BREXIT AND ITS CONSEQUENCES FOR THE GERMAN PHARMACEUTICAL INDUSTRY

What is the current need for action?
The Bundesverband der Arzneimittel-Hersteller (BAH), the German Medicines Manufacturers’ Association, represents the interests of the pharmaceutical industry in Germany, and is comprised of global companies as well as local small and medium enterprises (SME). By company membership BAH, with its over 450 members, is the leading trade organization of the pharmaceutical industry in Germany. BAH members create about 80,000 jobs in Germany. BAH caters for the entire range of the industrial landscape, from self-medication medicines (‘OTC’) through to prescription drugs (‘Rx’) and medical devices. BAH advocates for safe and responsible self-medication through professional medical and pharmaceutical advice. Therefore, BAH strongly supports the statutory protection of the owner-operated pharmacy as the primary institution for distribution. BAH is a competent, reliable and trustworthy partner for the federal government, politicians, authorities and institutions in health policy and constitutes a strong link between the different stakeholders.
BREXIT AT A GLANCE - ACT NOW!

The withdrawal of the UK from the European Union – known as BREXIT – will have a significant impact on the pharmaceutical sector. This guide is intended for BAH Members to highlight which areas could be affected by BREXIT and where there is already a need for action.

Companies wishing to hold their marketing authorisations in the European Union (EU 27) will be obliged to have an affiliate in the Union. Equally UK marketing authorisations will require a company affiliate within the UK.

The new European regulation to conduct clinical trials establishes harmonised procedures in the European Union. However, as this regulation is likely to be applied after BREXIT, it is currently unclear how the UK will proceed. Ongoing clinical trials may lose their approval and regulatory acceptance.

Marketing authorisations obtained in the central procedure will lose their legal basis in the UK; in the EU 27, these will remain valid. It can be assumed that the UK will create a national basis for those marketing authorisations granted under the centralised procedure. This would imply that these products would continue to be available in the UK for the time being. In the case of authorisations from the decentralised procedure or the mutual recognition procedure (DCP / MRP), national approvals will still be valid, both in the UK and in the EU 27. If the UK was involved as the Reference Member State (Rapporteur or RMS), this role must be transferred to another country. In this uncertain phase, it is recommended companies do not select the UK as RMS for new applications. All ongoing procedures (approval, renewals, variations, etc.) in which the UK is involved should be completed before BREXIT.

Disruption to established supply chains will threaten the production and assessment of medicinal products. As soon as the UK becomes a third country, the import of active substances and finished medicinal products will require additional certificates and documentation and customs duties may be levied. If the negotiations will not establish mutual recognition agreements (MRAs), delays and disruption to imports and exports will occur.

Obstacles will also occur in the field of pharmacovigilance. Pharmaceutical companies will need to establish structures in the UK including a Qualified Person responsible for Pharmacovigilance (UK-QPPV). If the EU-QPPV has so far been based in the UK, it will need to relocate into the EU 27 or a new QPPV will need to be established here. In addition, reporting requirements and databases in the UK will need to be established in addition to the existing European tools operated by EMA.

Other areas, e.g. patent, trademark or liability right may also be affected.
THE MOST LIKELY SCENARIO FOR BREXIT

BREXIT negotiations officially started on 19 June 2017 and are taking place within the boundaries of international and European treaties. Article 50 of the Treaty on the Functioning of the European Union (TFEU) defines the procedure and constitutes the timeline and termination of negotiations by 30 March 2019, if no extension is unanimously agreed. The outcome of the negotiations is currently difficult to predict. In its White Paper, the UK Government declared its ambitions to become a third country. This guideline from the BAH Management Board is therefore based on the assumption that the UK will become a third country for the EU on 30 March 2019. Recent statements or positions from the UK Government do not affect this assumption.

I. PRINCIPLES

I.1. UK’s takeover of the entire European acquis

Pursuant to Article 50 (3) of the TFEU, the European Treaties will no longer be applicable in the UK from the date of the withdrawal of the UK from the European Union (30 March 2019). With the BREXIT, the entirety of European law, or acquis communautaire, will no longer apply in the UK. This includes all regulations (such as the central marketing authorisation procedure or the regulations concerning variations, orphan drugs, pediatrics, etc.) or decisions taken by the EU institutions (e.g. central marketing authorisations) or decisions of the European Court of Justice. The EU directives which have been transposed into national law in the UK including the Community Code 2001/83/EC will remain valid after BREXIT as national law.

To avoid a "black hole in our statute book" and "disruption to business", the UK will transfer the entire European acquis communautaire, and thus the entire EU drug law, into national UK law on the date of withdrawal. However, the development of UK law thereafter will lie solely in the hands of the UK Parliament, which is able to change or abolish national law at any point. In the medium term, it is expected that after the UK’s withdrawal, UK law will be changed to diverge from EU drug law, so that pharmaceutical companies should prepare for different drug regimes.

A priority objective of the UK Government is to free the UK from European legislation as quickly as possible. Thus, the negotiations have to bring arrangements forward, which will define responsibilities and procedures for disputes currently being dealt with by European courts (e.g., arbitration procedures for centralised admissions). It is unlikely, however, that such agreements will be made quickly.

Based on this premise and the facts known so far, this guideline describes and analyses the effects of BREXIT on pharmaceutical companies in Germany and the EU 27. The aim is to raise awareness of the potential effects of BREXIT among BAH Member Companies, to assist them in making the necessary decisions.

BAH will monitor and analyse the ongoing BREXIT-negotiations and future relations between the UK and the European Union and will keep its Member Companies informed of relevant developments.
I.2. Double structures for pharmaceutical entrepreneurs

After BREXIT, if no mutual recognition agreements have been put in place, pharmaceutical companies that seek to distribute their medicinal products both in the UK and the EU 27 must have two independent and appropriately equipped affiliates that entail all rights and obligations in the UK and in the EU 27 (see also comments on the pharmacovigilance and manufacturing and quality controlling of medicinal products). These two structures mean that pharmaceutical companies will require additional financial and human resources. In view of the threat to the freedom of movement of people, the acquisition of qualified personnel could also be problematic for German pharmaceutical companies. These novel dual corporate structures must also serve the corresponding double structures on the authority’s side in the EU 27 (as before) and the UK (partially new).

I.3. Additional burden on EU 27 regulatory authorities

Through BREXIT, the representatives of the UK have to leave all EMA committees and related functions. This implies that the work packages previously supported by the UK representatives will have to be transferred and compensated by the remaining EU 27 competent authorities. Furthermore, in the case of decentralised approval procedures and mutual recognition procedures (MRP / DCP), the RMS role of the UK have to be transferred to another Member State (see chapter IV). The same applies to collaboration in the field of pharmacovigilance.

I.4. Important questions for pharmaceutical companies

This BAH guideline is intended to offer BAH Member Companies advice as they assess the company’s immediate concerns and the implementation of any necessary measures in response. The BAH management recommends member companies act now in order to ensure that medicines remain available in both the UK and the EU 27 markets after 30 March 2019.

If one of the following statements applies to your company, BAH’s management recommends to carry out a detailed assessment of the implications of BREXIT:

1. Your company markets medicinal products in the UK.
2. Your company has an affiliate (or other company or legal entity), or a manufacturing or releasing site in the UK.
3. Your company is marketing medicinal products in the EU 27 or in the UK based on a centralised procedure, a mutual recognition or decentralised procedure.
II. IMPACT ON THE REGISTERED SITE OF THE COMPANY

The holders of EU 27 marketing authorisations who wish to place medicinal products on the EU 27 market after 30 March 2019 will be required to show presence in one of the EU 27 Member States. A company based only in the UK would no longer be satisfactory due to the requirements of European drug law. Thus, if a company is regulated under UK law, the relevant authorisations must be transferred to a company or an entity established in the remaining EU Member States, or the company’s base must be transferred to the EU 27. For marketing authorisations in the UK, the holder concerned must have a UK base.

Since such a relocation requires a whole series of legal and organisational actions, it is highly recommended that companies initiate the necessary measures in good time. Especially since the capacity of the courts and authorities concerned may be limited. Appropriate financial resources must also be allocated to this work.

Special care is required in the case of companies established under UK law (such as “Ltd.” or “PLC”), but with headquarters within the EU.

III. IMPACT ON CLINICAL RESEARCH

The new regulation (EU) No. 536/2014 for the implementation of clinical trials (EU-GCP regulation) will replace the current European GCP Directive 2001/20/EC. The aim of the new Regulation is to substantially harmonise licensing and reporting procedures for clinical trials and the introduction of a common European assessment for multinational clinical trials in the European Union. While each Member State will continue to issue the necessary authorisation for a clinical trial nationally, it will be carried out following a joint evaluation conducted by a reporting Member State. This procedure is based on the established European procedures for the marketing authorisation of new medicines.

If, after 30 March 2019, the freedom of establishment for corporations pursuant to Art. 49, 54 TFEU will drop, the remaining EU 27 will no longer be obliged to recognise UK companies with sites in the European Union as legal entities. However, provisions should also be made for companies in the European Union with an administrative base in the UK.
the old and new procedures where both procedures will exist in parallel.

It is therefore necessary to examine whether an application for approval of a clinical trial involving the UK will still be appropriate before 30 March 2019. Through BREXIT, the new EU GCP Regulation - contrary to the national law on clinical trials - ceases to be valid in the UK. It is currently unclear how to proceed with clinical trials involving UK trial centers that will not be finalised by 30 March 2019.

IV. IMPACT ON THE REGULATORY FIELD

IV.1 Central Marketing Authorisations

IV.1.1 Recognition of central marketing authorisations in the UK

Central marketing authorisations are decisions and/or implementing decisions of the European Commission, thus European acts, which immediately apply to all EU Member States. With BREXIT, central marketing authorisations will no longer be valid in the UK. For a transitional period, however, it is expected that central marketing authorisations will remain valid based on national regulations, as already announced by the UK. It is unclear, however, whether the UK will permanently approve European central marketing authorisations or whether, for example, a separate national procedure will be established. In the latter case, the UK regulatory authority could re-examine assessments conducted by EMA and CHMP.

IV.1.2 Ongoing central marketing authorisation procedures

Authorisations will not apply in the UK, if a central marketing authorisation is applied for before 30 March 2019 but will be issued afterwards (if the UK Government does not prepare otherwise see IV.1.1). It should therefore be examined whether companies should pursue an application for a national marketing authorisation, in addition and parallel to the application for a central authorisation. This, however, will only be possible for medicinal products for which the central procedure is optional and not compulsory. Further implications should be considered, for example the establishment of a legal entity, commissioning of an importer or the transfer of the central marketing authorisation within the company group (see relevant sections of this guide).
IV.2 MRP / DCP Procedures and Approvals

The consequences of BREXIT for medicinal products, which are to be approved in the decentralised procedure (DCP) or the mutual recognition procedure (MRP) and for those which have already been authorised in one of the two procedures are very different.

IV.2.1 Existing MRP / DCP approvals

In the case of existing decentrally authorised medicinal products, it is of major importance whether the UK has been involved as Reference Member State (RMS) or a Concerned Member State (CMS). If the UK features a RMS role, this role must be transferred to another EU Member State which was involved as a CMS in the decentralised procedure and in which the authorisation in question is still valid. The change of the RMS requires that no regulatory activities (e.g. renewal or variation proceedings) are pending. The transfer of RMS function should be immediately prepared. To this end, the CMDh has already published a guide¹ and referred earlier to measures to ensure the transportability of medicines².

If authorisations for the EU 27 are currently held by a UK-based Marketing Authorisation Holder, they must be transferred to another company in the EU 27. Such transmissions are complex and generally require numerous variations with respect to other suppliers, production sites, responsibilities, etc. (see effects on the production and quality control of medicinal products). In addition, companies must adapt to the need for two material supply chains and production lines (one for EU 27 and one for the UK), and that existing functions in companies need to be replaced or newly created. In addition, up-to-date central documents, master files with the corresponding SOPs, need to be replaced by new documents. This shows that many areas within a pharmaceutical company will be affected by BREXIT (see also effects on pharmacovigilance).

To ensure the continuous availability of medicinal products in the UK and the European Union, it is advisable to complete all activities mentioned concerning the transfer of authorisations, as well as other activities that involve the UK regulatory authority by 30 March 2019.

The following questions can be used as a guide:

- Are there marketing authorisations in the UK?
- Is the applicant resident in the UK?
- Does the UK act as RMS or CMS?
- Are substances used originating from or produced outside the UK?
- Do production processes take place in the UK?
- Does the release for sale and placing on the market take place in the UK?
- Are all or single company functions or structures located in the UK?

² Notice to marketing authorisation holders of national authorised medicinal products for human use. CMDh/360/2017 02 May 2017.
IV.2.2 New marketing authorisations

It is highly recommended for companies to refrain from choosing the UK as an RMS in order to avoid a necessary short-term transfer of the RMS role after completion of the procedure. The UK should only be involved in new DCP as a CMS if it can be ensured that the procedures will be concluded by 30 March 2019. For ongoing procedures, dependent on the participation of the UK, all efforts should be made to complete them before the BREXIT deadline.

It is currently unclear whether, to what extent and over what period the UK will be involved in ongoing DCP beyond the deadline. However, only a national marketing authorisation can secure the continuous trade of medicinal products in the UK.

Companies intending to carry out an MRP or DCP with the participation of the UK, that is not expected to be completed before 30 March 2019, should in addition seek a national marketing authorisation in the UK. Even though such a parallel national procedure is not permitted by Articles 17 and 18 of Directive 2001/83, it is expected that there will be no objections due to the special circumstances resulting from BREXIT. In addition, pharmaceutical companies based in the UK could also be involved in national procedures.

New applications in the UK will no longer be able to be submitted through established electronic EU portals after BREXIT; the same applies to variations and other regulatory processes. The UK, however, is likely to establish its own portals.

IV.3 Variations in the case of BREXIT-related changes

In most cases, the transfer of Marketing Authorisations will also involve changes in manufacturing-related information. It will become necessary to seek alternatives for material applications and production processes outside of the UK. The number, extent and duration of the variations (at least some of them classified as Type II variations) may depend on this⁳. Companies are therefore advised to manage variations quickly, as resources within authorities and companies will be stretched. This concerns variations for the EU 27 as well as for the UK. Corresponding (personnel and financial) resources should be considered.

⁳ See Questions 6 - 8 in Questions and Answers related to the United Kingdom’s withdrawal from the European Union with regard to national authorised medicinal products for human use. CMDh/361/2017 31 May 2017.
IV.4 Existence of authorisations in the UK

Companies should immediately examine which marketing authorisations are economically important to be maintained after BREXIT. Additional costs resulting from setting up and maintaining a legal entity as well as an independent product management for the UK need to be individually considered. Moreover, the burden of maintaining registrations in the UK (for example, fees for variations, establishing a variety of new processes) can influence individual company decisions.

As the UK will no longer participate in the European variation procedure after the BREXIT, corresponding changes to the approvals need to be established through UK national rules.

V. IMPACT ON THE PRODUCTION AND QUALITY CONTROL OF MEDICINAL PRODUCTS

V.1 Import of active substances from the UK

Subject to other arrangements between the European Union and the UK, active substances imported into the European Union from the UK will be considered as originating in a third country after 30 March 2019. For the import from the UK to the EU 27 a national UK GMP certificate (written confirmation), which is recognised by the EU 27, will be required.

For active ingredients which are of human, animal or microbial origin or which are produced by genetic engineering, an additional authorisation will still be required in addition to a recognised GMP certificate for imports from the UK (Section 72 (1) AMG). It is unclear whether an agreement with the UK on the mutual recognition of GMP certificates (MRA) will be negotiated by 30 March 2019. Because the same GMP standards currently apply in the UK as in the other EU Member States, a corresponding agreement would be justified.

If there is no mutual recognition of GMP certificates, an inspection of an EU authority in the country of manufacture is required, based on which a GMP certificate is issued.
V.2 Import of medicinal products from the UK

Medicinal products imported from the UK after 30 March 2019 will have third country import status. Therefore, an import licence is likely to be required. This applies not only to medicinal products manufactured in the UK, but also to those manufactured in another country and imported into the European Union through the UK (e.g. for logistical reasons). Drugs imported through a British transport route may not be placed on the market in the EU 27 until they have been released in the Union (EU batch release). In addition, the variations needed for this purpose must be completed. Furthermore, as described under V.1, there must be a GMP certificate that is either mutually recognised or issued based on the inspection of an EU authority.

V.3 Batch release in the UK

Batch releases in the UK may not be applicable for EU 27 after 30 March 2019. If no other agreement applies, the batch release for the EU 27 market must therefore take place in an EU Member State. This change, in turn, would entail a corresponding variation. The internal process must then be repeated within the company. The production SOPs should be revised and adapted to the required reorganisation. Changes in the product flow, however, can result in an additional tax burden.

A separate batch release is expected to be required for the EU 27 and the UK market.

V.4 Wholesale of medicines

The internal distribution concepts could be particularly affected, if medicinal products are currently being sold centrally for the European market from a UK branch to an EU branch or other EU wholesalers. As the UK will no longer be bound by European law after 30 March 2019, companies should examine to what extent such structures will be accepted by the supervisory authorities. There are already differences in the perception of the conditions under which cross-border wholesaling of medicinal products from a third country is accepted.
VI. IMPACT ON PHARMACOVIGILANCE

VI.1 Before BREXIT

Pharmacovigilance is probably the most harmonised area, with numerous shared work activities across the EU.

On 22 November 2017, the rules on the submission of adverse drug reactions will be transferred to a single notification within the Eudravigilance database of the European Medicines Agency (EMA) in the EU. The periodic safety reports (PSURs) have been established for years, based on a list of EU-wide harmonised birth dates and are sent exclusively to the EU PSUR repository operated by the EMA; the evaluation of the reports is largely harmonised by a designated EU Member State. Similarly, risk references (so-called "signals") and the procedures for minimising risks (referrals) have been evaluated almost exclusively at European level for many years, and on this basis measures have been taken, as well as the most important guidelines on risk information to be sent by the licensees. The EMA Pharmacovigilance Committee (PRAC) has a central function. In addition to the legal requirements in Directive 2001/83 and EU Regulation No. 726/2004, a large number of detailed rules are laid down in the Good Pharmacovigilance Practices Guidelines (GVP), which are created and maintained by EU working groups under the umbrella of EMA. Inspections of the company’s pharmacovigilance systems are carried out by an EU 27 agency, which is recognised by other authorities. In individual cases, post-authorisation studies (PAISA / PASS) are also launched and monitored by the PRAC. The studies are entered in a publicly accessible EU register (ENCePP).

In addition, EU law requires each company to appoint a qualified person responsible for the company’s pharmacovigilance activities in the European Union (Qualified Person Responsible for Pharmacovigilance – EU-QPPV). The corresponding activities and methods of work are also to be described in detail in the Pharmacovigilance System Master File (PSMF); both – the QPPV and the localisation of the PSMF – are to be displayed across Europe (via the EU database xEVMPD).

VI.2 After BREXIT

In many areas, BREXIT will put this high level of harmonisation at risk. As already mentioned above, the United Kingdom will require a UK-QPPV representative to distribute drugs in the UK market. An EU-QPPV resident in an EU 27 country cannot take on this task and vice versa. If the existing EU-QPPV is currently based in the UK, a QPPV based in one of the EU 27 Member
States has to be designated as of 30 March 2019. As it is already very difficult to appoint appropriately qualified people for this specialised task, problems are expected. Audits that ensure compliance with the pharmacovigilance guidelines would then become necessary for the UK branch.

For UK, presumably a separate UK-PSMF will need to be prepared and submitted describing products and pharmacovigilance activities in the UK. How to notify the UK-QPPV and the UK-PSMF remains unclear; the EU 27 portal will no longer be available for this purpose.

The UK as a third country will no longer be linked to the EU-wide portals for individual and periodic reports, the UK national competent authority MHRA will need to set up its own portals and databases. For this reason, the companies should establish additional reporting channels and a qualified IT support exclusively for the UK.

After 30 March 2019, individual case reports from one of the EU Member States in the UK and vice versa are to be reported as third country reports. This will include changes in the submission processes. In addition, the regulations on signal generation and, for example, the literature research in the UK are to be revised in accordance with the future UK guidelines. Since the content of the pharmacovigilance regulations in the EU has been significantly influenced by the UK agency, MHRA, changes are not expected immediately. Furthermore, it remains unclear, whether future PSURs will be able to be drawn up based on the list of EU birth dates and submitted in the UK. In the medium term, it is possible for the UK to carry out its own risk assessments (referrals). In this case, modified or additional requirements for MHRA pharmacovigilance measures are likely to follow, resulting from differentiated textual requirements for use and expert information on their own UK risk management plans, as well as additional PASS / PAES and restrictions of the authorisations.

In either case, the additional reporting channels and the establishment of an additional UK-QPPV require that all Pharmacovigilance Work Instructions (SOPs) need to be reviewed and adapted to these duplicate structures. For local activities in the UK, additional SOPs should be established, as well as for the mutual information and definition of responsibility personnel involved (as is required for all other third countries). For this, additional personnel resources will be required. The double notifications in the UK and the European Union will also incur additional charges, and different measures in the EU 27 and UK jurisdictions will also increase the costs for businesses.

The responsibility for inspections of the company’s pharmacovigilance system in the UK will be the sole responsibility of MHRA, which will also review them. It is expected that MHRA will intensify its inspection activities.

The United Kingdom will require a UK-QPPV representative to distribute drugs in the UK market. An EU-QPPV resident in an EU 27 country cannot take on this task and vice versa. If the existing EU QPPV is currently based in the UK, a QPPV based in one of the EU 27 Member States has to be designated as of 30 March 2019.
VII. OTHER AREAS CONCERNED

VII.1 Data protection

As of 25 May 2018, the new European Data Protection Principles (DSGVO) will also apply in the UK. So far, the UK Government has said it intends to adapt national legislation accordingly. The UK, however, turning into a third country, will also be subject to data protection law, which will lead to considerable consequences, particularly in the transmission of data from the European Union to the UK. How this data protection issue will be resolved (e.g. in clinical trials) has not been addressed. It would be desirable to adopt an adequacy decision, which establishes an appropriate level of protection in the UK.

VII.2 Patent law

The immediate impact of BREXIT on patents and procedures in the UK is likely to be manageable. This is because the European Patent Convention (EPC) provides the legal framework for the distribution of patents to the contracting states of this Convention. The EPC is not European law, therefore already non-EU countries, such as Switzerland, are included. Even as far as the European patent is concerned, there is no immediate need for action after 30 March 2019.

VII.3 Supplementary protection certificates for medicinal products

Supplementary protection certificates (SPCs) are issued under a European regulation by the national patent offices of an EU Member State. This will no longer apply in the United Kingdom as of 30 March 2019. However, it is currently the intention of the UK Government that this Regulation, like other European regulations, should also apply in the UK after BREXIT. It is important to note that SPCs are based on an EU regulation, but are issued by national patent offices. Thus, the SPCs applied for and granted in the UK are national rights. For such SPCs, which were granted before 30 March 2019, there should be no need for action. In the case of pending applications submitted after 30 March 2019, it will be a question of whether the UK will acknowledge the relevant EU regulation. To what extent future applications for SPCs can still be granted under the European SPC regulation is a question of (future) UK law.
VII.4 Trademark law

Within the EU, there are trademarks registered under national law and a union-wide union mark, which is registered by the Office of the European Union for Intellectual Property (EUIPO), based in Alicante. After 30 March 2019, problems could arise for union marks, since their legal status is derived directly from a European regulation and their scope extends only to the EU Member States. In view of this, it is for UK law to provide solutions for already registered marks. It is likely, however, that by virtue of national law, union trademarks can continue to be applied and enforced in the UK. However, companies should examine whether a national application for the mark at the International Property Office (UKIPO) is beneficial on a case-by-case basis and ensure that any legal developments in the UK are carefully observed.

Where a union trademark is used only in the UK, the expiration of the mark is possible. A union mark can expire if it has deliberately not been used for five years in a serious manner. Hence, using a union mark solely in the UK can lead to a loss of trademark rights in the EU.

VII.5 Liability right

The degree of harmonisation is relatively low with regard to liability law. The European Product Liability Directive has been transposed into national law in the UK. BREXIT will therefore have no short-term impact on liability law in the UK.

VII.6 Parallel imports

Parallel imports to and from the UK will probably no longer exist after 30 March 2019.
The timetable for the BREXIT negotiations is defined through European law and only provides two years. Due to submission of the withdrawal bill on 29 March 2017, BREXIT will become effective as of 30 March 2019, unless an extension is unanimously granted. This, however, appears unlikely as European elections will take place in early 2019 and extended negotiations would imply a longer UK-membership. The timetable for the highly complex negotiations is therefore very ambitious, and it is currently questionable, whether the available time can provide for both, an orderly UK-withdrawal from the EU and a framework for future cooperation. However, it is possible for the negotiation parties to easily establish Mutual Recognition Agreements (MRA) to define cooperation and standards, especially since most standards are currently identical through EU framework. Hopefully, BREXIT-negotiations will deliver the right results for patients and companies alike, in order to ensure the continuous access to medicines in the UK and the EU. Due to the difficulty of negotiations and strategic approaches of the UK government and the European Commission, concrete results can only be expected towards the end of the given timeline. Therefore, it is advisable for companies to prepare for a hard BREXIT with UK leaving the EU without any mutual agreements of further cooperation. Any negotiation progress should be closely monitored and its impact should be individually assessed in order maintain business in the UK and the EU alike.
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEUV</td>
<td>Treaty on the Functioning of the European Union</td>
</tr>
<tr>
<td>AMG</td>
<td>German Drug Law</td>
</tr>
<tr>
<td>CHMP</td>
<td>Committee for Human Medicinal Products</td>
</tr>
<tr>
<td>CMDh</td>
<td>Coordination Group for Mutual Recognition and Decentralised Products (human)</td>
</tr>
<tr>
<td>CMS</td>
<td>Concerned Member State</td>
</tr>
<tr>
<td>DCP</td>
<td>Decentralised Procedure</td>
</tr>
<tr>
<td>DSGVO</td>
<td>General Data Protection Regulation</td>
</tr>
<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
</tr>
<tr>
<td>ENCePP</td>
<td>European Network of Centers for Pharmacoepidemiology and Pharmacovigilance</td>
</tr>
<tr>
<td>EPÜ</td>
<td>Convention on the Grant of European Patents</td>
</tr>
<tr>
<td>EU IPO</td>
<td>European Union Intellectual Property Office</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Product Regulatory Agency</td>
</tr>
<tr>
<td>MRA</td>
<td>Mutual Recognition Agreement</td>
</tr>
<tr>
<td>MRP</td>
<td>Mutual Recognition Procedure</td>
</tr>
<tr>
<td>PAES/PASS</td>
<td>Post Authorisation Efficacy /Safety Study</td>
</tr>
<tr>
<td>PRAC</td>
<td>Pharmacovigilance Risk Assessment Committee</td>
</tr>
<tr>
<td>PSUR</td>
<td>Periodic Safety Update Report</td>
</tr>
<tr>
<td>QPPV</td>
<td>Qualified Person responsible for Pharmacovigilance</td>
</tr>
<tr>
<td>RMS</td>
<td>Reference Member State</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>SPCs</td>
<td>Complementary protection certificate</td>
</tr>
<tr>
<td>TFEU</td>
<td>Treaty on the Functioning of the European Union</td>
</tr>
<tr>
<td>xEVMPD</td>
<td>Extended Eudravigilance Medicinal Product Dictionary</td>
</tr>
</tbody>
</table>