BioIndustry Association – Written evidence (EEH0020)

What is your assessment of the relevant provisions in the UK-EU Trade and Cooperation Agreement, and their impact on your business or policy area?

Medicinal Products Annex

The free trade agreement includes a Medicinal Products Annex. This includes mutual recognition of good medicinal practice (GMP) inspections, and includes a commitment for the UK and EU to *"endeavour to cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines including, where feasible, through the presentation of joint initiatives, proposals and approaches in the relevant international organisations and bodies…"*

The existence of this annex is positive, there were times during the negotiations when it appeared there would be no annexes due to a lack of progress on the deal necessitating a smaller agreement. Mutual recognition of GMP reduces the duplication of bureaucracy for medicines manufactured by one party and exported to the other. This allows each party to accept the other party's regulatory authority assessment that manufacturing facilities comply with GMP.

The agreement also creates a Medicinal Products Annex Working Group. This Group will oversee the articles of the annex. It will also be responsible for the cooperation quoted above. We are pleased that there will be a formal group to explore continued cooperation between the UK and EU. As yet there are no details on this group, or other structures to monitor implementation of the deal.

Horizon Europe

The trade deal was accompanied by a Joint Declaration on Participation in Union Programmes. This made clear that, subject to agreement of the deal, the UK would continue to participate in Horizon Europe. This is positive, the UK has historically benefited significantly form participation in Horizon 2020 and coordinated more Horizon 2020 projects than any other nation involved. The key benefit is that involvement will allow the UK to continue to be able to join and coordinate collaborations, working more closely on research with countries around Europe. However, while membership of Horizon Europe is positive, we note that UK SMEs will not be able to access blended finance support (equity and loans) from the European Innovation Funding Council and understand this was a UK Government decision not to seek it. This, combined with the UK's decision not to participate in the European Investment Bank and associated Fund, raises concerns about threats to the availability of equity finance for UK SMEs. The British Business Bank, which provides equity and loans to SMEs, should receive increased funds to address the potential shortfall.

Phased approach to medicines regulation in Northern Ireland

The Joint Specialised Committee announced a phased process for implementing medicines regulation in Northern Ireland, delaying the point that new medicines

regulatory requirements would come into force for 12 months until 21 December 2021. This allows companies more time to prepare for the new arrangements including requirements around batch testing and the Falsified Medicines Directive. This is helpful given pharmaceutical supply chains take time to adapt to new arrangements. Companies now have 12 months to find ways to supply Northern Ireland, solutions include supplying Northern Ireland directly or using the Common Transit Convention.

We have concerns that this 12 month period will not be long enough. Focus is currently on the 'teething problems' around customs and other issues, and issues are compounded by the pandemic. We welcome Michael Gove's recent letter to the Vice President of the EU Commission which included a request that an extension to this phased approach to ensure medicines can continue to be supplied to Northern Ireland.

What do those provisions achieve?

See above.

What, if any, challenges arise because of those provisions? How could these challenges be resolved?

Batch testing

Unfortunately, the Medicinal Products Annex failed to go as far as the draft Medical Products annex the UK had published earlier in 2020. The original draft annex included mutual recognition of batch testing certificates and mutual recognition of Official Control Authority Batch Release (OCABR). No mutual recognition of batch testing means that each batch of medicine manufactured will need to undergo a second test for quality and safety when being exported from one party to the other. This creates additional bureaucratic burden on companies, and additional delay in supply chains and medicinal products reaching patients.

The UK has unilaterally agreed to continue to accept batch testing conducted in the EU until 1 January 2023. The EU has not reciprocated.

Supplying medicines to Northern Ireland

Unfortunately, the customs and logistics issues in relation to Great Britain and Northern Ireland mean Government has not yet been able to focus on the solutions to continuing to supply Northern Ireland in the long-term. We are hopeful that immediate issues can be resolved and that an extension to this period may be granted to avoid further disruption on 1 January 2022.

Data adequacy agreement

The trade agreement is accompanied by a transition period or bridging mechanism maintaining existing data sharing requirements between the UK and EU for up to six months. This is to allow the EU Commission to assess whether it

will grant the UK a data adequacy agreement. The UK will continue to allow data to flow to the EU, or to any country the EU has recognised as having adequate data protection.

If a data adequacy agreement is not granted, then EU data exporters will need to explore a number of measures to continue to transfer personal data from the EU to the UK. This will add additional bureaucracy and the need for safeguarding checks for any organisation transferring personal data from the EU to the UK.

What should the UK seek to accomplish with the EU in relation to your industry or policy area within the parameters of the Agreement in the short- and mid-term?

Working Group on Medicinal Products Annex

The UK and EU should immediately establish a Working Group on the Medicinal Products Annex. This should be created in collaboration with the life sciences sector and regulators in both the UK and EU. This group should have an ambitious remit to cooperate and find collaborative ways to facilitate trade and joint working between the UK and Europe, while also maintaining both parties' sovereignty.

A Mutual Recognition Agreement for batch testing

The UK's made a unilateral decision to continue to accept batch testing conducted in the EU for two years, this was to protect the supply of medicines to patients in the UK. Now the negotiations are concluded, we believe the Government should announce a permanent acceptance of batch testing conducted in the EU. In addition, the UK Government should seek to negotiate a Mutual Recognition Agreement (MRA) for batch testing in addition to the free trade agreement. There is precedence for the EU signing MRAs with other third countries.

UK Domestic state aid regime

The UK has given little indication of its priorities for the UK's domestic state aid regime now that the UK has left the EU. EU State aid rules no longer apply, except in respect of aid in scope of the Northern Ireland Protocol. Subsidies instead must meet the terms of the UK/EU Trade and Co-operation Agreement (TCA) as well as the other Free Trade Agreements we have reached with the rest of the world. We understand a consultation on this will be launching in the near future.

The UK has now launched its consultation on this and we look forward to working with Government to design the future domestic state aid regime. The UK biotech sector includes a large proportion of companies which are focused on drug discovery and research, but not yet with any products on the market. Many of these treatments will become the next generation of medicines including cell and gene therapies. Biotech companies account for 80% of potential medicines in the global clinical pipeline. These companies have in the past been restricted in their access to some state aid programmes because of inappropriate rules

within the EU state aid regime. The Government should develop its state aid regime to support this sector, developing future British success stories, and delivering new treatments for patients around the world.