Brexit White Paper – The Future Relationship between UK and the EU

We now have more detail and clarity for the sector following the publication by Government of their Brexit White Paper, which you can read in full here

The Paper builds on previous Government communications and provides more public confirmation that UK Government would like the UK to retain regulatory cooperation on medicines with the EU as part of the desired future relationship.

Over the last two years, BIA has consistently advocated that Government pursue a number of policies essential to members and industry as well as patients and public health. It is good to see much of this reflected in the White Paper and it shows that the UK Government has listened to the needs of patients, public health and the UK life science ecosystem.

This a White Paper – it's a statement of policy by Government. It's not the final deal, but it does provide the basis for detailed future relationship discussions with the EU. Turning the policy into reality needs to be a priority now for UK Government in the negotiations.

Key Points from the White Paper

Economic Partnership
As outlined in the Chequers Deal, the UK proposes a free trade area for goods. The goods arrangements would sit alongside new arrangements for services and digital, "recognising that the UK and the EU will not have current levels of access to each other's markets in the future". The White Paper proposes to:

- Establish a new free trade area and maintain a common rulebook for goods, including agri-food, covering only those rules necessary to provide for frictionless trade at the border. The UK would also seek participation in EU agencies that facilitate goods being placed on the EU market, and the phased introduction of a new Facilitated Customs Arrangement (FCA). Participation would include the **European Medicines Agency** and involve "accepting the rules of these agencies", and being an "active participant" and contributing to their costs, under new arrangements that recognise the UK will not be a Member State
- Include new arrangements on services and investment that provide regulatory flexibility, recognising that the UK and the EU will not have current levels of access to each other's markets, with new arrangements on financial services
- End free movement – but establish a new framework.

1 Regulation

European Medicines Agency key points:

- Participation in the EMA
- "Accepting the rules"
- "Active participant"
- Contribution to costs
- No voting rights

- Able to conduct technical work - including acting as a "leading authority"
- Participation in other activities – including ongoing safety monitoring and the incoming clinical trials framework.

Transition/Implementation Period key points:
- All manufactured goods authorisations, approvals, certifications, and any agency activity undertaken under EU law, completed before the end of the implementation period, should continue to be recognised as valid in both the UK and the EU
- Any processes underway as the UK and the EU transition from the implementation period should be completed under existing rules, with the outcomes respected in full.

Manufactured Goods
Manufacturers should only need to undergo one series of tests in either market in order to place products in both. This would be supported by arrangements covering all relevant compliance activity, supplemented by continued UK participation in the agencies including for medicines and chemicals. Proposals cover all of the compliance activity necessary for products to be sold in the UK and EU markets – including:
- Manufacturing and quality assurance processes – including **Good Laboratory Practice and Good Manufacturing Practice**
- Role of nominated individuals – including **"responsible persons"**
- Provisions for human and animal medicines - including the release of individual batches by a qualified person based in the UK or EU, and the role of the **qualified person for pharmacovigilance, responsible for ongoing safety monitoring of potential side effects**
- Testing products to see if they conform to requirements – including labels and marks applied to show a good meets the regulatory requirements
- Accreditation of conformity assessment bodies – testing the testers within a jointly agreed accreditation framework, to provide mutual reassurance that UK and EU conformity assessments are robust
- Licensing regimes and arrangements - such as export licenses.

The UK is seeking to secure **access to relevant IT systems** to ensure the timely transfer of data between UK and EU authorities. For the EMA, seek to ensure that all the current routes to market for human and animal medicine remain available, with UK regulators still able to conduct technical work. This includes acting as a 'leading authority' for the assessment of medicines, and participating in other activities like ongoing safety monitoring and the incoming clinical trials framework.

Rules and EMA
The UK would respect the rules under which those bodies or agencies operated and the remit of the CJEU "such that if there was a challenge to a decision made by an agency that affected the UK, this could be resolved by the CJEU, noting that this would not involve giving the CJEU jurisdiction over the UK".

Intellectual Property / Unified Patent Court Agreement
The UK wants to explore staying in the Court and unitary patent system after the UK leaves the EU. The Unified Patent Court has a unique structure as an international court that is a dispute forum for the EU's unitary patent and for European patents, both of which will be administered by the European Patent Office.

Health Security

The UK proposes:

- Continuing close collaboration with the Health Security Committee and bodies such as the **European Centre for Disease Prevention and Control (ECDC)**, including access to all associated alert systems, databases and networks
- Ongoing cooperation with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Collaboration with the European laboratory surveillance networks to monitor the spread of diseases across Europe
- Continued collaboration between the EU and the devolved administrations in these areas, including direct sharing of information with ECDC and the ability for Microbiology Reference Laboratories in Glasgow, and Public Health Wales, to provide European Public Health Microbiology (EUPHEM) training.

2 Trade

Facilitated Customs Agreement

The UK proposes a Facilitated Customs Agreement (FCA), which aims to maintain current frictionless trade between the UK and EU. The proposal aims to maintain the integrity of the EU Customs Union, while also allowing the UK to pursue an independent trade policy.

- In the FCA, the UK would apply the EU's tariffs and trade policy for goods intended for the EU. The UK would also apply its own tariffs and trade policy for goods intended for consumption in the UK
- In the FCA, the UK would mirror EU's customs approach at its external border would ensure that goods entering the EU via the UK have complied with EU customs processes and the correct EU duties have been paid
- This would remove the need for customs processes at the UK-EU border, such as customs declarations, routine requirements for rules of origin, and entry and exit summary declarations
- A good reaching the UK border would pay the higher UK or EU tariff. A repayment mechanism will be in place if the good's destination was in the lower tariff jurisdiction
- The UK proposes to explore an approach with the EU using existing concepts, such as those within the Regional Convention on pan-Euro-Mediterranean preferential rules of origin
- Trusted traders, who can robustly demonstrate the destination, would be able to the correct tariff at the outset
- The implementation of the FCA would be phased and agreed between the UK-EU.

The UK also proposes a range of unilateral and bilateral facilitations, including:

- Accede to the Common Transit Convention – the application process for accession has begun
- Agree mutual recognition of Authorised Economic Operators (AEOs)
- Introduce a range of simplifications for businesses, including self-assessment to allow traders to calculate their own customs duties and aggregate their customs declarations.

Tariffs and Rules of Origin

UK proposes:

- Zero tariffs across goods (including manufactured goods, agricultural, food and fisheries products), with no quotas
- No routine requirements for rules of origin between the UK and EU

- Arrangements that facilitate cumulation with current and future Free Trade Agreement (FTA) partners with a view to preserving existing global supply chains. This would allow EU content to count as local content in UK exports to its FTA partners for rules of origin purposes, and UK content to count as local content in EU exports to its FTA partners. Diagonal cumulation would allow UK, EU and FTA partner content to be considered interchangeable in trilateral trade.

3 Movement of Talent

Future Mobility Arrangements
Seek "reciprocal arrangements, consistent with the ending of free movement" that:

- Support businesses to provide services and to move their talented people
- Allow citizens to travel freely, without a visa, for tourism and temporary business activity
- Facilitate mobility for students and young people
- Streamline the process
- Provides for other defined mobility provisions e.g. pensions.

Mutual recognition of professional qualifications
Proposes establishing a system that includes:

- Broad scope, covering the same range of professions as the Mutual Recognition of Qualifications Directive
- Includes those operating either on a permanent or temporary basis across borders.

4 R&D / Funding

Science and Innovation
The UK proposes a "science and innovation accord" that:

- Provides for UK participation in EU research funding programmes – including Horizon Europe and Euratom Research and Training Programme
- Enables continued cooperation through joint participation in networks, infrastructure, policies and agencies which are to the UK's and the EU's joint benefit – including:
    - European Reference Networks – "which support European cooperation and knowledge sharing related to clinical care and research on rare diseases"
    - European Research Infrastructure Consortia – including European Social Survey and INSTRUCT, which are hosted in the UK and promotes innovation in biomedical science by making high-end technologies and methods in structural biology available to users.
- Establishes channels for regular dialogue between regulators, researchers and experts.

Digital technology - AI
Seeks to explore new models for regulatory cooperation between the UK and the EU to tackle shared challenges and advance shared objectives in the future, such as artificial intelligence (AI). It highlights that the European Commission recently committed to set up a European AI Alliance to develop draft ethics guidelines by the end of 2018, and states that after the UK withdraws from the EU, the UK's Centre for Data Ethics and Innovation intends to participate in this.