Sciences manufacturing accounts for 8.9 per cent of total manufacturing GVA; and
    - As a percentage of total UK economy GVA, the pharmaceutical industry contributed about 0.9 per cent in 2015, and this has been similar over the last 5 years[8].

20. In 2010, Life Science GVA accounted for approximately 12 per cent of total Manufacturing GVA and 1.2 per cent of total economy GVA. Since then, GVA of the Life Sciences sector has declined and Life Science GVA is now 8.9 per cent of total manufacturing GVA and 0.9 per cent of Total economy GVA (see Figure 3).

21. A combination of declining returns to R&D and the 2011/12 patent cliff (where several worldwide patents for prescription drugs expired) have had a significant impact on the sector's productivity (which is not unique to the UK), with a 30% decline in output per worker since 2009. While pharmaceutical productivity growth has declined since the recession, output per worker is higher than comparable sectors and more than double the manufacturing average. The sector makes up around a fifth of manufacturing R&D and is highly profitable.

[8] Life Sciences consists of SIC categories 21 for pharmaceuticals and sub-categories of 26.6 and 32.5 for medical technologies. ONS do not provide GVA estimates at the sub category level in the national accounts (NA) so these have been estimated by Office for Life Sciences using sub category data from the Annual Business Survey (ABS) where estimated GVA26.6 = GVA26 NA * (aGVA26.6 ABS / aGVA26 ABS)

Figure 3: Historical Trends in Life Science GVA



Source: ONS National Accounts. National Accounts estimates are combined with Data from the Annual Business survey to estimate Medtech exports.

22. The sector is globally integrated. Exports of pharmaceuticals and medical technology products form a significant proportion of UK trade, accounting for 5.2 per cent of UK goods and services exports by value.

23. In 2016, the UK exported approximately £30.7 billion of Life Science goods and imported approximately £35.5 billion. Life science exports consist of approximately 84 per cent pharmaceutical products and 16 per cent Met Tech products. In 2016, 48 per cent of Life Science exports were to the EU.

24. Exports also include the production of ingredients and components which are part of the supply chain for pharmaceuticals and devicesLife Science exports have been steadily increasing since 1998, with a dip in 2011-12, driven by a fall in pharmaceutical exports (see Figure 4).

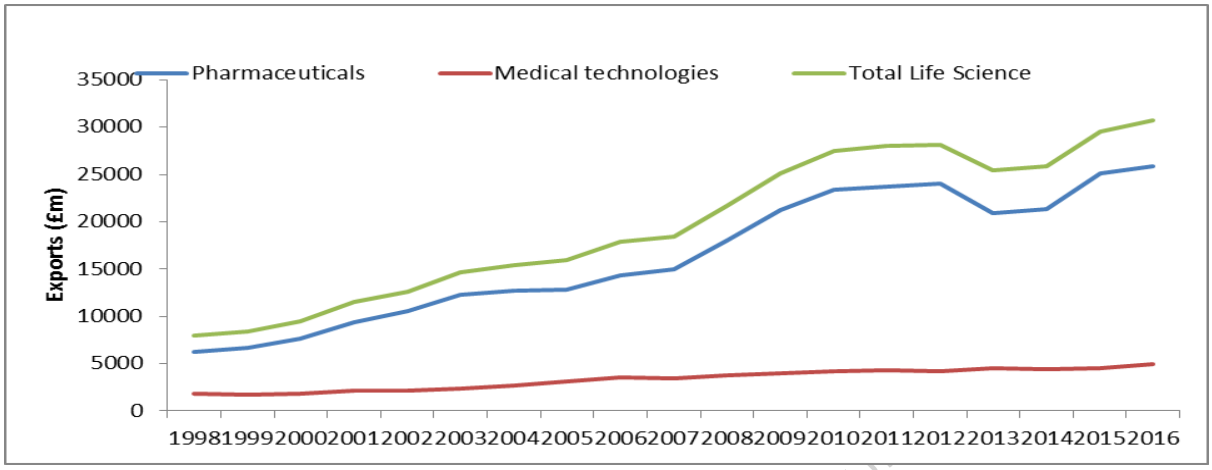
25. Both imports and exports of Life Science goods have been increasing over time. The trade balance was positive (exports exceeded imports) until 2012. In 2016, the trade deficit in pharmaceutical goods was £4.6bn (see Figure 5).

26. In 2016, the UK exported 48% of its Life Science manufacturing products to the EU, with 52% to the rest of the world (see Figure 6).The US represents the UK's largest trading partner after the EU and exports to the US are growing faster than for any other market. US imports of UK pharmaceutical products have been particularly strong over the past decade, growing by 226% to represent the largest category of UK goods exports to the US.

27. In 2015, 74% of Life Science imports were from the EU, and 26% were from the rest of the world (see Figure 7).

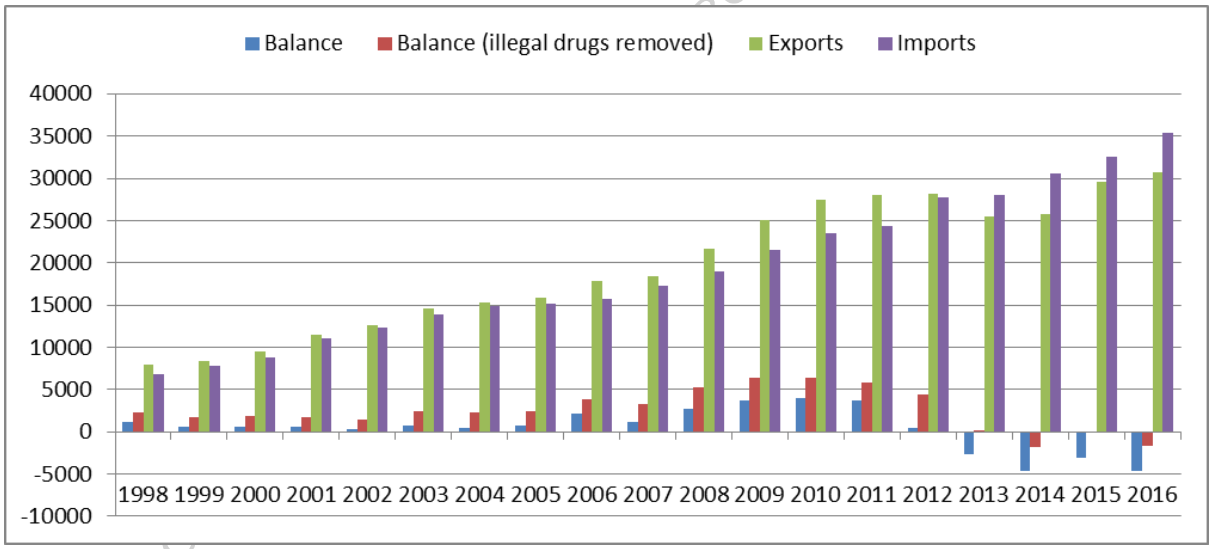
28. The global market for pharmaceuticals imports, excluding the UK, was worth around £307 billion in 2016. Countries besides the 27 other EU Member States accounted for £169 billion, or 55%, of this global market[9].

Figure 4: Historical Trends in Life Science GVA



Source: ONS Balance of Payments data[10]

Figure 5: Life Science Balance of Trade

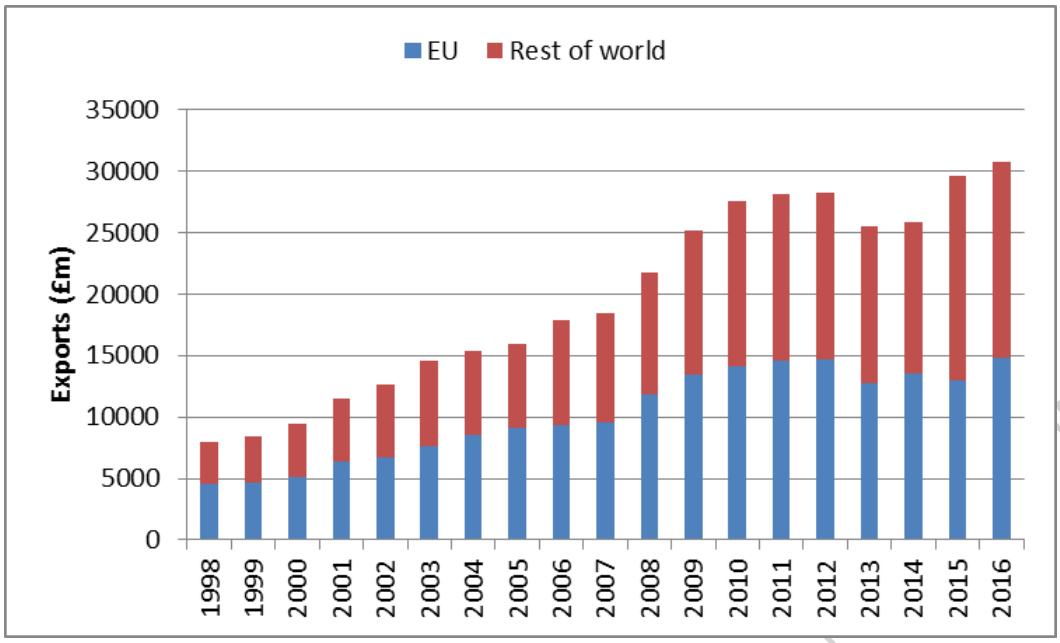


Source: ONS Balance of Payments data[11]

[9] Data obtained from ITC, which is based on UN COMTRADE statistics. The value of the global market is defined as the sum of every country's imports for whom data was available, minus the value of the UK imports. As a rough approximation, the pharmaceuticals sector has here been taken to comprise HS chapter 30

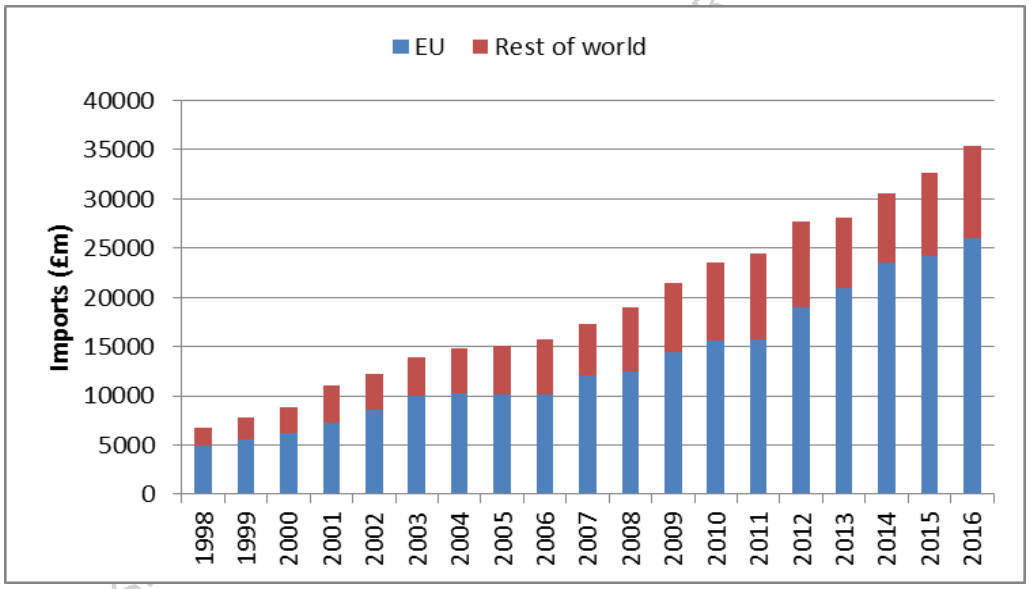
[10] https://www.ons.gov.uk/businessindustryandtrade/internationaltrade/datasets/uktradeingoodsbyclassificationofproductbyactivity

Figure 6: Life Science Exports



Source: ONS Balance of Payments data[11]

Figure 7: Life Science Imports



Source: ONS Balance of Payments data[11]

29. Across the whole sector, over a quarter of employment involves highly skilled research development roles and commands a wage premium

30. The UK has strengths in Life Sciences Research and Development (R&D). In 2013, the UK spent around $2.6 billion of government spending on health R&D, ranking second among selected comparator countries, behind only the USA ($29 billion in 2014). The UK's share of Life Science academic citations was 13 per cent in 2012, ranking second among selected comparator countries, although significantly behind the US (44 per cent). The UK's

share of the top 1 per cent (most cited) Life Science citations was 19 per cent in 2012, again ranking second behind the US (58 per cent).[11]

31. ONS Business Expenditure on Research and Development (BERD) data shows that almost 20 per cent of total business R&D was on pharmaceuticals in 2014. This proportion has declined from its peak of 29.1 per cent in 2010. This is the highest proportion of any manufacturing sector.

32. Health and Life Sciences industries also benefit from significant UK direct funding*:*

    i. Direct and indirect funding support for businesses and relevant wider infrastructure is available through the National Institute for Health Research (NIHR), Small Business Research Initiative (SBRI) Healthcare and Innovate UK programmes, as well as local funds administered by the 39 Local Enterprise Partnerships (LEP) and Local Authorities.

    ii. The UK Research Partnership Investment Fund (RPIF) is supporting 19 projects relevant to the Life Science sector. The RPIF contribution is £282 million, leveraging in an additional £728 million of third party funding and supporting research in areas across areas including regenerative medicine, translational research, med tech, big data and manufacturing.

The current EU regulatory regime

33. The Life Sciences sector is subject to a large number of EU Directives and Regulations as set out in Table 3. These regulations have acted to provide consistency in requirements across Member States and in many cases the UK has played a pivotal role in their development. For the purpose of this report, table 3 summarises Regulations and Directives that directly impact upon the sector. The text following the table then describes in more detail the regulatory frameworks as they relate to medicines, medical devices and clinical trials.

[11] Charts 9, 12A and 12B of Life Science Competitiveness Indicators (May 2016)

Table 3: EU legislation and area of impact on the Life Sciences Sector

Law	Life Sciences area of impact
Directive 2001/83/EC, as amended	Principal Legislation for EU rules on the authorisation, import and production of medicines for humans
Regulation (EC) 726/2004, as amended	Principal Legislation for the regulation of medicinal products – laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Commission Regulation (EC) 507/2006	Conditional Marketing Authorisation (requires less comprehensive data for assessment) for medicinal products within the scope of Regulation (EC) 726/2004 that meet criteria relating to severity of the disease, treatment of public health threats and orphan medicines.
Commission Regulation 1234/2008	Examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
Commission Regulation (EC) 2141/96	Application for the transfer of a marketing authorization for a medicinal product
Regulation (EC) 1901/2006 and amending Regulation 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation 726/2004	Facilitates the development and accessibility of medicinal products for use in the paediatric population
Regulation (EC) 141/2000	Community procedure for the designation of medicinal products as orphan medicinal products (treat rare medical conditions) and to provide incentives for the research, development and placing on the market of designated orphan medicinal products
Regulation (EC) 1394/2007 and amending Directive 2001/83/EC and Regulation 726/2004	Regulation of advanced therapy medicinal products (cell, gene and tissue based products) which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process
Regulation (EU) 536/2014 repealing Directive 2001/20/EC	Rules governing clinical trials on medicinal products for human use

Directive 2005/28/EC	Principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products
Directive 2003/94/EC	Lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use
Directive 2011/62/EU	Prevention of the entry into the legal supply chain of falsified medicinal products
Regulation (EU) 2017/745, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	Principle legislation: Sets out the rules for the placing medical devices and their accessories on the Union market.
Regulation (EU) 2017/746, repealing Directive 98/79/EC	Principle legislation: Sets out the rules for the placing in vitro diagnostic medical devices and their accessories on the Union market.
Directive 98/79/EC	Principle legislation: The safety, health protection and performance, characteristics and authorisation procedures for in vitro diagnostic medical devices
Directive 93/42/EEC	Principle legislation: The safety, health protection and performance characteristics and authorisation procedures for medical devices
Directive 90/385/EEC	Principle legislation: The safety, health protection and performance characteristics and authorisation procedures for active implantable medical devices
Regulation (EC) 469/2009	Supplementary Protection Certificate for Medicinal products providing extended IP protection
Council Regulation (EC) 297/95, Regulation (EU) 658/2014	Defines the fees payable to the European Agency for the Evaluation of Medicinal Products
Council Regulation (EC) 2049/2005	Rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises
Directive 2004/9/EC and	Sets out the rules for the inspection, verification and

2004/10/EC	application of good laboratory practice
Directive 2009/35/EC	Sets out rules on the colouring that may be added to medicinal products
Directive 2010/63/EU, Commission Decision 2007/275/EC, Regulation 1/2005, Directive 64/432/EEC, Directive 93/119/EC, and Regulation 1255/97	Set out rules for the transport and use of animals in studies
Directive 92/65/EEC, Directive 90/425/EEC,	Set out rules for the transport and technical requirements for use of human and animal tissues and cells
Directive (EU) 2015/566 implementing Directive 2004/23/EC, Directive 2012/39/EU amending Directive 2006/17/EC, Directive 2004/23/EC, Directive (EU) 2015/565 amending Directive 2006/86/EC, Directive (EU) 2015/565 amending Directive 2006/86/EC, Directive (EU) 2015/566 implementing Directive 2004/23/EC	Provides regulatory framework for research on human tissues and cells, including quality and safety of imported tissue, technical requirements for testing tissues and cells, setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and technical requirements for coding tissues and cells
Regulation 511/2014	Rules relating to the access and use of genetic resources
Directive 2002/98/EC	Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
Regulation (EC) No 470/2009	Rules setting residue limits in medicines
Directive 95/46/EC, Regulation (EU) 2016/679 repealing Directive 95/46/EC, Directive (EU) 2016/680 repealing Council Framework Decision 2008/977/JHA	Data protection framework

EU Customs Union and Single Market

34. Articles 28-37 of the Treaty on the Functioning of the European Union (TFEU) set out the Treaty provisions on the free movement of goods, including the establishment of the Customs Union. This has been achieved by establishing the Customs Union within the EU and by preventing Member States imposing customs duties or formalities on goods imported from other Member States. In addition, these rules prevent Member States

imposing restrictions on the quantity of imports and exports of a particular item (e.g. quotas or an import or export ban).

35. This legal framework also prevents non-tariff barriers that may restrict imports and exports in less direct ways, for example, by applying product standards and regulations that make it harder in practice for goods coming from one Member State to be sold within another. The exception is where those restrictions can be justified on certain grounds. The legal framework has been achieved by establishing a common set of product rules, underpinned in many cases by voluntary standards. or for goods not covered by those rules and standards, the principle of mutual recognition has been developed (whereby once goods have been lawfully manufactured and marketed in one Member State, another Member State cannot then require it to comply with additional product rules). Finally, goods imported from other Member States must be treated in the same way as goods produced nationally.

Medicines Regulations

36. Medicines in the EU and UK are regulated under Medicines Regulations (see Table 3) by the European Medicines Agency (EMA) based in London, drawing on scientific assessments from national agencies of Member States. The EMA was established in 1995 and responded – in part – to industry calls for a harmonised EU-wide approach to medicines approvals.

37. EU legislation covers not just licensing of medicines, but the approval of clinical trials, post-market pharmacovigilance and inspections, all of which are embedded in the EU framework. The EMA is also responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. It was announced on 20 November that it will be moving to Amsterdam after the UK leaves the EU[12]. Member State competent authorities can bid to be 'rapporteurs' to lead assessments of drugs through a centralised approvals process and to carry out ongoing assessment of quality procedures.

38. There are four licensing procedures to apply for a marketing authorisation (MA) in EU Member States:

    i. National Procedure: To license a medicine in one Member State only. Assessment is undertaken by the relevant Competent Authority of that Member State;

    ii. Mutual Recognition: If the product has a national license in at least 1 Member State then industry can apply to a 'reference Member State (RMS)' to assess its application to market the product in other concerned Member States (CMS);

    iii. Decentralised procedure: To request marketing authorisation in more than one Member State. One Competent Authority (The Medicines and Healthcare products Regulatory Agency (MHRA) in UK) is approached as the RMS and the other states as CMS. The RMS leads the evaluation in consultation with CMS;

    iv. EMA centralised procedure: A single market authorisation is submitted to the EMA. If successful, authorisation is valid across the EU and EEA. The centralised

[12] https://www.consilium.europa.eu/en/policies/relocation-london-agencies-brexit/#

procedure is mandatory for certain types of medicines, some new active substances and biotechnology products.

39. The holder of a MA must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the MA and do not place patients at risk due to inadequate safety, quality or efficacy. Good manufacturing practices (GMP) inspections are intended to ensure that the medicine is manufactured in compliance with the MA. Batch testing ensures that no batch of the medicine is released to market until it has been tested and certified by a Qualified Person (QP) employed by the manufacturer. The EMA uses inspectors from Member States to ensure compliance with GMP.

40. EU law requires each marketing authorisation holder, national competent authority and the EMA to conduct pharmacovigilance to monitor the safety and efficacy of a medicine when used on a large number of people over a prolonged period of time. The data gathered is shared with the EU Member States through the EudraVigilance database.

Medical Devices Regulations

41. Devices regulation differs from medicines licensing in that there is a far greater reliance on post-market scrutiny of devices, rather than pre-market authorisation, under a risk-based approach. Regulation of medical devices falls under the EU's 'New Approach' where audits of manufacturers and conformity assessments, which allows manufacturers to issue CE marks, is outsourced to private Notified Bodies (NBs) across the EU (plus EEA, Switzerland and Turkey).

42. Each NB is designated and overseen by the competent authority of the Member State in which it is located (MHRA in the UK). Industry can approach and pay any designated NB to audit their manufacturing processes, and in the case of the highest-risk devices, individual assessments of their medical device, issuing a certificate that will typically be valid for five years, which means the manufacturer can declare conformity with the full regulatory requirements and market their devices anywhere in the EU, EEA, Switzerland and Turkey.

43. The current regulatory system is being updated and the new Medical Devices and In Vitro Diagnostic Medical Devices (IVDs) Regulations will be applicable to EU Member States in full in May 2020 and May 2022 respectively.

Clinical Trials Regulations

44. The Clinical Trials Directive (Directive 2001/20/EC) and the Good Clinical Practice (GCP) (Directive' 2005/28/EC) requires clinical trials of medicinal products in human subjects to be authorised by the Competent Authority in each country that the trial is taking place, receive a favourable opinion by an ethics committee and to be conducted according to GCP.

45. The UK implements this Directive in The Medicines for Human Use (Clinical Trials) Regulations 2004/1031 as amended. The MHRA is the competent authority. As a result, the MHRA approves 100 per cent of clinical trials that take place in the UK.

46. The Directive introduced a more harmonised system including the introduction of a common application form and core submission documents, harmonised safety reporting requirements and a public EU database of trials.

47. The new Clinical Trials Regulation (536/2014) – agreed in 2014 – is designed to further harmonise the clinical trial application and assessment process. It will set up a single portal for all EU clinical trials and simplify reporting procedures, including for multi-Member State trials.

48. Under the new framework all clinical trial applications in the EU will go through an EU portal to be developed by the European Medicines Agency (EMA). There will be one application only, regardless of the number of Member States the trial will take place in. This replaces the current individual submissions to both regulators and ethics committees in Member States.

Existing frameworks for how trade is facilitated between countries in this sector

49. The arrangements described in this section are examples of existing arrangements between countries. They should not be taken to represent the options being considered by the government for the future economic relationship between the UK and the EU. The government has been clear that it is seeking pragmatic and innovative solutions to issues related to the future deep and special partnership that we want with the EU.

50. There are a number of existing arrangements which govern the way in which non-EU Member States trade in medical devices and pharmaceuticals with the EU. Around the world, other countries have also created arrangements for trading specific categories of manufactured goods.

Medical devices - regulatory frameworks

51. Manufacturers from outside of the EU wishing to export medical devices to the EU need to meet the requirements set out in any applicable EU legislation. As described in Section 2, an important part of this process for many medical devices is conformity assessment before a product can be placed on the market, and audit of the production processes, both carried out by a notified body.

52. Importers and distributors of medical devices from manufacturers based in third countries must certify that the products comply with EU legislation, which may require certification by a third party conformity assessment body in some circumstances.

53. Countries can use bilateral Mutual Recognition Agreements (MRAs) which allow conformity assessment bodies in either market to carry out product testing and certification to each other's legislative requirements. The authorities in both parties agree to accept conformity assessment decisions issued by bodies recognised in one another's markets. Manufacturers still need to ensure that products meet the requirements set out

in the legislation where they plan to market the product. For example, the EU has agreed MRAs for medical devices with Australia, Switzerland and New Zealand.[13]

54. The EU has concluded MRAs with seven countries, covering a variety of sectors. Some of the EU's bilateral MRAs have been integrated into Free Trade Agreements (FTAs). One example is the Comprehensive Economic Trade Agreement (CETA), between Canada and the EU, which has identified medical devices as a priority area for mutual recognition of conformity assessment in the future. CETA also contains provisions for voluntary cooperation on data exchange to support market surveillance activity and exchange of information about the development of technical regulations.

55. Other existing agreements, such as the EU-Swiss agreements and the EEA Agreement, provide for further mutual recognition. For example the EU-Swiss MRAs provide mutual recognition across around twenty product types, including medical devices, and are linked to an agreement that recognises Swiss legislation as equivalent. Where legislation is deemed equivalent, notified bodies' certificates of conformity with the product rules in the EU will be recognised as proving conformity with Swiss legislation, and vice versa. They also cover cooperation on market surveillance of products already on sale.

56. In the EEA agreement, for industrialised goods, EEA countries adopt EU product legislation into their domestic legislation, and goods that originate from these countries are treated as products from Member States. The agreement also includes a system of surveillance and enforcement.

Pharmaceuticals - regulatory frameworks

57. Manufacturers from outside of the EU wishing to export pharmaceuticals to the EU need to meet the requirements set out in any applicable EU legislation, which is implemented through the EMA as set out in Section 2. This includes having a market authorisation holder, Qualified Person and Qualified Person for pharmacovigilance based in the EU. These individuals, and any importers and distributors, must be satisfied of the safety of medicines and ensure all legislative requirements are fulfilled.

58. In the area of pharmaceuticals, agreements with third countries to facilitate trade have typically focussed on reducing duplication of regulatory activity during the compliance process, whilst ensuring a high level of protection of public health and patient safety. Through MRAs, as outlined above, the EU has agreed mutual recognition of batch release testing of medicines and mutual recognition of inspection of quality assurance processes (GxP), such as Good Laboratory Practices and Good Manufacturing Practices. For example, the EU-Swiss agreement provided for mutual recognition of batch release testing and GxP inspections; and CETA provides mutual recognition of batch release testing and of certificates of GMP compliance.

59. In some areas, the development of legislative requirements and agreements is informed by international organisations which facilitate the development of common approaches across countries, drawing on best practice. These organisations bring together national regulators. For example, the OECD adopted the Mutual Acceptance of Data (MAD) to

[13] https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en

avoid duplicative testing of chemicals to meet regulatory requirements. MAD requires that test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment. The EU has adopted the OECD GLP principles and revised OECD Guides for Compliance Monitoring Procedures for GLP as annexes to two EU GLP Directives, and these underpin the mutual recognition agreements.

60. In addition, to support pharmacovigilance, the EMA cooperates with regulatory bodies around the world and the EU has specific agreements in place with the USA, Canada, Japan, Switzerland, Australia, New Zealand and Israel that enable this.

Customs

61. There are many customs facilitation arrangements in international agreements. These include the EU's agreements with a number of third countries, such as Canada, Korea, and Switzerland. These agreements differ in the depth and scope of customs facilitation offered. Examples of customs facilitations include: simplifying customs procedures, advance electronic submission and processing of information before physical arrival of goods, and mutual recognition of inspections and documents certifying compliance with the other parties' rules.

Tariffs

62. In the absence of a preferential trade agreement, goods imported into the EU from non-EU countries must pay tariffs on goods for which tariffs are charged. Tariffs are custom duties levied on imported goods. Under the World Trade Organisation (WTO) Most Favoured Nation (MFN) a country's tariff schedule must be consistently applied to imports from countries it trades with, except those where a preferential trade agreement exists. EU MFN tariff rates vary depending on the good. The EU's MFN applied duty is zero for the large majority of medical devices tariff lines[14].

63. The Pharmaceutical Tariff Elimination Agreement has meant the elimination of tariffs on thousands of pharmaceutical entities. It includes a commitment to not replace tariff barriers with non-tariff barriers and extends to cover products imported from states not signatory to the Agreement. All finished pharmaceutical products are automatically covered by the Agreement, however, active ingredients and intermediates (used in the manufacture of finished pharmaceuticals) do not automatically qualify for zero tariffs and must be formally added to the list of eligible products.

64. The EU has agreements with a range of trading partners that amend the tariff rates applied to goods. Where these create tariff preferences for the minority of pharmaceutical products that are not covered by the Agreement, exports must meet a Rule of Origin in order to enjoy that tariff preference.

[14] Medical devices are within HS4 categories 9018 to 9022. Tariffs for specific products are available at https://www.trade-tariff.service.gov.uk/trade-tariff/chapters/90

Rules of origin

65. The EU includes rules of origin in all of its FTAs, which are restrictions on the originating content of products that exporters must comply with to gain tariff preferences. These rules typically reflect both the supply chains of both the EU and its FTA partner. Many of the EU's rules of origin arrangements are based on the Regional Convention on Pan-Euro-Mediterranean Preferential Rules of Origin, which includes provisions that allow producers to treat content from some third countries as if it comes from their own country. Several arrangements aim to reduce the administrative requirements associated with origin certification, including the EU's Registered Exporter (REX) system, which lets businesses register for self-certification of origin using an online system, avoiding paper certificates.

Sector views

[This information was provided by the Government to the Committee, but the Committee has decided not to publish this section]

Annex: Stakeholder Engagement on European Union Exit (EU Exit) in the Department for Business, Energy and Industrial Strategy

[This information was provided by the Government to the Committee, but the Committee has decided not to publish this section]