BDI

POSITIONS | EUROPE POLITICS | BREXIT

Market Access

Challenges of Brexit for Business

27 February 2018

Core Recommendations

- Safeguard the single market for products and its integrity and efficiency as a major accomplishment of the EU.
- Keep the systems of technical products regulation including the standardisation system coherent and strictly in line with the New Legislative Framework.
- Avoid differing approaches in vehicles approval. UK law should remain strictly in line with EU automotive regulations, any deviation from EU or UNECE equivalents must be avoided.
- In aviation, retain open and liberalized market access between the EU27 and UK while ensuring reciprocity.
- In order to provide for secure access to medicaments, safeguard coherent regulation of pharmaceutical products. Keep the UK in the systems designed to protect public health across Europe.
- Safeguard supply chains for chemicals. Establish transition provisions for UK-owned registrations and authorisations and keep the regulatory approaches coherent. Avoid costly double registration or authorisation.
- Provide for a quick registration process for those EU27 companies, who may become importers from one day to the other. Check options for transfer of registrations and authorisations from UK to EU27 companies free of additional costs.
- For biocides develop a process of acknowledgement and cooperation.
- Provide for open markets as regards Refuse Derived Fuel.

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BDI-Task Force Brexit

The BDI is committed to supporting the Brexit negotiation teams with in-depth expertise in a number of areas of economic policy. In summer 2017, the BDI set up a Brexit task force together with its member organisations, company representatives and partners including the Association of German Banks (BdB), the German Insurance Association (GDV), the Federation of German Wholesale, Foreign Trade and Services (BGA), the Confederation of German Employers' Associations (BDA) and the Association of German Chambers of Commerce and Industry (DIHK).

The BDI Task Force Brexit has established ten project teams to address specific policy areas: (1) Trade in Goods, (2) Transportation and Logistics, (3) Data and ICT, (4) Taxation, (5) Legal consequences of Brexit in core areas of business law, (6) Energy and Climate Policy, (7) Market Access, (8) Workforce Mobility, (9) Banking, Finance and Insurance, (10) Negotiation Process (including Northern Ireland, Research and Development, Defence, Financial Commitments).

The objective of the project teams is to identify the potential risks posed by the exit of the UK from the EU and to propose constructive approaches to countering these risks. The project teams are looking at the regulatory issues in the individual policy areas on the European and the national level. The BDI is also a member of a similar task force at Business Europe, the umbrella organisation for European business. The work of the BDI Task Force Brexit will progress in line with the official negotiations.

This position paper is based on the background information developed by the BDI Task Force Brexit. The views expressed in this position paper are those of the BDI and do not necessarily reflect those of the other members of the Task Force.

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Market Access: Challenges of Brexit for Business

The field of “market access” covers environmental protection, occupational health and safety, technical products, automotive, aviation and tourism, pharmaceutical products, chemical substances, biocidal substances and waste shipment.

The acquis[1] of EU directives has, with a few exceptions,[2] been completely transposed into UK law and will therefore remain in force in the UK. EU regulations could be taken over into UK law as a complete package (“Great Repeal Bill” for about 20 000 EU laws), even without full parliamentary scrutiny; changes could be made by secondary legislation. This step would safeguard far-reaching harmonisation with EU law. Even then, however, major problems would nonetheless arise, for instance, where EU legislation refers to EU committees or is specified in implementing provisions of EU legislative institutions.[3] It remains to be clarified, whether future UK law will allow for such references to what will then be external EU institutions, and, if so, whether this will be accepted by the UK government. In any case, decisions of the European Commission and the European Court of Justice will no longer be binding to the UK if this is not otherwise settled in the negotiations.

There are many specific technical issues that urgently need to be addressed and agreed on in good time before Brexit. Key elements here include mutual recognition and transitional provisions. Looking beyond the transitional phase, negotiations for a more permanent cooperation, possibly in the shape of a free trade agreement, should address the future regulatory cooperation between the EU27 and the UK. The BDI proposes formulating common principles with the aim of avoiding a deep divide in future regulatory approaches.

The high standards that have been reached by the EU in order to protect health and environment should be maintained on the current harmonised level.

[1] A peculiarity in environmental protection and occupational health and safety is that according to the EU treaty no full harmonisation is required here. Differences between member states are thus commonplace.
[2] Example of a directive so far not transposed: Radio Equipment Directive (RED) 2014/53/EU.
[3] Such as e.g. Commission regulations under the ErP regulation (energy-related products).

Identified Issues: Assumptions and Measures

1. Environment and Environment-Related Protection of Health and Safety

Assumptions

Legislation at EU level for the protection of the environment only stipulates minimum requirements so full harmonisation is not given. Although the directives on e.g. air quality, wastewater and waste treatment are transposed into national law, national legislation may exceed EU minimum requirements or take account of regional particularities.[4] It is not foreseeable, whether and, if so, to what extent, the UK will veer away from EU plant permission procedures over time after Brexit.

Aside from the minimum requirements stipulated in EU environmental legislation, EU member states work together on a voluntary basis on areas that leave scope for national regulations. For example, member states are obliged to take all necessary measures under Article 10 of the Council Directive 98/83/EC on the quality of water intended for human consumption ("Drinking Water Directive") to ensure that no substances or materials are used in drinking water installations that could be detrimental to human health. France, Germany, the Netherlands and the UK have agreed to cooperate on convergence and mutual recognition in this area. Specifically, they jointly define acceptance procedures for materials regarding their impact on water quality and have agreed on a common basis for assessment procedures for materials in their national regulations.

Measures

EU27-UK negotiations: Voluntary cooperation within the framework of EU legislation and with the participation of the UK should be upheld in order to maintain common standards.

2. Occupational Health and Safety

Assumptions

Occupational health and safety legislation at EU level also only stipulates minimum requirements, so full harmonisation is not given in this field either. In the UK, the Health and Safety at Work Act regulates occupational health and safety. Furthermore, occupational health and safety management systems (OSHAS 18001) play a more important role in the UK. Companies with production sites in the UK either have this kind of management system in place or are covered through their supply chain.

Measures

None, as Brexit is not anticipated to have any direct consequences on in-plant occupational health and safety.

[4] For instance, the Industrial Emissions Directive (IED) has been transposed in England and Wales by the Environmental Permitting Regulations 2013, in Scotland by the Pollution Prevention Control Regulations 2012 and in Northern Ireland by the Pollution Prevention and Control (Industrial Emissions) Regulations 2013.

3. Technical Products – General

Assumptions

"One standard, one test, accepted everywhere" is a primary goal of the EU single market. The key to achieving this is harmonised standards, developed on the basis of a mandate by the European Commission. The single market for products has become fully integrated in nearly all fields. Technical products are regulated extensively and are subject to the rules of the "New Legislative Framework" (NLF). Directives and regulations define requirements for all products within their scope, and are then technically concretised by harmonised EU standards for the individual product groups. The application of these harmonised standards leads to the conformity assumption. It is assumed that through the application of harmonised standards products fulfil the legal requirements, although this presumption of conformity can be refuted in individual cases. Nevertheless, adherence to these directives, regulations and the specifying harmonised standards forms the basis of CE labelling and the free circulation of products.

Following Brexit, the UK may choose to impose different legal requirements on products. The application of existing regulations could drift apart even without this, if the UK ceases to participate in EU bodies, agencies and committees. If the jurisdiction of the European Court of Justice on the single market acquis is no longer binding for the UK, interpretation will begin to diverge. The EU27 and the UK would slowly drift apart in regulatory terms, triggering severe consequences for the markets. If requirements, practices of application, enforcement and jurisdiction differ, EU27 manufacturers would face additional burdens and have to design products specifically for the UK market. Other non-tariff barriers to trade that could arise are additional technical product requirements (e.g. for construction, labelling, accompanying documentation), specific kinds of conformity assessment, national certification labels, administrative and permit procedures.

Measures

EU27-UK negotiations: The single market for products represents a major accomplishment of the EU. Its integrity and efficiency must not be endangered by Brexit whatever shape it takes. On the single market, products that comply with the legal requirements can circulate without any other bureaucratic or financial barriers. Common principles should be negotiated to help shape regulatory development in as much definition as possible. Moreover, the exchange of information between the UK and the EU27 should be maintained in as many fields as possible to maintain close liaison between the two sides. Aspects for collaboration here are the non-legal level of standardisation, market surveillance and accreditation.

3.1. Technical Products – Conformity Assessment

Assumptions

Until now the UK determines conformity assessment procedures according to the NLF framework. Every product regulation under the NLF establishes how compliance with the legal requirements ("conformity") is to be assessed and declared by the manufacturer. The EU Decision 768/2008/EC lays down various procedures for conformity assessment and declaration. Most product directives permit the application of module A, according to which the manufacturer carries out the conformity assessment procedure itself in line with the requirements described there. The manufacturer assesses and declares conformity autonomously ("self-declaration"). Additional verification procedures are stipulated for a few product groups, for which non-compliance is particularly high-risk. Certification for

these product groups is carried out by authorised private inspection institutes. These external inspection bodies (so-called notified bodies) either verify the product itself or internal company processes (management system).

In future, the UK may choose to favour third-party assessment, thus increasing the cost, bureaucratic effort and period of time needed to place products on the UK market. This would be problematic for a wide range of products (including machinery, electrical products and plant engineering), for which currently around 80% of the procedures are based on self-declaration.

Within the single market, third-party certification from notified bodies verifying the legally defined conformity required for some products or processes are recognised in all member states. After Brexit, certification from notified bodies of the EU27 may no longer be recognised in the UK.

Measures

EU27-UK negotiations: A free trade agreement should include a chapter on common regulatory principles that stipulates that both sides continue to apply EU law for products and mainly prefer the manufacturer's self-declaration on product requirements according to EU law. In order to avoid additional technical barriers to trade, the certificates of notified bodies should be mutually recognised. Furthermore, in order to ensure a common level of testing, avoid a hub of low level and unreliable testing bodies in the UK and, thus, ensure fair competition between all business operators on the EU market, testing bodies as such as well as testing procedures in the UK should be aligned to EU standards, if accepted under EU law in future. In addition, testing results of accredited, but not notified bodies should be accepted in the UK.

3.2. Technical Products – Standardisation, in Particular Harmonised EU-Standards

Assumptions

Harmonised standards play a key role in the single market for products. The relevant legislation follows the NLF and thus abstains from detailed legal prescriptions, but describes the respective regulatory objective in a generic and technology-neutral way. The product specific concretisations, which are decisive for the correct transposition of the legal requirements, are developed by technical experts in standardisation organisations.[5] There are three EU standardisation organisations, CENELEC for electrotechnical standards, ETSI for telecommunications standards and CEN for the development of standards in the remaining areas. National standardisation bodies are members of CEN and CENELEC. It is doubtful whether the BSI (British Standardisation Institute) can keep its membership, as, so far, only members of EU and EFTA are admitted to CEN and CENELEC. ETSI membership is based on the signatory status of CEPT[6], which has not been called into question by the UK so far.

Measures

EU27-UK negotiations: The practical functioning of the EU single market is largely based on harmonised standards. The BSI would need to remain in the CEN and CENELEC to ensure that the future UK legal system of rules continues to be closely linked to harmonised technical standardisation. This would curb divergence between the EU and the UK markets. The transferability of EU standards to the

[5] EU-Regulation 1025/2012/EU is the basis of the EU standardisation system.
[6] Conférence Européenne des Administrations des Postes et des Télécommunications with 48 member states throughout Europe.

global level provides added incentive to the UK to continue cooperation with the CEN and CENELEC in future. Continued cooperation here must be ensured.

3.3. Technical Products – Accreditation

Assumptions

The accreditation system is relevant for bodies that intend to certify processes or products, processes, tests, services, persons, etc. In the interest of a consistent application and quality assurance, inspection bodies have to be accredited by the respective competent national body according to defined standards to verify their competence. The establishment of the national bodies that conduct the accreditation also follows clearly defined rules laid down in EU Regulation 765/2008/EC. Each member state is only authorised to have one accreditation body, which, in the UK is the United Kingdom Accreditation Service (UKAS). The regulation also stipulates that all national accreditation bodies have to be affiliated to the European Co-Operation for Accreditation (EA). This organisation only admits accreditation bodies of EU member states, EFTA states and so-called neighbour states. The collaboration of these organisations within the EA is important as it ensures that accreditation is consistent in its member states, thereby laying the foundation for the mutual recognition of certificates and test results.

Measures

EU27 internal: The UK should be given the status of a neighbour state in the list of countries cooperating in the EA. This would ensure that accreditation practices of the EU27 and the UK do not drift apart.[7]

3.4. Technical Products – Market Surveillance

Assumptions

Market surveillance in the UK until now follows EU Regulation 765/2008/EU, which does not include any detailed prescriptions regarding the organisation of market surveillance.[8] The UK system therefore has its own national character and is implemented by around 200 local and a few national authorities.

In order to facilitate consistent enforcement across the EU and enhance efficiency, electronic exchange platforms (RAPEX and ICSMS) provide market surveillance authorities with information on products tested in other member states and whether these were declared as not conforming. UK market surveillance authorities also currently use these systems.

Beyond that, national market surveillance authorities regularly use EU platforms to communicate on surveillance activities. If the UK stops participating here, it is to be expected that enforcement in the UK and the single market will drift apart. Among other things, this could lead to products having to be tested twice or to different corrective measures being requested by the market surveillance authorities in the UK and the EU27 in the case of field incidents (e. g. warning, recall, sales stop). This would increase the bureaucratic and financial burden of manufacturers. After Brexit, EU manufacturers could

[7] Respective adaptation of rules on EA level is under negotiation (status: November 2017).
[8] New EU regulation currently in preparation.

thus be disadvantaged through the enforcement and interpretation of technical requirements that deviate from EU practices.

An additional market surveillance mechanism on the EU level is the "business application platform". Business operators can use this platform to meet their legal obligation to notify unsafe products and inform all member states simultaneously with one notification. As business operators would otherwise have to inform the market surveillance authorities of each concerned EEA state separately this reduces bureaucracy in the case of hazardous products. Business operators thus save resources that they can better use to eliminate the hazard.

Measures

EU27-UK negotiations: Cooperation between authorities could be simplified by the participation of the UK as a third state in the information exchange systems RAPEX and ICSMS, based on certain agreements on cooperation in market surveillance. Apart from that, the information exchange on market surveillance practices and the notification duty in the business application platform should be maintained in order to avoid drifting apart in this field.

4. Automotive – General

Assumptions

Separating the UK regulatory system from that of the EU, whilst ensuring market stability and regulatory coherence, needs to take into account the various industry needs including regulatory continuity, regulatory alignment with other key issues, appropriate lead time, technical feasibility and technology neutrality.

Measures

EU27-UK negotiations: The German Automotive Industry will continue to manufacture vehicles and automotive products according to EU and UNECE standards and regulations (safety standards, homologation and type approval, ELV recycling quota).UK law should thus remain strictly in line with EU automotive regulations, any deviation from EU or UNECE equivalents must be avoided.

With regard to CO_2-emission regulations it is important to avoid UK-specific requirements including vehicle fleet limits. The example of Switzerland shows that it would induce additional efforts and costs, if averaging across the internal EU market would no more be possible.

4.1. Automotive – Safety Standards and Type Approval

Assumptions

European Whole Vehicle Type Approval (WVTA) is the certification by a member state Type Approval Authority (TAA) that a vehicle meets all relevant environmental, safety, performance and security standards of the EU. Today, the holder of an approval certificate can use it to market that type of vehicle throughout the EU, without further certification or approval procedures in any member state. Currently, Framework Directive 2007/46 ensures consistent application of the appropriate standards of WVTA across the EU. TAAs are also responsible for ensuring a manufacturers' ability to achieve conformity of production (CoP), which is an integral part of the approval process. Essentially, this

involves the evaluation by the TAA and/or its technical services that the manufacturer has the capacity to ensure that each product is manufactured in accordance with the approved specification. The TA process typically takes 6 to 12 months and costs € 1 to 2 million for a whole vehicle to be approved for the first time. Amendments to an existing type take less time but are dependent on what system or component is to be approved.

After Brexit, in principle EU27 WVTA would no longer be valid in the UK, and vice versa. This immediately creates uncertainty with regard to goods already placed on the single market prior to the Brexit and WVTA validity afterwards. The effect would be an immediate reordering by manufacturers of their type approval processes. Cars for sale in the EU27 will need to be WVTA approved in the EU27 and cars for sale in the UK will have to be certified by UK authorities. Thus, the same types would have to be approved twice, thus doubling both the financial cost of the process and the human resource capacity needed. A significant hidden cost will also be incurred in the process of adapting to work with new TAAs and their technical services.

Measures

EU27-UK negotiations: Vehicles that comply with UNECE or EU product-related regulatory standards, such as homologation/type approval standards and procedures and safety standards must seamlessly retain the right to UK homologation after Brexit. Any UK-specific variations of these standards that would require UK-specific model variants or would otherwise hinder free trade of automobiles, parts and components between the UK and other markets should be avoided.

Similarly, vehicle variants that have been accredited in the EU should receive type approval in the UK without further bureaucratic burden and vice versa. Type approvals granted by the British Vehicle Certification Agency (VCA)[9] should remain valid within the EU27. In that respect, the UK should stay within the UN1958/98 agreement system and refrain from UK-specific standards and labels.

The UK should continue to implement and contribute to the WVTA process and should continue to play an active part in the regulatory agenda setting at UN level, as well as continue direct relationships with international key players. The UK should sustain its expertise and global standing in technical policy areas and ensure the UK continues to engage with the EU27.

An early confirmation of the continued legal compliance of goods placed on the market at the time of Brexit is needed for vehicles, systems, parts and services. In order to avoid duplication of procedures when UK and EU27 requirements are equivalent, both parties should mutually recognise reports, certificates and authorisations issued by the conformity assessment bodies of either the UK or any of the EU27 member states.

Due to the duration and the costs related to certification, any WVTA certification process underway on the date of Brexit should maintain its validity in the UK and EU27 even if the certificate itself is issued after that date. An existing certificate issued by one authority should be amendable, i. e. approval extensions remain possible through the same authority, and a certificate should maintain its validity in the UK and EU27.

One option could be the Switzerland approach: Bilateral Mutual Recognition Agreements (MRA) promote trade in goods between the EU and third countries and facilitate market access by providing

[9] British Vehicle Certification Agency (VCA): Executive Agency of the UK Department for Transport and the UK national approval authority for new road vehicles, agricultural tractors and off-road vehicles.

greater options to conformity assessment. Since 2010, the EU and Switzerland have implemented a mutual recognition agreement in relation to conformity assessment for vehicles (amongst many other sectors). This agreement allows for the recognition by both parties of each other's approvals and is based on Switzerland adhering to Directive 2007/46/EC by adapting "its legislation to all the European Union type-approval legislation in force". Administrative procedures like the handling of end of series vehicles should also be included in such an agreement.

4.2. Automotive – End of Life Vehicles Directive (ELV Directive)

Assumptions

The ELV Directive forms the statutory framework of end-of-life vehicle-related requirements for economic operators. It has proven to be highly effective in preventing waste disposal from vehicles, increasing re-use, recycling and recovery, as well as ensuring that ELVs are treated in an environmentally sound way. The shared responsibility concept obliges the respective parties to contribute actively to a reliable responsibility scheme. In addition, manufacturers constantly strive to make vehicles more durable by facilitating repair and service hence supporting circular economy and the waste hierarchy principles. In order to enable a "repair capability" as desired, the basic principle "repair as produced" is crucial and should be implemented consistently in all regulations.

Measures

EU27-UK negotiations: The UK should further fully comply with the ELV Directive, including the transposition of Annex 2 (specific exemptions to the prohibition of the use of hazardous substances in vehicles), and also with other related directives, such as the Landfill Directive, the Directive for Waste Electric and Electronic Equipment (WEEE), and the Battery Directive.

5. Aviation and Tourism

Assumptions

Upon the withdrawal of the UK from the EU, existing and future investments by EU investors in many sectors, among those the tourism and aviation sector, are at risk, to the further detriment of EU businesses and consumers. In the interest of EU investors, industry and consumers, these investments should therefore be protected reciprocally, and the status quo with the UK should be retained, at least during a reasonably long transitional period, which leaves a realistic timeframe for negotiating an open and liberalised aviation agreement.

Preparations for the holiday season 2019 and the respective flight schedules of European air carriers are underway, hence planning security is vital for the investments made by airline and tourism companies alike, as well as for customers from the EU and UK who want to be sure their holidays can take place as planned. Especially for member states in Southern Europe (e. g. Spain, Portugal, Greece) tourism is the most important economic factor. Current uncertainty around the Brexit can potentially have major implications for tourism flows in both directions and needs to be addressed urgently.

The liberalisation of the EU aviation sector since 1992 has allowed nationals from all EU member states to invest freely in airlines which have their principal place of business in another EU member state. This ability to attract more capital has been instrumental in creating the highly competitive European

aviation market of today, which has resulted in significantly lower prices and improved services to the direct benefit of European citizens and companies.

Aviation has rightly been identified by the European Commission as a strong driver of economic growth, jobs, trade and mobility for the EU. One euro value added in the air transport sector creates an added value of almost three euros in the overall economy. However as DG MOVE highlighted at the Rome EU-ECAC dialogue, it remains a capital-intensive business which is challenged in attracting sufficient committed finance. In its external aviation policy, the European Commission recognizes the benefits of creating investment opportunities with third countries based on mutual liberalisation of ownership rules.

Measures

EU27-UK negotiations: It is in the interest of the EU's investors, industry and consumers to retain an open and liberalized aviation market access between the EU27 and UK while ensuring the principle of reciprocity. This should therefore be an important goal for the EU in negotiating an agreement with the UK on aviation.

EU27 and the UK should agree on a transitional period that would provide a realistic timeframe for negotiating such a liberal and open agreement, including provisions that allow industry and investors sufficient time to adapt.

6. Pharmaceutical Products – General

Assumptions

The pharmaceutical industry (for human and animal medicines) is highly integrated across Europe, and regulated under EU law through legal and regulatory systems and arrangements between EU institutions, member states and national competent authorities.

A pharmaceutical protocol that ensures maximum alignment between EU and UK pharmaceutical laws should be agreed to ensure that patients and animals owners/keepers in the EU and the UK can continue to access medicines without any disruption. This is important for the following reasons:

- The UK leaving the EU single market and customs union may result in new customs compliance procedures for all products moving between the UK and EU27. It is essential that the new customs arrangements do not lead to delays in moving products between the UK and EU27. These arrangements should ensure that goods are not held either at border checks, in warehouses or manufacturing sites and/or are subject to extensive retesting requirements. Such a situation would lead to a severe disruption of supply chains and potentially disrupt the supply of medicines for patients across Europe.
- In the event of 'no deal', the EU and the UK would fall back to WTO terms and tariffs, and medicines currently exported from the UK to the EU may be subject to additional requirements such as import testing and Qualified Person (QP) release of products into the EU, as well as changes to supply chains. In the event of a WTO trade position, EU27-UK medicines trade may be affected by duty requirements at several stages of the supply chain. Whilst the WTO Pharmaceuticals Agreement includes a 'zero-for-zero' arrangement on most pharmaceutical goods and products in supply chains, not all medicines licensed since 2010, or many components of existing medicines, are covered. The current discussion to update the WTO Pharmaceuticals Agreement should be concluded.

- Companies also have multiple VAT registrations and VAT filing requirements across the EU. Import VAT will be payable on all non-UK sourced goods before they can be brought into free circulation within the UK, which may lead to considerable cash flow costs for exporting goods to the UK.

Measures

EU27-UK negotiations: A deep and comprehensive trade agreement is needed to secure ongoing alignment, cooperation and mutual recognition between the UK and EU27 regarding the authorisation, testing and surveillance of medicines. This agreement should maintain the ability to import or export pharmaceutical products between EU27, the UK and the rest of the world. The EU single market must not be undermined.

Medicines used by patients across Europe have integrated supply chains, which includes the UK. The UK and the EU should conclude a comprehensive agreement with a pharmaceutical protocol that ensures maximum alignment between EU and UK pharmaceutical laws. Any such agreement needs to avoid causing any disruption to existing quality control arrangements and must not disrupt the supply of medicines to patients in EU27 or the UK.

A transition period well beyond the two years stipulated in EU Treaty Art. 50 is needed. This period should adequately reflect the time needed to ensure relevant customs and regulatory procedures are in place and pharmaceutical companies are able to transition to a new framework. Due to the highly complex regulatory arrangements involved, it is extremely difficult for companies to accelerate contingency planning. The implementation period should be agreed as part of the negotiations in order to give companies the time required to make the necessary arrangements to avoid any unintended consequences regarding the availability of medicines to European patients.

6.1. Pharmaceutical Products – Access to Medicines

Assumptions

Duplicative regulation may affect how quickly patients in the UK and the EU27 have access to medicines. Any divergence over time of policy approaches by EU agencies affecting pharmaceuticals would cause further disruption. Duplication of regulatory processes for new or existing marketing authorisations would create additional and unnecessary delays and would impact on the availability of medicines to patients.

Measures

EU27-UK negotiations: Securing regulatory alignment and cooperation will be the best way of avoiding onerous duplication and the immediate issues of re-testing and re-release. Another important issue is enabling the use of shared packs (i.e. that the same pack can be used in different countries).

6.2. Pharmaceutical Products – Supporting Public Health and Animal Health and Welfare

Assumptions

The UK's engagement in systems designed to protect public health across Europe helps to ensure that these systems are as robust as possible. These include:

- Infectious disease control: The European Centre for Disease Control operates a centralised database that provides EU member states with information on 52 notifiable communicable diseases, outbreaks and public health risks.
- Pharmacovigilance: Reporting on medicines safety is covered by the EudraVigilance system that is operated and monitored by the EMA. Veterinary medicines safety is similarly monitored through EudraVigilanceVet.
- Falsified Medicines Directive: Verifying authenticity at the point of dispensing of human medicines. Scheduled to be introduced across Europe in 2019.
- Clinical trials portal: Single entry point for submitting human clinical trial applications and related information including results in the EU as of 2019. The EMA will make most of the information stored in the database publicly available.
- ESVAC: Monitoring the sale and use of antibiotics in animals, as well as antibiotic resistance.

The loss of the UK's engagement in these systems could significantly reduce their effectiveness.

Measures

EU27-UK negotiations: A procedure for the acknowledgement of and cooperation with the EMA and the European network of Regulatory Authorities needs to be developed and the UK's continued engagement in these systems ensured.

6.3. Pharmaceutical Products – European Medicines Agency (EMA)

Assumptions

The EMA functions as a regulatory network that licences pharmaceutical products for sale across Europe. The UK's national regulator, the MHRA, makes a significant contribution to the work of the EMA, and in 2016 was the rapporteur, leading the scientific assessment in up to 20% of all centralised procedures, and contributed to 40% of decentralised procedures. Likewise, the VMD, the UK's national regulator for veterinary medicines, makes a significant contribution to the work of the EMA. If the MHRA withdraws from the European regulatory network, this could lead to significant disruptions in the capacity and expertise for the review of medicines as well as the capacity across Europe for the surveillance and safety supervision of products. In addition, the necessary changes to marketing authorisations, packaging, Reference Member State (RMS) and rapporteur will add to the regulatory burden for both the Marketing Authorisation (MA) holder and regulator, and may jeopardize the supply of medicines in the EU.

Measures

EU27 internal: The relocation of the EMA from London to Amsterdam must be carried out in such a way as to minimise disruption that could negatively impact the functioning of the Agency, business continuity and hence access to medicines for patients. A process of acknowledgement of and cooperation with the EMA needs to be developed and transfer processes with less administrative burden agreed.

6.4. Pharmaceutical Products – Manufacturing and Supply (including Clinical Trial Supply)

Assumptions

Medicines currently exported from the UK to the EU and vice versa will be subject to additional requirements that will delay the supply to patients and lead to costly changes. These include additional import testing, Qualified Person (QP) release into the EU, as well as changes to supply chains. This is a significant problem as the UK exports around €11 billion worth of medicines to the EU27, including both commercial and clinical trial products.

Measures

EU27-UK negotiations: A process of acknowledgement of and cooperation with the EMA needs to be developed.

7. Chemical Substances – General (incl. REACH, CLP)

Assumptions

Especially in the context of REACH and CLP, divergent legal requirements on registration, evaluation, restriction, authorisation, classification, labelling and packaging of chemical products would create bureaucratic barriers to trade. Importers into the UK may then face divergent requirements, e. g. in terms of prohibited substances.

In the case of a hard Brexit, it is highly unlikely that the UK will manage to adapt its chemicals law in time, as the EU regulatory system is based on the approaches of the EU member states with cooperation and mutual obligations, recognitions, control regulations, etc. The proposed Great Repeal Bill with simple and quick amendments may therefore not be sufficient at all. It would also mean that enforcement is no longer consistent.

Measures

EU27-UK negotiations: In general terms, transition provisions are indispensable. A preservation of the status quo is urgently needed (grandfathering). The internal market for chemicals must be safe-guarded, with sufficiently long transition periods at the very least. Furthermore, mutual recognition of the chemicals regulation, as agreed with e.g. Switzerland, or voluntary adherence to the REACH Regulation as agreed e. g. with Norway, Iceland and Liechtenstein, may be an option for the UK.[10]

7.1. Chemical Substances – Registration and Supply Chains

Assumptions

UK-companies will no longer be based in the EU and will therefore no longer be obliged to register their substances produced in or imported into the UK. Existing substance registrations of UK-based companies [11] would, according to the ECHA, become invalid. Immediately after Brexit, these companies will be neither obliged nor entitled to register. At the same time, EU-downstream users of

[10] There is no need to revise the REACH Regulation, considering that the REACH membership of e.g. Norway, Iceland and Liechtenstein (companies based there are entitled to register) was agreed in separate documents (association with full application of the whole REACH scope).
[11] UK-based registrants hold more than 10% of all registrations (October 2017).

UK-produced substances would become importers of substances from outside the EU27. These substances could then no longer be marketed in the EU27 without (new) registration. EU27 customers would have to submit a registration themselves in their new role as importer, in the process of which imports could well be interrupted with severe consequences for supply chains. Registration costs would have to be borne by the new registrants. This problem may even become more severe after the end of the third registration phase for the 1 – 100 t/y band on May 31, 2018, with the increase in the number of substances registered. A further dimension that needs to be addressed is a constellation where a UK-based company is lead registrant.

Measures

EU27-UK negotiations: A permanent or transitional continuation of REACH in the UK would ensure that registrations held by UK companies retain their validity.

EU27 internal: Despite Brexit, the marketing of substances subject to registration across the border between the UK and the EU27 must continue without interruption. Transitional arrangements and periods must be established in order to maintain the flow of imports to the EU27 and exports to the UK (see above: EU27-UK negotiations). EU27 customers that register as importers because of Brexit, should be permitted to import the respective substance without a waiting period.

A possible option here would be the transfer of existing registrations from UK manufacturers to EU27 customers or Only Representatives (OR) without any additional registration fees. A transfer to an OR, at least, could be executed via a legal entity change. The ECHA would then only charge a fee for a legal entity change.[12]

On the time scale, this kind of transfer could already be permitted prior to Brexit or, alternatively, transition regulations could apply.

Company level: Companies should

- verify, for all substances, which of their suppliers are located in the UK und whether these are lead registrants for the respective substance,
- check whether their UK supplier has an affiliate company in the EU27 or intends to establish one, to which the registration could be transferred, if this is made legally possible,
- check whether their UK supplier is willing to and will arrange for a registration by an OR,
- check alternative supply options within the EU27,
- check whether an own registration could be envisaged for a future role as importer.

7.2. Chemical Substances – Registration and Data Sharing

Assumptions

Brexit would also affect legal obligations on data and cost sharing in Substance Information Exchange Fora (SIEF) or consortia. SIEF members include registrants. Data and cost sharing, however, is regulated in specific contracts. How Brexit will affect claims on current and future financial obligations of UK companies will vary from case to case and contract to contract.

[12] ECHA FAQ 1418

Measures

Company level: A huge number of existing contracts would need to be adapted in order to clarify data and cost sharing issues and respective claims. EU27-based contract partners may face higher costs. In cases where a UK-based company is lead registrant, the involved SIEF members should organise the transfer of this function to a continental member.

7.3. Chemical Substances – Registration and Only Representatives (OR)

Assumptions

OR located in the UK[13] will no longer be EU-based and thus will no longer be entitled to hold a registration. Non-EU manufacturers with a UK-based OR would lose their access to the EU27 market. In this case, Brexit will also affect non-EU manufacturers making this a global issue beyond direct EU27-UK relations.

Measures

EU27 internal: It should be made possible to transfer existing registrations to another OR without additional fees. The last resort solution (OR based in the UK could move to the EU27 at any time and non-EU manufacturers could switch to an EU27-based OR) would cause costs for the OR and/or non-EU suppliers.

Company level: Companies should

- verify, for all substances, which of their non-EU suppliers are represented by a UK-based OR and what these OR intend to do with regard to their future legal status within the EU27.

7.4. Chemical Substances – Authorisation

Assumptions

Authorisations held by UK-based companies will, according to ECHA, become invalid together with all associated permits for downstream use. EU27-based downstream users (DU) could then no longer refer to authorisations granted to UK companies. EU27-DU could (re-)apply for an own authorisation at very high cost or consider changing suppliers. The UK company could try to undertake a legal entity change in order to transfer the authorisation to an EU27 company (e. g. an OR), but it is not yet clear whether this will be permitted. It should be possible to notify the change of OR, at least, as a legal entity change.[14] Consortia for authorisation could face problems comparable to those anticipated for registration (cf. registration and data sharing). Furthermore, UK suppliers will also no longer be able to issue notifications according to REACH Art. 7 (notification for the candidate list and articles), which would then have to be issued by the EU customer (importer except OR).

MEASURES

EU27-UK negotiations: A permanent or transitional continuation of REACH in the UK would ensure that authorisations held by UK companies retain their validity.

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[13] The UK has the highest number of OR in the EU28 (October 2017).
[14] ECHA FAQ 1239

EU27 internal: An alternative option would be to permit the transfer of existing authorisations to EU27-based companies without additional cost. The last resort solution (EU27 DU need to apply for an own authorisation) would mean high additional fees for EU27-based companies and leave UK-based companies with an expensive, yet useless authorisation, even if it was granted for e.g. 12 years. In such a case, supply chain disruptions are very likely to occur.

Company level: Companies should

- verify, for all substances, whether they are subject to authorisation held by a UK-based supplier,
- check whether their UK supplier has an affiliate company in the EU27 or intends to establish one, to which the authorisation could be transferred, if this is made legally possible,
- check alternative supply options within the EU27 to cover their own use,
- check whether an own authorisation could be an option.

7.5. Chemical Substances – SVHC in Articles

Assumptions

UK-based suppliers of articles will no longer be obliged (REACH Art. 33) to communicate SVHC contents[15]. EU27 customers will no longer be legally entitled to obtain this information.

Measures

Company level: EU27 customers of UK-based suppliers of articles should provide for respective obligations in their supply contracts to enable them to fulfil their obligations according to REACH Art. 7 (2 et seq.) in their new role as article importers.

7.6. Chemical Substances – European Chemicals Agency (ECHA)

Assumptions

After Brexit, the UK will not have an authority responsible for chemicals regulation.

MEASURES

EU27-UK negotiations: A process of acknowledgement of and cooperation with the ECHA needs to be developed.

8. Biocidal Substances

Assumptions

The Biocidal Products Regulation[16] regulates the placing on the market and use of biocidal products. The active ingredients in biocidal products protect humans, animals, materials or articles against harmful organisms such as pests and bacteria. All biocidal products require an authorisation before

[15] Substances of very high concern
[16] BPR Regulation (EU) 528/2012

they can be placed on the market (with some exemptions), which is only granted if all active substances contained in that biocidal product have already been approved.

The European Commission has stated that business operators should bear in mind that, according to Union law, holders of product authorisations must be based within the EU (or EEA countries or Switzerland). Active substance or product suppliers included in the list referred to in Art. 95 BPR must be based or have a representative based within the EU (or EEA countries or Switzerland). Authorisations held by UK-based companies will become invalid and must be transferred.

Art. 81 BPR stipulates that each member state designates a competent authority to apply the provisions of the regulation. After Brexit, the UK will not have an authority for chemicals regulation.

Measures

EU27-UK negotiations: A process of acknowledgement of and cooperation with the ECHA needs to be developed.

9. Waste Shipment

Assumptions

An important aspect for the waste treatment industry is the potential impact of Brexit on trade in waste between the UK and the EU27 and on waste shipments (especially Refuse Derived Fuel (RDF)[17]), in particular from the UK to the EU27. The UK has a substantial undercapacity for waste-to-energy plants and even after completion of works on new capacity, the UK will have to rely on substantial RDF exports as the landfilling of mixed municipal waste is no longer permitted under UK law. Moreover, the export of RDF from the UK to EU27 countries is a CO_2-friendly solution. Transport emissions are low and, considering that most of the exports go to Scandinavia, the Netherlands and Germany where waste-to-energy plants are largely combined heat and power (CHP) plants, the overall carbon footprint of these exports is low.

Although these shipments will remain legally permissible under EU and international waste law after Brexit, imports of RDF into the EU27 will, in case of a hard Brexit, become more expensive and more bureaucratic on account of customs regulations.[18]

Measures

EU27-UK negotiations: A trade agreement should be negotiated between the UK and the EU27 in order to avoid a duty rate on imports of RDF into the EU27 and any potential issues related to market access.

Many new waste-to-energy plants in the UK are being built by EU27 companies and will, in some cases, also be operated by EU27 companies. It is therefore important that work permits are issued in a non-bureaucratic manner and that secondments do not become more difficult and expensive.

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[17] Waste code 19.12.12

[18] RDF imports would have to be classified as “municipal waste” under combined nomenclature code 3825.10.00. The EU currently applies a conventional rate of duty of 6.5% (ad valorem duty) on third-party RDF imports.

Official Papers

European Chemicals Agency (ECHA): The UK's withdrawal from the EU, i. a. "Advice to companies / Q&As": https://echa.europa.eu/uk-withdrawal-from-the-eu

Imprint

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