Merck – Written evidence (LSI0118)

1. Introduction

1.1 Merck is a leading science and technology company working across healthcare, life science and performance materials. Founded in Germany in 1668, Merck is the world's oldest pharmaceutical and chemical company. Merck has a significant presence across the UK, having been active here since 1883.

1.2 Merck welcomes the House of Lords Science and Technology Committee's inquiry into Life Sciences and the Industrial Strategy. As a business operating across the life science supply chain, we are keen to work with the Government to ensure the strategy furthers the UK's productivity and future economic prosperity; ensures swift patient access to innovative medicines; and supports businesses like Merck to continue to invest in the UK.

1.3 In responding to the strategy and developing a sector deal for the life sciences sector, it is crucial Government facilitates a business environment that supports the expansion of UK R&D and provides companies with the flexibility to conduct research in novel areas. There must be a continued focus on ensuring patients have access to the most effective and innovative treatments, by facilitating a streamlined and flexible regulatory environment.

1.4 The future of the life sciences sector, particularly in the context of the UK's withdrawal from the European Union, requires access to a highly-skilled workforce, and effective international trade and knowledge exchange.

1.5 A summary of our recommendations is overleaf.

2. Summary of recommendations

Science and Innovation

- University research funding should continue to support ongoing collaboration between academia and industry.
- Establish a service to advise businesses on R&D tax relief claims.
- Protect and encourage EU-wide research collaboration post-Brexit.
- Continued access to the world's leading scientists is vital if the UK is to remain attractive as a research base for industry.
- Action should be taken to ensure that the cost and administrative burden attached to bringing EU and non-EU scientists to the UK remains minimal.
- Universities should be encouraged to collaborate with industry to ensure university courses support graduates to develop the appropriate skill-set to facilitate their transition into industry.
- Encourage more young people into careers in science at school level, in partnership with industry.

Industrial Strategy

- Build on the successes of the 2011 Strategy for UK Life Sciences to encourage further collaboration between industry, Government and the third sector.
- Ensure that sufficient resources are allocated to the delivery of the new Life Sciences Industrial Strategy so that it can achieves its aims.
- Put incentives in place to drive implementation and championing of the aims of the strategy at a local NHS level.
- Ensure that the proposed Oversight Board includes wider industry and NHS representatives.
- Ensure that activity to deliver the Life Sciences Industrial Strategy recognises and encompasses the whole supply chain– from research to the final release of the product.
- Ensure that the proposed actions set out in the strategy – including the early engagement forum and commercial access schemes – are an enabler for, not a barrier to, the uptake of innovative medicines.
- Consider other funding and approval models for multi-indication medicines to ensure that patients, particularly for conditions in areas with high unmet patient need, can access innovative and effective treatment.
- Merck has significant experience in partnering with the NHS to develop collaborative approaches to ensuring patient access. Early engagement with Merck on the forum and other proposals would be beneficial to delivering the aims of the strategy.
- The wider health economy – including industry, patient groups and the NHS – should work together with government to identify and develop the appropriate areas for investment to ensure a sustainable system for the future.

NHS Procurement and Collaboration

- Develop a holistic approach to building a sustainable NHS, which values medicines as an investment in the health and wealth of the nation, rather than solely seeing them as a cost.
- Develop procurement objectives and incentives on innovation to encourage collaboration with innovative suppliers, including in digital technologies.
- patients and industry.
- Implement the strategy's recommendation on streamlining access routes for new medicines, whilst also ensuring appropriate mechanisms are in place to assess orphan and ultra-orphan cancer medicines.

Responsibility and Accountability

- Develop clear lines of responsibility across Government for delivering the Life Sciences Industrial Strategy with regular appraisal of progress.
- Develop an agreed implementation plan for the Life Science Sector Deal with responsible figures from industry and Government leading delivery reporting to a cross-departmental oversight board.
- Draw on technical expertise, services and products within the broader life sciences industry to partner with Government in achieving its ambition to grow UK-based companies.
- Support further partnership working between industry and the NHS to develop effective pathways and improve efficiency.

- Ensure that there is accountability and oversight of life sciences across government.

Brexit

- Merck is committed to the UK. However, Brexit is creating significant uncertainty over a range of issues, including access to sufficient talent, the regulatory environment, the supply chain and R&D funding. Action is needed to ameliorate these concerns and ensure that the already tough commercial environment for the pharmaceuticals element of the life sciences sector does not become more difficult as a result of Brexit.
- We look forward to the life sciences industry being a priority in the Brexit negotiations and subsequent trade discussions, per the Government's stated ambition, in the interests of British and European patient safety and public health.
- Alignment with the EU regulatory framework will help to ensure ongoing safe decision-making on new products. Adopting a new regulatory framework after Brexit should not be pursued if it endangered the UK's participation in the EU regulatory frameworks.
- The Government should seek an MRA to maintain continuity of supply following the UK's exit from the EU and protect the life science industry from disruption that can result in lost revenues.

3. Science and Innovation

Question 1: How can investors be encouraged to invest in turning basic life science research into new innovations in treatment? Why has investment been lacking in this sector? Does the research base have the necessary infrastructure to be world-leading?

3.1 Merck plays a significant role in the UK's life science sector, supporting companies and manufacturers with services, tools and testing services to make research and biotech production better, faster and safer. We are a significant investor in the UK, with 20% of Merck's global healthcare venture capital invested in the country. Within the last month alone, Merck has broken ground on a £1.3 million site expansion at Irvine, allowing us to supply an additional 2 million litres of specialised cell culture media per annum to the global healthcare industry. This builds on a £20 million investment in a dry powder media facility opened in 2015.

3.2 The UK's world-leading universities underpin the nation's R&D success. University research funding should continue to support ongoing collaboration between academia and industry, which in turn will encourage industry investment.

3.3 R&D tax relief is an essential source of support for Merck's R&D activities in the UK. However, there are elements of the system that should be addressed in order to stimulate increased private sector R&D investment. The current tax relief system excludes some areas of research. For instance, Phase IV clinical trials generally do not qualify, with the exception of certain elements.

3.4 For large companies like Merck with a number of different sites, working on what is often highly confidential research, it can be very time consuming to confirm how much staff time is spent on eligible research and how much is not. The difficulty in defining the amount of time that clinical trials staff spend on Phase IV versus Phases I-III and allocating administration time, for example, to determine qualifying and non-qualifying activity is a significant barrier to applying for tax relief.

3.5 Merck, therefore, recommends the Government establishes a service to advise businesses on R&D tax relief claims, enabling companies to spend less money on advice from large tax consultants when first assessing their claims and freeing further money up for R&D investment.

3.6 Merck has some €30m in-kind invested in live or planned Innovative Medicines Initiative (IMI) projects, which includes research partners from many countries. A large proportion of these projects involve UK partners, including leading universities, and public bodies such as National Institute for Clinical Excellence (NICE), as well as small to medium sized enterprises.

3.7 We welcome the Government's prioritisation of continued international collaboration in this area and the access to funding it provides, and strongly welcome any move to make this a reality. This ambition should be given the highest priority during the Brexit negotiations with the EU.

3.8 The UK's involvement in EU-wide research collaboration needs to be protected and encouraged post-Brexit, as set out in the "Collaboration on science and innovation: a future partnership paper" published in September 2017.

3.9 Recommendations:

- University research funding should continue to support ongoing collaboration between academia and industry.
- Establish a service to advise businesses on R&D tax relief claims.
- Protect and encourage EU-wide research collaboration post-Brexit.

Question 3: What can be done to ensure the UK has the necessary skills and manpower to build a world class life sciences sector, both within the research base and the NHS?

3.10 The UK is already home to world leading capabilities in the life sciences sector, which requires specialist skills. For example, Merck's BioReliance business in Scotland is the leading biosafety testing provider to the biotech and pharmaceutical industry, providing critical data that supports the safe release of cutting-edge medicines to patients, in some cases for experimental treatments where no other alternative is available. There is, however, much that can be done in terms of improving skills and manpower that would enable the UK to build on what is already a strong life sciences sector.

3.11 Keeping the UK's door open to talent and trade is crucial if the UK is to remain attractive as a research base for industry, both for EU and non-EU nationals. We welcome the Government's commitment to attracting talent post-Brexit. However, we need assurance from the Government that action

will be taken to ensure that the cost and administrative burden attached to bringing EU and non-EU scientists to the UK remains minimal.

3.12 Part of the lifeblood of Merck's business in the UK is graduates, and we focus heavily on encouraging young people to pursue a career in science. For instance, our Irvine cell media manufacturing site works with the University of the West of Scotland to offer internships to students studying forensic science, some of whom have gone on to secure permanent roles on graduation. A number of students from the University of Glasgow also complete placements at our Merck BioReliance site in Glasgow.

3.13 Although a sufficient number of graduates is available, they often lack the hands-on skills and experience of a laboratory environment. For example, even within the past five years, we have noticed the decline in laboratory experience of biomedical science graduates.

3.14 To tackle this, Merck is in discussions with Skills Development Scotland and some Scottish universities to help develop courses to ensure graduates qualify with the appropriate skill-set which will facilitate their transition into industry. However, we would welcome further measures in England to improve the laboratory experience of graduates. This should include a greater focus on the way in which students' learning in the classroom relates to a career in science and technology. Merck is keen to work more widely to provide input on lecture courses to increase understanding among graduates of what it is like to work in a professional laboratory and develop necessary hands-on skills.

3.15 In our experience, industry placements as part of degree courses can also contribute significantly to developing a graduate's soft skills that are vital for a career in industry. Much of our work is customer-centric by nature and we see first-hand how students lacking soft skills can be restricted from getting into a career in science.

3.16 At school level, we would welcome any steps Government can take to encourage more young people into careers in science. Merck works with local schools and communities in this regard. For example, our Gillingham site is sponsoring Gillingham School's team to attend the Big Bang awards. Merck BioReliance also received the Scottish Life Science Award 2017 for its Community Engagement programme. Under this programme staff have volunteered their time and expertise to deliver science lessons to more than 1,250 students in the Glasgow and Stirling areas, inspiring young people to explore science-related careers.

3.17 Recommendations:

- Continued access to the world's leading scientists is vital if the UK is to remain attractive as a research base for industry.
- Action should be taken to ensure that the cost and administrative burden attached to bringing EU and non-EU scientists to the UK remains minimal.
- Universities should be encouraged to collaborate with industry to ensure university courses support graduates to develop the appropriate skill-set to facilitate their transition into industry.

- Encourage more young people into careers in science at school level, in partnership with industry.

4. Industrial Strategy

Question 5: What can be learnt from the impact of the 2011 UK Life Science Strategy? What evidence is there that a strategy will work for the life sciences sector? How can its success be measured against its stated objectives?

4.1 We believe a number of positive developments stemmed from the 2011 Strategy for UK Life Sciences, which helped to improve the opportunities for collaboration between individuals and organisations across the NHS, academia, industry and the voluntary sector.

4.2 However, a lack of resources due to budgetary pressures, a lack of champions and advocates to spearhead implementation at a local level, and an absence of strong accountability within Government in driving delivery of actions were crucial factors that hampered the consistency and speed of the 2011 strategy's implementation. It will be crucial for Government to ensure these lessons are learnt if the latest Life Sciences Industrial Strategy is going to succeed.

4.3 Collective action across Government, the NHS, its arms-length bodies, and the devolved nations is crucial to the strategy's success. Merck believes the implementation of the Life Sciences Industrial Strategy should be a cross-departmental priority. It is encouraging the current Secretaries of State for Health and BEIS were present with Sir John Bell, the author of the Life Sciences Industrial Strategy, for the announcement; and that they jointly penned an enthusiastic response conveying a good degree of support for the strategy on the day of publication.

4.4 A holistic approach encompassing the entire life sciences sector, from research to production to final release of the product, as well as a consideration of the wider economic, regulatory and domestic environment, will be required to ensure alignment between the Life Sciences Industrial Strategy and the wider Industrial Strategy so that it genuinely makes a positive impact for the sector and for patients.

4.5 The Government needs to ensure clear lines of accountability and responsibility exist, allowing the strategy to be successfully monitored and managed. The development of an Oversight Board will go some way in achieving this by regularly reporting on progress (at least annually) and escalating any delivery issues to the relevant government or sector participants. It is important this Oversight Board includes a broad group of sector stakeholders, including wider representatives from industry and the NHS, in order to secure buy-in, progress implementation and monitor effectiveness on the ground.

4.6 Recommendations:

- Build on the successes of the 2011 Strategy for UK Life Sciences to encourage further collaboration between industry, Government and the third sector.
- Ensure that sufficient resources are allocated to the delivery of the new Life Sciences Industrial Strategy so that it can achieves its aims.
- Put incentives in place to drive implementation and championing of the aims of the strategy at a local NHS level.
- Ensure that the proposed Oversight Board includes wider industry and NHS representatives.

Question 6. Does the strategy contain the right recommendations? What should it contain/what is missing? How will the life sciences strategy interact with the wider industrial strategy, including regional and devolved administration strategies? How will the strategies be coordinated so that they don't operate in 'silos'?

4.7 Merck welcomes the publication of the strategy, particularly its focus on encouraging more Government investment in key areas, as well as a more favourable fiscal, regulatory and reimbursement environment for the life sciences industry. We look forward to working with Government and other partners to implement the strategy's recommendations.

4.8 We welcome the strategy's focus on the implementation of the Accelerated Access Review (AAR) and, in particular, that the strategy goes further than the AAR recommendations in terms of streamlining and clarifying national routes to market.

4.9 Merck welcomes a medicines policy with a single, value-led, NICE-managed process with an integrated opportunity for flexible, confidential reimbursement and contractual arrangements. This will ensure patients receive innovative treatments in a more timely manner, and provide a supportive environment for companies like Merck, who are always keen to engage in discussions with NICE and NHS England around flexible reimbursement schemes.

4.10 The strategy also makes suggestions for a range of ways in which industry should collaborate with the NHS, including partnering to reshape clinical pathways and improve efficiency and collecting real-world data. Merck has significant experience in these areas, for example, through our work supporting service redesign to help facilitate improved NHS patient access to molecular diagnostics. We are also working with NHS England through our flagship project with the National Cancer Vanguard to lead service redesign by identifying ways of using NHS resources more efficiently within the secondary care setting by uniquely capturing patient symptoms, outcomes and experiences throughout their treatment. Our expertise and learning in these areas could be used to support NHS organisations to reshape clinical pathways, improve efficiency and collect real-world data.

4.11 The strategy also calls for the creation of a forum for early engagement around commercial access agreements and stresses the importance of appropriately equipping the NHS to agree partnership deals. These are welcome developments; however, any developments need to be carefully

thought through to ensure these are an enabler for creative commercial negotiations that increase uptake of innovative medicines, as opposed to an additional barrier to access. NHS England should also consider other funding models for multi-indication medicines, in particular outcomes-based schemes to ensure that all eligible UK patients are able to access to innovative and transformative medicines.

4.12 Embracing novel schemes could help ensure that all eligible UK patients – including those with conditions in areas with high unmet patient need – receive access to innovative medicines. Such schemes would support the NHS to make the latest innovations available to patients within the context of the extreme financial pressures the system faces.

4.13 The strategy highlights that the manufacture of today's medicines involves "a complex supply chain" and platforms that are "generally inflexible". Merck has significant expertise to offer in the implementation of the strategy's recommendations. Merck forms a vital part of the life sciences supply chain as a supplier of innovative devices, tools, laboratory supplies and testing services to the pharmaceutical industry, biotechnology companies, research institutes and academic centres across the UK.

4.14 It is vital the strategy recognises that life sciences, as a sector, is much more than medicines. Life sciences encompasses the products, mechanisms and processes involved in progressing a medicine from research to the final safe release of a product to a patient.

4.15 It is also important to ensure the strategy, and upcoming Sector Deal, align with the wider Industrial Strategy around cross-cutting areas such as skills, the tax environment, manufacturing and trade.

4.16 Recommendations:

- Ensure that activity to deliver the Life Sciences Industrial Strategy recognises and encompasses the whole supply chain– from research to the final release of the product.
- Ensure that the proposed actions set out in the strategy – including the early engagement forum and commercial access schemes – are an enabler for, not a barrier to, the uptake of innovative medicines.
- Consider other funding and approval models for multi-indication medicines to ensure that patients, particularly for conditions in areas with high unmet patient need, can access innovative and effective treatment.
- Merck has significant experience in partnering with the NHS to develop collaborative approaches to ensuring patient access. Early engagement with Merck on the forum and other proposals would be beneficial to delivering the aims of the strategy.

Question 8. Where should the funding come from to support the implementation of the strategy?

4.17 We welcome the funding that has already been made available through the Industrial Strategy Challenge Fund, including the £146m of Government funding for five new major initiatives detailed at the launch of the strategy.

4.18 Ensuring a thriving life sciences sector is dependent upon collaboration between industry, patients, the NHS and Government. It is only by working in partnership to identify the areas of greatest need, that we will ensure the sector is fit for the future.

4.19 Supporting the strategy's implementation is about how and where funding is focused, but also whether the right fiscal, regulatory, political and policy environment can be fostered so that any investment delivers the highest level of value for patients, the NHS and industry.

4.20 Government funding, for instance, through matched funding for capital investments in priority areas, and ensuring the NHS's finances are on a sustainable footing to support the introduction and uptake of innovation, are critical to the strategy's success. At the same time, industry must play its part. With the right incentives in place, industry will be much more likely to bring investments to the UK. Industry can also play a part through sharing risk with the NHS when bringing innovation to patients. Merck has a history in this area, through its involvement in the Multiple Sclerosis Risk Sharing Scheme, first established in 2002, which enabled MS patients to access disease modifying treatments. We are keen to engage with NHS England on novel risk share schemes for new medicines coming through our pipeline.

4.21 Through the Life Sciences Sector Deal, the Government has an opportunity to provide clarity on policy direction by endorsing the recommendations of the strategy to facilitate commercial decision-making and secure global investments in the life science sector in the UK.

4.22 Recommendations:

- The wider health economy – including industry, patient groups and the NHS – should work together with government to identify and develop the appropriate areas for investment to ensure a sustainable system for the future.

5. NHS Procurement and Collaboration

Question 10. How can public procurement, in particular by the NHS, be an effective stimulus for innovation in the life sciences Sector? Can it help support emerging businesses in the life sciences sector?

5.1 Decisions about NHS procurement should be made in the best interests of patients.

5.2 Merck understands the need to make efficiencies in order to ensure that the health service can meet both the current and the future needs of patients as the population grows and changes. However, while the NHS is facing significant financial pressure, this must not be the only or primary factor under consideration when medicines procurement decisions are being made by the NHS. Outcomes for patients should be the primary concern, and the

importance and value of innovative medicines in delivering better outcomes must be taken into consideration.

5.3 The Pharmaceutical Price Regulatory Scheme (PPRS) is the main mechanism through which the NHS procures medicines. In the most recent scheme, the industry agreed to a cap and to underwrite the growth in the branded medicines bill, refunding the NHS for any spending in excess of the agreed cap. The value of this rebate is sometimes neglected by the NHS and decision-makers, despite the contribution industry is already making to maintaining the expenditure on medicine within an agreed envelope.

5.4 The medicines bill can sometimes be seen as an easy target for short term savings due to its visibility and priority in the minds of decision-makers. A more holistic approach to making the NHS sustainable in the longer term is needed, that does not limit access to the most recent scientific advances for patients which deliver better clinical outcomes. This should include new patient pathways and structural change where appropriate.

5.5 Implementation of the Life Sciences Industrial Strategy should put a focus on viewing medicines expenditure as an investment into the health and wealth of the nation. Merck is keen to work with NHS England and Government to help to find the right balance between valuing innovative treatments that deliver better clinical outcomes and creating a sustainable NHS.

5.6 Effective procurement can also be an important enabler for innovation. The NHS can be a world leader in bringing the future of medicine to patients, which will drive growth, development and innovation in the UK life sciences sector. Supporting research is already a key objective of the Mandate and the Health and Social Care Act 2012, however, this should be made explicit in the context of NHS procurement. As such, procurement objectives and incentives should include innovation and procurement officers should be encouraged to collaborate with innovative suppliers. This will be particularly important as digital technologies become more important contributors to the delivery of swift and effective care for patients, an area which Merck has a growing interest in.

5.7 Recommendations:

- Develop a holistic approach to building a sustainable NHS, which values medicines as an investment in the health and wealth of the nation, rather than solely seeing them as a cost.
- Develop procurement objectives and incentives on innovation to encourage collaboration with innovative suppliers, including in digital technologies.

Question 11. How can the recommendations of the Accelerated Access Review be taken forward alongside the strategy? Will the recent changes to the NHS England approval process for drugs have a positive or negative effect on the availability of new and innovative treatments in the NHS? How can quick access to new treatments and the need to provide value for money be reconciled?

5.8 Merck welcomed the Accelerated Access Review (AAR) when it was published in 2016 and believes the aims behind it were good in principle. However, implementation of the AAR has not lived up to the laudable intentions set out in the final report. The Life Sciences Industrial Strategy's recommendation that the AAR's proposals be adopted to streamline and clarify national access routes is therefore welcome. This is particularly important as personalised medicines become more common where more flexible funding and approval models are needed to ensure that patients can access new and innovative treatments.

5.9 While industry is doing what it can to support the NHS to make efficient use of resources and ensure a sustainable future for health services, we have significant concerns that their implementation may be hampered by recent policy developments, in particular, the introduction of the Budget Impact Test. The Budget Impact Test represents an additional assessment hurdle over and above existing national cost control mechanisms (such as PPRS), designed to support NHS budget management, rather than focusing on the value a medicine provides in enhancing a patient's life. This radical change was introduced in haste, with limited collaboration with patients or industry.

5.10 Merck also has concerns the NICE appraisal processes may not offer the most appropriate route for orphan and ultra-orphan oncology medicines. In streamlining national routes to market, NICE should also consider how it can best provide the necessary flexibility to accommodate the inherent uncertainties involved in appraising orphan and ultra orphan cancer medicines. The revised Cancer Drugs Fund (CDF) is not, in all circumstances, able to address this issue, for instance, where the patient population is extremely small, additional data generated within the two-year CDF timeframe will still not address the inherent uncertainty.

5.11 Merck is committed to working in partnership with NICE and NHS England to achieve the best outcomes for patients. We are currently conducting positive conversations with NHS England and NICE to find a pragmatic way forward to facilitating access to our pipeline immuno-oncology medicine with an orphan cancer indication.

5.12 Recommendations:

- Review the Budget Impact Test policy introduced by NICE and NHSE, in partnership with patients and industry.
- Implement the strategy's recommendation on streamlining access routes for new medicines, whilst also ensuring appropriate mechanisms are in place to assess orphan and ultra-orphan cancer medicines.

6. Responsibility and Accountability

Question 13: Who should take responsibility for the implementation of the Life Sciences Industrial Strategy and to whom should they be accountable? What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

6.1 Merck believes the successful implementation of the recommendations of the Life Sciences Industrial Strategy requires collective action across

government, the NHS, its arms-length bodies, and the devolved nations. The Government needs to ensure that clear lines of accountability and responsibility exist, allowing the strategy to be successfully monitored and managed.

6.2 The strategy proposes that recommendations be taken forward by a subgroup of the Ministerial Industry Strategy Group, supported by the OLS and incorporating existing work being undertaken by NICE, NHS England, and industry. Merck is supportive of this.

6.3 Any sector deal must include an agreed implementation plan that sets out lines of accountability as well as clear milestones and timescales. Having each part of the sector deal overseen by an industry and a Government lead, who are required to report to an oversight board, will help to ensure greater accountability.

6.4 Recommendations:

- Develop clear lines of responsibility across Government for delivering the Life Sciences Industrial Strategy with regular appraisal of progress.
- Develop an agreed implementation plan for the Life Science Sector Deal with responsible figures from industry and Government leading delivery reporting to a cross-departmental oversight board.

Question 14. What is the role of companies within the sector, particularly the large pharmaceutical companies, in the implementation of the strategy? How are they accountable for its success?

6.5 Merck believes there is a crucial role for companies in the implementation of the Life Sciences Industrial Strategy. We are keen to play our part accordingly, as both a mid-size pharmaceutical company and a broader life science company with reach across the sector.

6.6 As Government seeks to grow new UK-based life science companies, Merck Life Science would be delighted to partner, where appropriate, in terms of offering its significant technical expertise, services and products to support that growth.

6.7 The strategy proposes medical technology and diagnostics companies should partner with the NHS to reshape clinical pathways and improve efficiency. Merck has already been working with the NHS to improve patient testing pathways for a biomarker test we have helped to develop. We have significantly helped improve NHS testing pathway turnaround times for this test, consistent with local first line clinical decision-making timelines, as a result.

6.8 This test helps physicians and their patients have an informed discussion about the most appropriate personalised treatment options, which may improve patients' long-term outcomes. As well as benefits in terms of improving patient experience and outcomes, performing this test provides value for money to the NHS by identifying and treating only those patients who are most likely to benefit from a treatment option.

6.9 To help the NHS to improve patient testing pathways, Merck has been working with leading oncology centres to facilitate solution-focused workshops, bringing together multi-disciplinary teams to identify where efficiencies can be made to the patient testing pathway. One centre was able to reduce their testing pathway turnaround time by eight working days. The service redesign model Merck has developed is transferable to any molecular test and Merck would be happy to share this expertise more widely with NHS England and Government.

6.10 We are also working with NHS molecular labs using testing agreements that enable tracking of laboratory KPIs and peer-to-peer benchmarking. NHS staff can reflect on this data and make decisions on how and where to make improvements accordingly, to positively impact patient experience and outcomes. This is an example of how industry can be accountable to ensure investment in the life sciences sector is a success.

6.11 We are keen to share the knowledge and insights we have gained to continue helping NHS organisations to improve patient pathways and efficiency. This will ultimately benefit patient experience and outcomes.

6.12 Recommendations:

- Draw on technical expertise, services and products within the broader life sciences industry to partner with Government in achieving its ambition to grow UK-based companies.
- Support further partnership working between industry and the NHS to develop effective pathways and improve efficiency.

Question 15: Does the Government have the right structures in place to support the life science sector? Is the Office of Life Sciences effective? Should the Government appoint a dedicated Life Science Minister? If so, should that Minister have UK-wide or England-only responsibilities?

6.13 For a holistic Life Sciences Industrial Strategy to be effective, everyone involved in the implementation of the strategy needs to come together behind a clear, commonly-held objective. The Office for Life Sciences is an important structure within Government to achieve this.

6.14 Accountability and oversight of life sciences and the implementation of the Life Sciences Industrial Strategy is needed at the highest level, whether through a dedicated minister or defined responsibilities cross-departmentally.

6.15 Recommendations:

- Ensure that there is accountability and oversight of life sciences across government.

7. Brexit

Question 16: What impact will Brexit have on the Life Sciences sector? Will the strategy help the sector to mitigate the risks and take advantage of the opportunities of Brexit?

7.1 Merck is committed to the UK, and we are making longer term plans for continued investment through expansion and growth across several of our sites up and down the country.

7.2 We welcome the Secretary of State for Health's recent joint letter to the Financial Times, together with the Business Secretary, calling for close regulatory cooperation on medicines after Brexit. We also welcome the Government's recent paper on maintaining the UK's involvement in European research collaborations.

7.3 However, more widely, we have concerns regarding the potential environment after the UK leaves the EU if the following issues are not addressed:

Continued access to R&D funding

7.4 We are calling on the UK Government to be ambitious in ensuring continued research collaboration with Europe, access to EU funding streams, and streamlining of UK research grant applications.

The regulatory environment for life sciences

7.5 We welcome the Secretary of State for Health's recent joint statement, together with the Business Secretary, calling for close regulatory cooperation on medicines after Brexit. However, uncertainty about the future of regulation in the UK is already affecting the life science sector.

7.6 Undertaking final product lot release testing (LRT) for medicines licensed in the EU is an important part of Merck's BioReliance business in Scotland, which employs 350 people. However, this activity will only be able to continue post-Brexit if the UK agrees a Mutual Recognition Agreement (MRA) with the EU, similar to agreements with other non-EU countries such as Switzerland, Australia, Canada, New Zealand and Israel.

7.7 Without an MRA post-Brexit, potential lost revenue on LRT for Merck BioReliance would be a minimum of £3.1m based on 2017 sales, with the potential for further knock-on impact on other related revenues, where customers seek to have a "one-stop-shop" supplier.

7.8 The uncertainty over whether, and when, the UK will be awarded an MRA is already costing Merck business to competitors in Europe. Several customers have already stated their intention to seek alternative suppliers based in the EU.

The impact of any trade barriers on our supply chain

7.9 Some 40-50% of goods sold through our Merck's UK Life Science business come from EU countries and some 12% is "drop-shipped" directly to the customer from Germany within 24 hours of order. This means a high-level, frictionless and organised customs/free trade agreement is vital.

7.10 Merck is one of the few leading pharmaceutical companies with multiple UK based sites providing world leading products. Our Haverhill site is the European centre of excellence for oligonucleotide (DNA and RNA) production and supplied material for the first human genome sequencing. It is the number one supplier in the UK but approximately half of the site's daily shipments are sent to EU countries.

7.11 This is not only an example of the crucial role Merck plays in the UK research and innovation field, but also the role we play in external trade and investment as a result. If the UK is to stay in the race as a world leader in Life Sciences post-Brexit, it is essential the Life Sciences Industrial Strategy continues to support this type of activity and potential future expansion of the Haverhill site.

7.12 Tariffs would have a potentially restricting effect on our business. Our site in Gillingham, for example, is a key distribution centre within Merck Life Science's European distribution network. With a catalogue of over 300,000 product lines, our Gillingham site supplies labs in almost every university in the UK. This supply is reliant on the constant flow of life science products to and from our Gillingham distribution centre. Additional costs incurred to bring supply into the country, whether directly as a result of tariffs or as a result of broader disruption to the flow of products, may have to be passed on to publicly funded organisations, including universities.

7.13 Merck has conducted an initial analysis of over 6,900 products from the Life Science division of the business, which were imported from the EU to the UK during September 2016. The current World Trade Organisations tariff rate for importing to the UK from a country outside the EU was applied to each product code to provide a "snapshot" of the potential cost should WTO rules be applied post-Brexit. The results are detailed below:

7.14 *Table 1: Analysis of September 2016 Life Science restock shipment of EU imports to the UK*

	September 2016	12 month extrapolation (using Sept 2016 tariff data on actual 12 month import value)
Value of imports to the UK	£2,343,461	£45,000,000
Cost of tariffs had the UK been operating under WTO rules	£82,777	£1,589,514
Average increase in cost of imports to the UK due to tariffs	3.53%	3.53%
Average WTO tariff for imports to the UK	3.76%	3.76%

7.15 It is clear from Merck analysis above that if WTO rules were to be applied post Brexit, there would be a significant impact

on our operations in the UK and this would likely be reflected across the sector.

7.16 Merck would also welcome reassurance from the Government that maintaining the 0% pharmaceutical tariff agreement (currently under the pharmaceutical elimination agreement) is a priority in trade negotiations, and that the impact of tariffs on chemicals and consumables for research and manufacturing within the wider life science ecosystem is considered.

Potential challenges to bringing highly skilled talent into the UK

7.17 Merck's businesses across the UK benefit from highly skilled EU nationals, both for specialist posts where there may not be sufficient UK nationals with the requisite skills and experience, but also as part of a wider global talent programme which sees senior leaders from the UK undertaking postings overseas and vice versa. Merck BioReliance in Scotland has recently brought in several EU nationals for specialist senior scientist and laboratory posts. Some 30-40% of the highly skilled researchers at our Performance Materials global R&D hub in Southampton are EU nationals. We would like to be able to access this talent at low financial and administrative cost, whilst also supporting the UK to upskill its own workforce to help address gaps. We would also welcome steps to ease the administrative and cost burden of bringing non-EU workers to the UK.

7.18 Recommendations:

- Merck is committed to the UK. However, Brexit is creating significant uncertainty over a range of issues, including access to sufficient talent, the regulatory environment, the supply chain and R&D funding. Action is needed to ameliorate these concerns and ensure that the already tough commercial environment for the pharmaceuticals element of the life sciences sector does not become more difficult as a result of Brexit.
- We look forward to the life sciences industry being a priority in the Brexit negotiations and subsequent trade discussions, per the Government's stated ambition, in the interests of British and European patient safety and public health.
- The Government should seek an MRA to maintain continuity of supply following the UK's exit from the EU and protect the life science industry from disruption that can result in lost revenues.

Question 17. How should the regulatory framework be changed or improved after Brexit to support the sector?

7.19 Merck welcomes the Life Sciences Industrial Strategy's position on the UK's regulatory framework for life sciences after Brexit, stating that the focus should be on alignment with the EU in order to deliver the best decision-making for patient safety.

7.20 Merck agrees with the strategy's sentiment that developing an innovative regulatory approach to emerging life sciences technologies outside of the EU would not be worth pursuing if it jeopardised the UK's participation in the EU systems and processes.

7.21 Merck also believes it is crucial that once the UK is outside the EU, the UK attempts to maintain the current balanced approach to data sharing regulations.

7.22 Recommendations:

- Continued close alignment with the EU regulatory framework will help to ensure ongoing safe decision-making on new products. Adopting a new regulatory framework after Brexit should not be pursued if it endangered the UK's participation in the EU regulatory frameworks.

8. Conclusion

8.1 Merck believes that in implementing the recommendations set out in the Life Sciences Industrial Strategy, Government should aim to facilitate an environment which supports businesses like Merck to make further investment in the UK, furthers the UK's productivity and future economic prosperity and improves patient access to innovative medicines.

8.2 This means a sector deal should support access to a highly-skilled workforce, effective international trade and knowledge exchange. Any deal must also recognise the challenges facing the sector as a result of the ongoing uncertainty created by Brexit.

8.3 For the strategy to be successful, all relevant government departments, its arms-length bodies and the NHS must take it forward together as a major priority. Engagement with industry also needs to be broad for the plan to be delivered, and representatives from across the health sector should be involved in discussions from the start.

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