HOUSE OF LORDS

Select Committee on the European Union

Goods Sub-Committee

Corrected oral evidence: Beyond tariffs: facilitating UK-EU trade in manufactured goods

Monday 22 June 2020

10.30 am

Watch the meeting

Members present: Baroness Verma (The Chair); Lord Berkeley; Baroness Chalker of Wallasey; Lord Faulkner of Worcester; Lord Inglewood; Baroness Kramer; Lord Lamont of Lerwick; Lord Lilley; Lord Russell of Liverpool; Lord Shipley; Lord Turnbull; Lord Wood of Anfield.

Evidence Session No. 4 Virtual Proceeding Questions 40 - 53

Witnesses

I: Dr Louise Gill, Head of Policy, Global Regulatory Affairs, GlaxoSmithKline; Richard Ayton, Director of Government Affairs, Dow Chemical UK and Ireland.

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Examination of witnesses

Dr Louise Gill and Richard Ayton.

Q40 **The Chair:** Good morning, colleagues. We are having an evidence session today and we have our witnesses here. Dr Louise Gill is head of policy, global regulatory affairs, at GlaxoSmithKline, and Richard Ayton is director of government affairs at Dow Chemical UK and Ireland. I would like to welcome both our witnesses here this morning. This is a live broadcast. There will be a transcript, which will be sent to you after the session. If you feel that any corrections need to be made, please make them and send them back to us as quickly as possible.

Colleagues, you will have all received the questions that you will put to the witnesses. If other colleagues wish to come in with supplementaries, it would be very useful if you could signal so that we keep the session as smooth as possible during this time of Covid. It is unusual for all of us to be coming in on Zoom.

Thank you very much to Dr Gill and to Mr Ayton for coming in. To start the session, I will ask both of you if you would like to make a small opening statement. I would also ask all colleagues to keep questions as crisp and precise as possible, and witnesses to do the same in their responses.

Dr Louise Gill: Good morning and thank you for the invitation to give evidence today. GlaxoSmithKline is a research-led healthcare company that produces medicines, vaccines, consumer products and devices. We are a global company with research and development and manufacturing sites, not only in the UK, but in Europe and other third countries.

Richard Ayton: Good morning. I would also like to thank you for the invitation. I work for Dow, which is a leading global chemicals and materials science company. It is US-based but has major facilities around the world. Our largest plant in this country is a strategic silicones facility in Barry, South Wales.

Q41 **The Chair:** You have had sight of the questions already, so I will start with the first one. How will non-tariff barriers affect your businesses at the end of the transition period? How costly will it be?

Dr Louise Gill: We want to ensure the ease of movement of goods across borders and swift access to our products by both patients and consumers. This is our priority.

On costs and numbers, the European Federation of Pharmaceutical Industries and Associations has noted that, every month, 45 million patient packs are supplied from the UK into Europe. Similarly, 37 million packs are supplied from Europe into the UK. Non-tariff barriers will introduce additional processes into that movement. Of note is the requirement for duplicate testing. The European Federation of Pharmaceutical Industries and Associations is conducting a study looking at the cost estimates in relation to the free trade agreement and the introduction of a mutual recognition agreement. This will be published in

the coming weeks and we will be happy to share the data, once published, with the Lords.

Preliminary draft data that I can share today shows that pharma exports are expected to drop by 22.5% with no deal, 22% in a simple free trade agreement without mutual recognition, but only 12.6% where we have a free trade agreement and a mutual recognition agreement. It would reduce the loss of exports by around €2 billion per year for the UK if we can have the free trade agreement and mutual recognition agreement.

Additionally, due to the WTO zero-for-zero agreement that puts tariffs almost to zero for pharma products, a tariff-only deal will not do much for our industry. The biggest impact for our sector is having a mutual recognition agreement that supports good manufacturing inspections and allows the acceptance of batch testing performed in either the UK or the EU.

Richard Ayton: We are a very trade-heavy company. Almost all our production in the United Kingdom is exported, and a very large proportion of our sales in the United Kingdom are imported. Over 700 suppliers from the United Kingdom supply our facilities in the European Union, so it is clearly a very significant issue for us in terms of both tariffs and non-tariff barriers.

I would underline two particular issues on the non-tariff front. The first is customs and the flow of goods, which I know we will discuss in more detail. The second, on the regulatory side, is REACH, and I have plenty to say on that, too. Those are two very important issues for us. There is no doubt about that. Our trade body has come up with some numbers for the potential impact, particularly on the REACH side. For a company like us, it will clearly be a very significant cost.

The Chair: If you had the opportunity to go back to the Government and pose one specific question to them, what would it be?

Richard Ayton: My question would have to be on intentions and timeframes, because we are already at the stage where we are looking to source materials. We need to understand, if possible, what the intentions really are and at what point we will have some certainty about the terms on which we will be importing and exporting from this country.

Dr Louise Gill: In addition to what Richard said, we also want clarity on the guidance that, from a regulatory perspective, would support in particular the supply of goods to Northern Ireland.

Q42 **Lord Lamont of Lerwick:** Could you say a word about the preparations that both your firms have made for the end of the transition period? Louise, you outlined three different scenarios. Presumably, you have had to make preparations as best you can for each of those different scenarios. How have they gone?

Dr Louise Gill: Our overriding priority in our preparations is to maintain continuity of supply of our medicines, consumer healthcare products and

devices to patients not only in the UK but in the European Union. We took a risk-based approach in planning and mitigating, and I am pleased to confirm that we now have our new post-Brexit operating model in place.

In order to achieve that, we needed to put a significant amount of work in place. To give you an idea of scale, just in my area, from a regulatory perspective, we had to transfer more than 700 marketing authorisations: that is, the owner of the product licences. We had to adapt more than 5,000 packaging components for our products. To implement duplicate testing capabilities for both our marketed products and clinical trials, this required more than 1,000 regulatory approvals to be obtained.

Additionally, we have put support in place for our employees who are personally affected, to help them with their residency status and to enable them to remain either in Europe or in the UK. We have had to ensure that we have the right capabilities and capacity in the right locations and in our manufacturing sites to implement our post-Brexit operating model.

One concern, which is out of our control, is disruptions at the border. A number of our products need to be transported through temperature-controlled shipments, and any delays could impact the integrity of our products. This is of particular concern in relation to clinical trials, where we typically have limited material available.

Richard Ayton: We have had a taskforce-style team operating on these issues for the best part of two years. That has involved a very large amount of analysis of trade flows, as well as of the risks related to REACH registrations. At various points during this process, we changed the modes of transport and our storage and sales strategies to mitigate the risk. We have set ourselves up in a very good position to know where the risks sit, but for various reasons, particularly on the REACH front, it is very difficult for us to know the exact detail of the issues we will face. We will not know that until the dust has settled on the new normal, and I am happy to explain why that is when we discuss REACH. We have done a very large amount of work on this.

Lord Lamont of Lerwick: You mentioned at the beginning mutual recognition as your first concern. Can you say where we are on that and what the Government tell you about what they would like on that? What is the likely outcome?

Richard Ayton: In terms of mutual recognition, on the regulatory front we work very closely with the European chemical trade body, Cefic, as well as the Chemical Industries Association here. We are looking for data sharing at this moment, which is recognition that there will not be associate membership of the European Chemicals Agency but that the British Government will need a system in place to discharge the statutory duties on chemical regulation and will need the data to discharge those duties.

The data-sharing proposal which Cefic has submitted to the Commission is based on Article 120 of the REACH regulations. That data-sharing status has not been achieved in prior free trade agreements or agreements related to mutual recognition; it is, on a qualitative basis, a new level of co-operation with ECHA. It is one that is foreseen very clearly in the REACH regulations, so there is a basis for that. That really is what we are focused on.

Dr Louise Gill: In the pharmaceutical industry, our focus in mutual recognition is alignment on an acceptance of good manufacturing practice and batch testing of our products in one jurisdiction by the other. These asks have precedent and are part of the mutual recognition agreements that Europe already has with seven other countries: Canada, Australia, New Zealand, Israel, Switzerland, Japan and the US. We are really pleased that the UK has rolled over most of the mutual recognition agreements with those countries, but we would see significant benefit in having mutual recognition with Europe. I would like to note that this does not have to be part of the free trade agreement, but it could be done as a technical agreement outside a free trade agreement.

Q43 **Lord Inglewood:** You have told us a lot about the problems that you and your industry will face. In particular, you have touched on issues relating to mutual recognition. Could you each give us an idea of which, for you, taken in the round, are the most important problems you are currently facing in response to what the new world may be beginning to look like?

Richard Ayton: The biggest problem that we are facing is the REACH issue. It is an issue of registrations of chemicals and the duplication of data dossiers. In brief, these dossiers are very complex documents based on a large amount of research, and duplicating a dossier is a big task if you have to go about it. These dossiers are held at ECHA for each substance. They are not the property of ECHA; they are the property of consortia of companies that submit them. If you want access to these dossiers, you have to agree access and obtain a letter of access to that dossier from its owners, which will be a consortium. That consortium might, in the contractual arrangements that established it, have a restriction that it be shared only within the European Union. That exists, so that has to be dealt with.

We will not know what the costs for each letter of access will be until we apply for it. The costs change and are dependent on the nature of the substance, on the volume band and on the nature of the registrants. That dossier might have cost £5 million to put together for one substance.

In terms of timeframes, if you have to do a cancer study as part of that, it would take two years. With the timeframes involved in the United Kingdom REACH regime coming in, and the need to register substances with the British regulator, that brings up a wide range of issues, some of which might not be solvable.

We have a very large number of registrations in the European Union, but we will have to register substances that we are not the registrants for, because inevitably we will have to register for some customers who do not have the capacity to do that. We will have to register some substances simply because we do not want to give out business-critical information that will allow someone else to do that.

There is a very large burden, and an idea of confidential business information is central to that. Even if that data is shared with the British authorities, there then comes into play not only a confidentiality requirement but the ownership requirement that this data needs to continue to be owned by the consortia in the European Union that came up with these dossiers. That ownership needs to be maintained, so there is an IP element there.

Quite a few things could be done to ease that burden. For instance, within the British system there could be the ability to consolidate importers, rather than having separate registrations for each importer. There could be a differentiation of timeframes on the basis of volume bands. ECHA has four volume bands, which relate to the quantity of material being shipped. There are different things that I know are being considered and discussed. Particularly given the global tariffs that have been announced by the United Kingdom, which have gone some way to mitigate our risks related to tariff costs for imports into our plants there, the regulatory issue really stands out on its own as a very significant one for us. There are also things about customs, but REACH is the biggest one.

Dr Louise Gill: One of our key areas of concern is borders and customs as well as the technical regulatory processes, especially in Northern Ireland. The UK issued technical guidance in preparation for no deal at the end of last year. This has been withdrawn. We would really like to see it reinstated as rapidly as we can and with minimal changes included in it. This is particularly important if there is no deal and no mutual recognition by the end of this year.

To cite three areas, for products that are currently reviewed and assessed by the European Medicines Agency on behalf of Europe as a whole, we will need to register those products in the UK under a UK licence. We need guidance on how to do that. We may have products that are under assessment in Europe at the end of this year. To ensure that UK patients have similar and timely access to those new products in conjunction with our European patients, we would really like guidance to be issued on how to manage ongoing applications and variations.

Finally, the UK Government had issued some good guidance on supporting implementation periods to give industry time to implement the changes that it could not necessarily make prior to leaving Europe. This could, for example, be changing administrative information on a patient leaflet with the new marketing authorisation holder, which for us is just a different name of one of our companies. It causes no risks to patients by having these administrative changes phased in over time.

Lord Inglewood: One thing that struck me, particularly with Richard's evidence, was the potential role here of IP. As the jurisdictions diverge, will IP become an increasingly difficult issue for you in this context?

Dr Louise Gill: I am not an IP expert, so I would need to take that question away and come back to you separately.

Richard Ayton: With strict regard to REACH, clearly this issue needs to be dealt with. I would not be able to give you any more valuable indication of IP in general. I would have to do that in writing.

Q44 **Lord Turnbull:** Can I come to issues of governance? One of the trickiest items in these negotiations is dispute resolution: who has the right to rule on something and who can arbitrate on it. Is it the Commission, the ECJ or something different? Mutual recognition, as Dr Gill told us, can be very important, but who affirms that there is equivalence and who can withdraw that if we move away with regard either to product specification or to rules of origin?

Are there any lessons to be learned from how other trade agreements deal with this? The key issue here for both the chemical and pharma industries is that Switzerland is a major player but not an EU country. Can we learn anything from how it has reached these various agreements with the EU that we can adopt for ourselves?

Dr Louise Gill: We certainly can learn from the mutual recognition agreements that have been put in place. I have referred to seven examples of where Europe and third countries have come to an agreement on how to implement mutual recognition. One of the key points for us is that good manufacturing practice aligns itself with global standards. If we can align on global and international standards, it helps to ensure that we have that alignment and that it is not just an issue between Europe and the UK. We are talking about international standards. We would encourage the UK to align with international standards and be a party sitting at the table, at, for example, the International Council for Harmonisation[1].

Richard Ayton: I thoroughly agree with what Dr Gill has just said on the need to focus as much as possible on international harmonisation. Some agreements have helped Switzerland in simplifying certain aspects of trade. The EUROMED agreement on rules of origin[2] has allowed the harmonisation of terminology, which certainly helps us in many ways. Our European structure is based in Switzerland, so we have quite a lot of dealings with Switzerland.

In terms of further treaties, many treaties involve bilateral dispute resolution bodies. I have talked about data sharing, but none of the agreements has reached the level that we would like to see on that particular issue.

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[1] The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

[2] Regional Convention on pan-Euro-Mediterranean preferential rules of origin

Lord Turnbull: We have six months left until the end of the transition period. Are you optimistic or pessimistic that the necessary agreements on mutual recognition and the governance of them can be reached in that time?

Dr Louise Gill: I am always an optimistic individual and I would urge both Europe and the UK to continue to drive forward to get agreement. For us, as I have highlighted, mutual recognition does not have to be within a free trade agreement; it can be agreed as a separate annex. We have examples of where these have been agreed with other countries, so we should be looking at and using the information and agreements of other companies to enable us to have a swift agreement, particularly on the mutual recognition of good manufacturing performance and batch testing.

Richard Ayton: I come back to data sharing rather than mutual recognition, but in the case of chemicals they are intrinsically linked. Because of the presence of Article 120 in the REACH regulations, it is very easy, in treaty terms, to achieve. It can be an exchange of letters; it does not have to be in the agreement. We hope that there would be a chemicals annexe in the agreement, and if it can be in the agreement, all the better, but in technical terms it is not difficult. I am optimistic about getting to that point. We are, however, planning as far as we can for that not to be the case.

Q45 **Lord Wood of Anfield:** I wanted to ask specifically on governance arrangements about the apparatus for market surveillance that will be in place. What form should market surveillance take in your sector? How confident are you that that apparatus will be put in place? With your sector being so central to the public health issues at the moment, there is great concern that any post-Brexit arrangements are not to the detriment of public health and safety. Are you confident that that will also be the case?

Dr Louise Gill: We believe that there is definitely a benefit for the UK and Europe to co-operate on the sharing of data for safety requirements, and particularly post-marketing. The UK has been a key contributor of data into the European system. As a company, we will submit our data to every regulatory authority, in line with national requirements, but we believe that there is a public health benefit in sharing and having access to collective data.

In the event that this is not achieved, the MHRA[3] will still have access to data that we, as individual companies, submit. It can also access the WHO databases. This is definitely an opportunity to encourage Europe and the UK to continue exploring in order to enable us to share data and expertise, not just between the UK and Europe but when looked at from an international perspective, as you quite rightly note the current situation that we are in.

[3] Medicines and Healthcare products Regulatory Agency

Richard Ayton: There are two aspects to market surveillance. One is the functions conducted at present by the Health and Safety Executive, and I am sure it will continue the high standard of inspections and the control of chemicals per se within the country.

One concern might be if we do not have an agreement on data sharing and British regulators lose access to ECHA data. It would be for them to say to what extent they have a concern over the period between losing access and dossiers being submitted to them in full. They would have those dossiers on new chemicals, but if the ones that are currently registered are registered in Europe, and we rely on the grandfathered rights of ECHA registrations, that is the crux of the policy issue about data submission to the new chemical regulatory body in this country.

Q46 **Lord Wood of Anfield:** Louise, you mentioned data sharing through a WHO framework rather than through bilateral EU-UK agreement frameworks. For a lay audience, of which I am certainly a member, can you give us a sense of what proportion of data sharing would happen across European countries anyway through membership of the WHO, which does not require a separate bilateral agreement? In other words, how central is the bilateral agreement, particularly with Covid and other health-related issues, to enabling the free flow of data sharing that will be needed, over and above what the WHO membership already demands?

Dr Louise Gill: I am not an expert on pharmacovigilance and I can follow up, if needed, with some specifics. Companies are required to upload and share a greater level of information through the European systems versus the information which the MHRA can access through the WHO systems. If you would like me to come back with some more information on those differences, I can do so.

The Chair: That would be helpful. Lord Wood, would you like Richard to do the same?

Lord Wood of Anfield: It is less central to Covid, but it would be interesting from his sector, as it is such a crucial one.

Q47 **Lord Lilley:** Are there any areas where either the EU or the UK should be more ambitious in their negotiating offers and requests, particularly in areas of regulatory co-operation?

Dr Louise Gill: Our ambition is to see more global alignment and co-operation across all regulators. We have seen the value of that in our current situation. There are a couple of bodies that it is important for the UK to either join or continue to be part of. One is the International Council for Harmonisation, which we would encourage the UK to apply to and be a member of, so that it can be at the forefront of shaping regulatory guidelines and support harmonisation and alignment globally.

The organisation of which the UK is already a leading member, and we would encourage it to continue, is the International Coalition of Medicines Regulatory Authorities. Last year, the UK chaired this authority. This is

another body where it would be important for the UK to have a driving seat, to be influencers in that global community.

Lord Lilley: In this country, we often criticise the EU for regulations in other spheres that ultimately come from the international bodies that you have just mentioned. In pharmaceuticals and chemicals, do these international bodies lay down some rules, the EU puts them into legislation, they apply in the UK, and we blame the EU for any difficulties that originated at an international level?

Richard Ayton: There is a UN process at the moment that is focused on chemical management. That will not supersede the current European measures. If anything, with chemicals, it is almost the opposite. Europe is actively driving regulation globally on this issue. It is exporting its regulatory model on chemicals through its free trade agreements and has done so with South Korea, which also operates a REACH system based on the precautionary principle rather than the risk principle that you would find in the United States. In the chemicals sector, the European Union is driving international standards to some extent rather than the other way round.

Lord Lilley: I used to represent a constituency in Hertfordshire, where lots of people work in the pharmaceutical industry. They used to lobby me on things like the clinical trials directive and the pharmacovigilance directive. Will we be able to amend how we work in those respects when we leave? Will it have consequences on cross-border trade if we do?

Dr Louise Gill: The European clinical trials directive is what we use as the basis for registering clinical trials and for our pharmacovigilance guidance in the UK. When we leave, the UK will have the right to amend legislation to potentially create opportunities. We would encourage the UK to consider continuing to align on global standards. If there is a process that is more advantageous or that would make the UK seem more attractive for companies conducting clinical trials, we would suggest, this would be an area of focus, while maintaining alignment with the global regulatory standards on what we need to provide to support the clinical trials.

Q48 **Baroness Chalker of Wallasey:** There is a danger of no agreement on regulatory co-operation, but what consequences might this have for the UK and the EU? Is it true that product availability will be affected? That seems the most likely outcome to me, so we have to examine this.

Richard Ayton: There will be an issue of product availability. That will not come from the company I work for. We have a lot of capacity to deal with a lot of these issues, which smaller companies might not have. With registrations, part of the problem is that until you go into the new normal on a customs and supply chain basis, and until the dust settles on what will inevitably be a certain amount of shakeout on supply chains because of tariffs and border controls, it is difficult to say exactly which suppliers will continue to supply what and to whom. That is one of the issues we face when we are dealing with our very large number of suppliers.

Will products be withdrawn? Inevitably, there will be companies that might not find it economic to move certain products. A tariff of 6.5% for commoditised products might be higher than the margin on a particular product, some of which are pretty thin. Add to that a regulatory burden, the need to submit registrations to operate an only representative in the European Union or in the United Kingdom, and the customs-related costs, and you might well have issues with availability of certain products that are not made in this country.

Will it go both ways? It might well. The potential for it being more of an issue in this country perhaps just comes from the scale of the Europe-based chemical industry. I could not tell you exactly how that will play out. As I said, it is difficult to say how it will play out.

Dr Louise Gill: In addition to what Richard has said, as I have touched on, having global regulatory alignment makes it much easier for us to do studies that can then support submissions throughout the world.

There is another area that I would like to note. The European Medicines Agency has cluster meetings with other third-country agencies such as the US Food and Drug Administration. If the UK could join this and sign the appropriate confidentiality agreements, it would also help the MHRA be part of those discussions with the other key regulators to discuss various aspects of the development of our products.

It is also worth noting that regulatory approval is only one part of doing our business in our country. Countries need to consider the end-to-end process to ensure that patients get timely access to medicines. We need to look at the whole process in the UK and the attractiveness to support the future.

Q49 **Lord Shipley:** What unilateral measures might the UK take to reduce the regulatory barriers to UK-EU trade in both your sectors? Put another way, why do we not just recognise EU standards?

Richard Ayton: There are two things here. Strictly on the regulatory front, it brings us back to what I said earlier about the role of the British regulator and its need for the appropriate data to discharge its statutory duty. It could be possible for Britain to recognise ECHA registrations and to have a system in place, under another article of REACH, with ECHA, whereby it would verify that a registration exists, and you would have the summary data for that.

If British regulators thought that that was enough, you could pursue a much lighter road of regulatory burden, but that is a very important policy issue that needs to be decided by those who are politically responsible for chemical management. The answer that they have given thus far has certainly been that that would not be enough. If that is not enough, it inevitably drives you to the position where you have to have all the data here. At that point, the only fire exit out of the situation is Article 120 and the data sharing that I have mentioned many times before.

If I might make a very short comment on unilateral measures at the British end on customs, it would be hugely useful if the authorities here could build a package of operational measures around the authorised economic operator registration that involved the consolidation of declarations, so that we were not declaring on single shipments and could declare and pay away from the border, in arrears.

Some of these things are already available, to some extent, under the European Union's own customs freight simplified procedure, which we make use of and will widen our use of, I am sure. Some of them were announced as a temporary measure under the transitional simplified procedures that were meant to be in place in the case of a no-deal Brexit, but those have now been withdrawn.

If you go down that road, at least for bigger businesses—and I am speaking only to businesses that can maintain that AEO status—you might significantly reduce friction at the border, particularly for roll-on roll-off traffic across the short straits, which would be useful.

Dr Louise Gill: I have touched on this, but one of the key areas is reinstating our no-deal guidance, particularly the UK accepting testing from other countries such as the EU and those listed in the mutual recognition agreements which the UK is putting in place.

Lord Shipley: Historically, the UK has been a very attractive place to do business internationally and has attracted a lot of inward investment. Given what you have said about regulatory barriers and the environment we are currently in, might they have an impact on the attractiveness of the UK as a place to do business?

Dr Louise Gill: From our perspective, we need to focus on the end-to-end process that the UK puts in place, not just regulatory approval but the subsequent steps that will allow access of product to patients in a timely manner.

Q50 **Baroness Kramer:** This may be a question only for Mr Ayton, although, Dr Gill, please come in if you think it is relevant. I am asking about rules of origin, and with the pharmaceutical tariff elimination agreement there is probably not much relevance to the pharma sector. I understand that there are chemicals in virtually every product manufactured in this country or across the EU, often with very complex supply chains, the criss-crossing of borders and a great deal of value adjustment. Could you help me understand what you need to see on rules of origin in the agreement?

Richard Ayton: It is a very important issue, because the rules of origin determine whether any of the other agreements that you come to on the tariff front can be effectively used. Our position on rules of origin is that we favour harmonisation and simplification, not just in the terminology but in the implementation of those treaties. For instance, the EU-Japan treaty has quite simple criteria terminology, but we have found it very difficult to incorporate into our systems the required information to take

advantage of that, because it requires a slightly higher standard of information on the declaration. We have not been able to resolve that fully, despite that agreement having entered into force some time ago, and we know that that is not just an issue for us.

We would like to see simplification. We would like to see harmonisation. The British have an opportunity. It might conflict with the time pressures over the conclusion of these free trade agreements, but they have an opportunity to ensure that we do not have a situation like the one with the European Union where there are different treaties with different qualification criteria and different declaration procedures. Some require you to be a registered exporter; some require you to be an authorised exporter. You have to know and work through all these, which, for a company that has a dedicated preferences team, is still complex but is possible. For companies that do not have people dedicated to those issues, it will be very difficult. That might well apply to some of our suppliers and customers.

Those are the main issues that we would always bring up when we are talking about that and perhaps point to different treaties that would more or less meet those requests. CETA is quite good in the breadth of criteria that it allows and the different qualification criteria that it includes. Britain's agreement with Korea is very simple in that regard but is much more restrictive in the criteria. You have to work through all of these.

The proof of the pudding on these free trade agreements and on rules of origin is always in the eating. If it is really difficult to implement and to meet those criteria on a day-to-day basis, you have a situation where a very large amount of your exports might not even be exported under the terms of the free trade agreement and people will end up paying duty.

I seem to remember that in the note to Britain's free trade agreement with South Korea from the DIT only about 60% of exports from Britain to South Korea were duty-free, even though they were eligible to be duty-free.[4] That is simply money down the drain from a corporate perspective.

Baroness Kramer: You mentioned earlier that the situation for small manufacturers is very different from that of big manufacturers such as Dow. Does the rules of origin problem, if not adequately resolved, mean that you will change the character of your supply chain? Is there an implicit risk to small British suppliers that form part of that supply chain at present?

Richard Ayton: You are right. Of course, if it is difficult to meet the criteria and to make the declarations, it will probably have an economic impact on the cost of the products being supplied by smaller companies,

[4] Note by the witness: The DIT document 'Continuing the United Kingdom's Trade Relationship with the Republic of Korea', September 2019, states: 'in 2016, the evidence suggests that 62% of the UK's eligible goods exports to Korea (defined as those which occurred under tariff lines where a preferential rate was offered under the agreement) actually utilised the tariff preferences'.

particularly if they are still paying duties. It really shows that there has to be a simple procedure and government support for companies to understand that and to be able to take advantage of these agreements.

Q51 **Lord Faulkner of Worcester:** I would like to ask you both about the impact of the likely new UK-EU customs checks at the end of the transition period. What effect will they have on your businesses? What are your specific concerns about them?

Dr Louise Gill: As I mentioned previously, GlaxoSmithKline has done everything it can to prepare for the end of this year, but borders are one of the areas that are out of our control. We want to ensure that there is ease of movement of goods across the border, without delays. I touched earlier on the impact on temperature-sensitive material. We import and export globally, so we will be able to handle the additional checks but we need this process to be easy and smooth. We would like to further understand how the process will work at the borders.

Lord Faulkner of Worcester: But you do not know yet.

Dr Louise Gill: No.

Richard Ayton: I have already talked about the authorised economic operator scheme and how it might be used as the basis for ameliorating some of the issues that might arise. We are concerned about the border. We use the short straits a great deal. We also have container traffic coming in and going out. We have a considerable quantity of goods going into and out of the European Union every month. At our plant in Barry, the greater part of that material goes for finishing in Belgium, and a chunk of that will come back for sale to British-based companies, so there will be this backwards and forwards, which a lot of companies have.

On the impact of that, we make 200 to 300 declarations a month at the moment, and we would expect that to increase perhaps four to fivefold. Say we have an extra thousand declarations a month, which admittedly would be in the higher range, although it makes it easier to calculate the impact. If each declaration through the broker was costing £50, we might be paying an extra £50,000 a month simply on the broking.

We have concerns about capacity and infrastructure, like everyone. It is an industry-wide question. But in addition to the broking costs per se, we also have to employ extra people to manage the broking relationships. Something that will have an impact on smaller businesses also needs to be recognised. We manage a bonded warehouse and we also have an inward processing relief licence for one substance that goes into Barry. We have to make sure that these declarations are correct, so we have to check them. The broker does not just get on with it and we do not have to check these things. We have to check them, because the liability as far as Her Majesty's Revenue and Customs is concerned lies with us. We will have to have additional headcount. We have a large logistics team. We will be able to shift from one mode to another, from one port to another, so we will do our best to make sure that that works.

One specific issue that thankfully was resolved with the good offices of Defra last year, and which was critical to us, was the arrangement for the licensing of hazardous waste across the border into the European Union. We ship used sulphuric acid to Germany, where it is recycled and returned fresh to Barry. That is not available in the United Kingdom as a service. We would have to burn it, or have it burnt, as waste in the United Kingdom if we did not do that. It requires specialist tanks, which we own, and special routes that cannot be diverted from, so there is limited ability to mitigate that by choosing other options. The licences are in place and you have to follow that set route. That is a critical waste stream for the plant in Barry, so we will make preparations for storage and other things if there are delays.

We will work to mitigate as much as possible, but a whole range of issues arise, from cost to practicality to supply.

Lord Faulkner of Worcester: You have answered what was going to be a supplementary question and anticipated what the additional cost would be, but maybe I could ask Louise that question. Can you say how much the customs checks would add to your business?

Dr Louise Gill: Unfortunately, I cannot. I am not a customs expert, so I cannot answer that question.

Q52 **Lord Berkeley:** I apologise for not being present at the start of the meeting.

Following on very briefly from Lord Faulkner's questions, Richard, you have given us a good idea of the extra costs that are likely to be incurred. Presumably there is a bit of extra stockpiling as well in case there are delays at the frontiers. You will recall the Prime Minister saying in the last week or so that if there was a problem at the end of the transition period he would be pleased to relax all border customs checks for a certain time until everybody got used to it. How would that affect your businesses? Of course, he is only able to do it in one direction.

Richard Ayton: To the second part of your question, we will work through the European chemical trade body, Cefic, to engage in Brussels on the European systems as well. Some of the so-called easements that will be in place early next year, as I said earlier when I was talking about the authorised economic operator model, could be incorporated for AEO holders into a more permanent system, which we would certainly welcome, for how and when declarations are made, and when payments are due. Ultimately, even if there is a delay, we will still have to submit all these declarations, which we will do with a high level of compliance, as we would, unquestionably, with these sorts of issues.

The biggest problem is almost certainly in the short straits and with roll-on roll-off traffic. It is probably slightly less of an issue with container traffic coming in. Where the Government can do anything to ensure that that flow is kept going and that the infrastructure is in place, it is not news to anyone that we would support that, and I am sure that the whole of industry would.

Lord Berkeley: Do you feel the same way, Louise? It is a different business but there is still all the paperwork to do and it will cost more, as you have both said. Will it cause more stockpiling and more delay, especially if the initial easing of restrictions only happens in one direction?

Dr Louise Gill: In terms of stockpiles, we aim to make our stock available to satisfy normal demand for patients across the globe, and to ensure consistent and fair distribution of medicines and consumer healthcare products. We have extensive experience of managing our complex supply chains. In situations where we may face delays, we will take mitigating actions for products whose supply may be affected. If we anticipate issues, we will inform and discuss options with the regulator at the earliest opportunity. That is the only additional point that I wanted to bring up over and above the comments Richard made.

Q53 **Lord Russell of Liverpool:** I have four related questions. First, in your internal discussions in your business, how likely do you, your colleagues and your leadership team think a no-deal result is? Secondly, what would the consequences of that be for your business? Thirdly, do you feel you are prepared for that eventually? Fourthly, if that is the case, what is the least amount of time that you need, in the worst-case scenario, to prepare for no deal?

Richard Ayton: In the first instance, our preparations are, in general, based on an assumption of not having a free trade agreement, to the extent that that helps us identify risk and understand where it sits. I have always squashed any internal demand for percentages or likelihood on the basis that it is better for us to prepare for the worst case of the likely scenarios. That, essentially, is my position and I will stick to that.

We have covered quite a few of the consequences of not having a free trade agreement. For a period, in terms of REACH, there would be grandfather rights, so it is not an immediate issue that would arise on 1 January, but if not having a free trade agreement also means not having a data sharing agreement for REACH, that would be a very significant issue. The costs involved in that, as well as the effort and time, would be substantial.

In terms of customs, there would be an issue if there was no free trade agreement. I know we are not talking specifically about tariffs, but as I said earlier, the consultation on global tariffs, although very quick, allowed us a good opportunity to engage with the Government. The tariff position with regard to our production in the country has come out of that pretty well, but it goes only some way to mitigating the tariffs that we will have to pay, particularly if the European Union applies full Union code tariffs on our products going in.

Are we prepared? We are prepared to be prepared, I would say. We know where the risk sits. We have done a lot of work in a number of areas. Our project team is meeting this afternoon, following the decision to officially rule out an extension to the transition, and we will probably meet

monthly. We understand where the risk sits, as I said. The problem we have is that, until the new normal is in place, we cannot know the detail of the consequences of those risks.

In terms of timing, I have to say we are already starting to sign sourcing arrangements now for next year into the country. We are doing that on the basis that the new global tariff will be in place. That is already impacting our supply chain and the assumptions that that implies. We need to know, as everyone does, as soon as possible. That is not in the gift of the Government.

However, we still want a deal. If time needs to be taken to achieve a free trade agreement, I would not say "walk away now, because it would give us six months to prepare for no deal". If there is a credible chance of a free trade agreement, we would support the Government making every effort to achieve that.

Dr Louise Gill: I would support what Richard has just said. Again, in terms of waiting for a free trade agreement, as we have noted, we could achieve some of our key asks in relation to mutual recognition agreements outside a free trade agreement and therefore implement those more rapidly.

GlaxoSmithKline feels prepared for a no-deal outcome in the areas that I have previously addressed. Our main concern is the process at the borders and the impact on supply of material into Northern Ireland. As a global multinational company, we have always said that, over the long term, the UK's exit will not have a material impact on our business. However, as a science-led healthcare company, we continue to believe that there is mutual benefit in scientific and technical collaboration and co-operation in the interests of patients and public health. Therefore, we would support pursuing the deal by the end of this year.

The ideal lag time depends on what we need to implement. The issue is the unknown areas around Northern Ireland and the border. Until we understand the detail of what we will need to do, it is hard to comment on the lag time that we would need to implement.

The Chair: Colleagues, that brings our evidence session to an end. I want to thank our witnesses for joining us this morning and giving us a very candid, frank view from their different perspectives. Once again, if, when our witnesses receive the transcript, there are any corrections to be made, please send them to us as quickly as possible. Thank you very much again, Richard and Louise, for joining us this morning.