Brexit: The Implications for the Life Sciences Sector

30 April 2019

DLA PIPER

Table of Contents

Introduction

Brexit is highly fluid and subject to frequent change. Accordingly, the advice within this interactive Life Sciences guide (including imposed UK Government deadlines) is accurate as of **26 April 2019.**

This guide assumes an Exit Date of **31 October 2019**; however this is subject to change. For further information see Brexit Scenarios on page 9.

This guide is best viewed on-screen to make use of the hyperlinks within it.

For further information please contact **Caroline Scott** or **Paul Hardy**.

Click here to begin.

Key contacts

Caroline Scott
Senior Associate, Life Sciences
T +44 (0) 131 242 5077
caroline.f.scott@dlapiper.com

Paul Hardy
Brexit Director
T +44 (0) 207 153 7099
paul.hardy@dlapiper.com

Key contributors

Bonella Ramsay
Partner, Life Sciences
T +44 (0) 20 7796 6028
bonella.ramsay@dlapiper.com

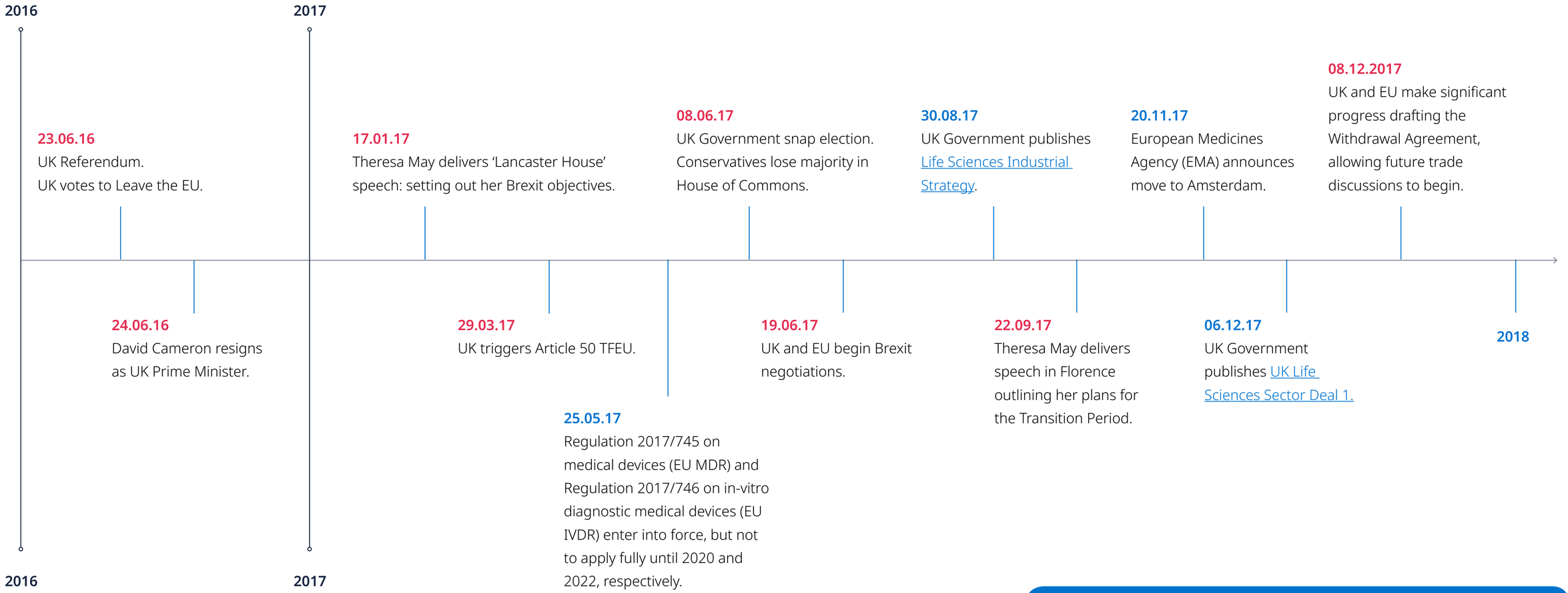
Sam Mitchell
Trainee
T +44 (0) 207 153 7552
sam.mitchell@dlapiper.com

The Brexit Picture

Click on each time-period to see how Brexit has developed, or what it means for each aspect of Life Sciences

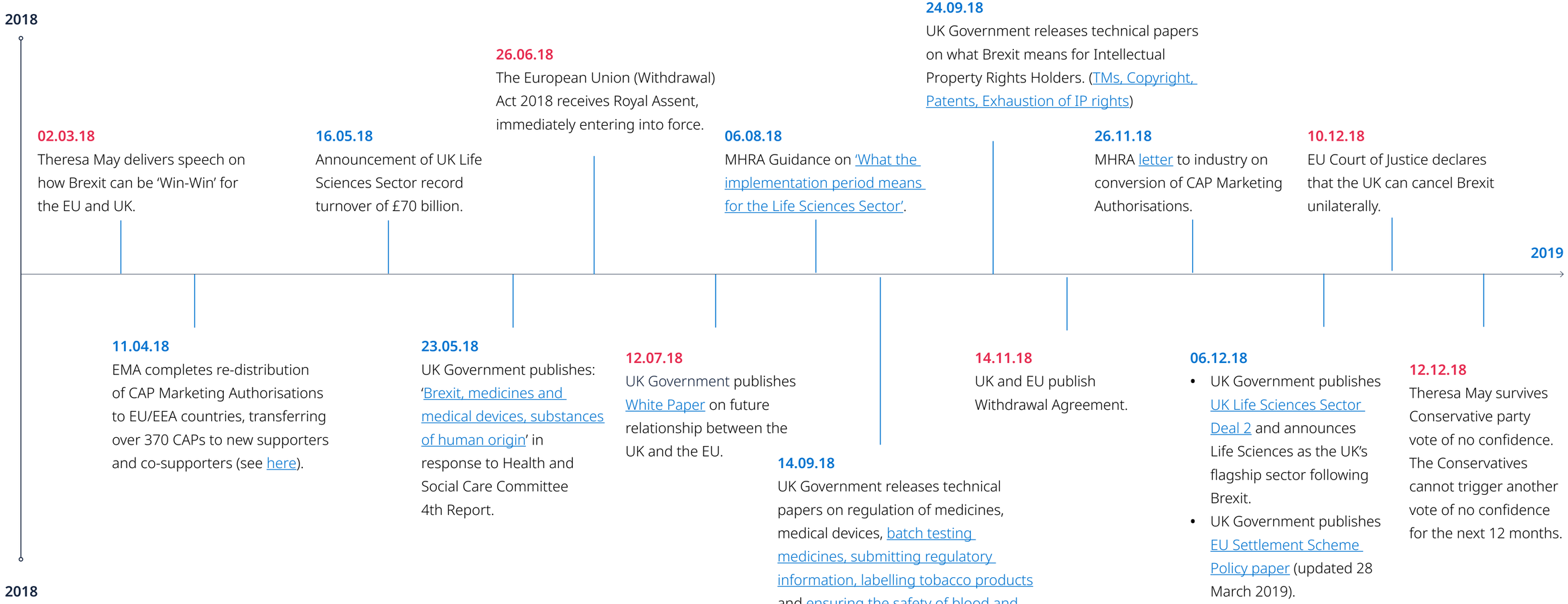
MEDICINES | MEDICAL DEVICES | CLINICAL TRIALS | ORPHAN DRUGS & MUMS | MANUFACTURING & SUPPLY | BATCH TESTING & PARALLEL IMPORTS | PATENTS & SPCs & PEs | TRADE MARKS & DESIGNS | COPYRIGHT & DATABASE RIGHTS | DATA PROTECTION & PRIVACY | PEOPLE & MOVEMENT | UK GOVERNMENT SUPPORT | FURTHER AHEAD | GLOSSARY OF TERMS

2016 – 2017



Note to reader: Dates in **blue** reflect key dates for the **Life Sciences** sector.

2018


2018
02.03.18
Theresa May delivers speech on how Brexit can be 'Win-Win' for the EU and UK.
11.04.18
EMA completes re-distribution of CAP Marketing Authorisations to EU/EEA countries, transferring over 370 CAPs to new supporters and co-supporters (see here).
16.05.18
Announcement of UK Life Sciences Sector record turnover of £70 billion.
23.05.18
UK Government publishes: 'Brexit, medicines and medical devices, substances of human origin' in response to Health and Social Care Committee 4th Report.
26.06.18
The European Union (Withdrawal) Act 2018 receives Royal Assent, immediately entering into force.
12.07.18
UK Government publishes White Paper on future relationship between the UK and the EU.
06.08.18
MHRA Guidance on 'What the implementation period means for the Life Sciences Sector'.
14.09.18
UK Government releases technical papers on regulation of medicines, medical devices, batch testing medicines, submitting regulatory information, labelling tobacco products and ensuring the safety of blood and blood products.
24.09.18
UK Government releases technical papers on what Brexit means for Intellectual Property Rights Holders. (TMs, Copyright, Patents, Exhaustion of IP rights)
14.11.18
UK and EU publish Withdrawal Agreement.
26.11.18
MHRA letter to industry on conversion of CAP Marketing Authorisations.
06.12.18
• UK Government publishes UK Life Sciences Sector Deal 2 and announces Life Sciences as the UK's flagship sector following Brexit.
• UK Government publishes EU Settlement Scheme Policy paper (updated 28 March 2019).
10.12.18
EU Court of Justice declares that the UK can cancel Brexit unilaterally.
12.12.18
Theresa May survives Conservative party vote of no confidence. The Conservatives cannot trigger another vote of no confidence for the next 12 months.
2019
2018

January and February 2019

2019

01.01.19
EMA temporarily shuts down services due to physical relocation.

02.01.19
MHRA issues second letter to CAP Holders advising on conversion of CAP to UK MAs and providing Product Licence Numbers.

03.01.19
- MHRA response to consultation on EU exit no-deal legislative proposals.
- MHRA issues guidance on regulation of medicines, medical devices and clinical trials.

15.01.19
House of Commons holds first vote on the Withdrawal Agreement: defeated by 432 votes to 202.

16.01.19
Theresa May survives Labour party vote of no confidence. No limit on the number of times Labour can call this vote.

24.01.19
UK Government announces Contingency Legislation to ensure UK Legal system can continue to operate without gaps or defects.

29.01.19
House of Commons votes against delaying Brexit and asks Theresa May to renegotiate the controversial Irish Backstop in the Withdrawal Agreement.

31.01.19
MHRA issues updated guidance on no-deal scenario.

01.02.19
EMA issues guidance for Medicinal Products in no-deal scenario (revised on 04.02.19).

05.02.19
UK Government publishes updated guidance on IP & Brexit (further updated 02.04.19).

07.02.19
UK and EU re-open Brexit talks.

14.02.19
UK and USA sign Mutual Recognition Agreement on Conformity Assessment.

18.02.19
Group of 8 Labour MPs resign from the Labour group. Further Labour and Conservative resignations followed.

21.02.19
UK Government publishes guidance on how EU trade marks will be converted into UK trade marks and the numbering policy to be used.

26.02.19
UK Government publishes guidance on medical devices and further guidance on how medicines, medical devices and clinical trials will be regulated in a no-deal scenario.

2019

March 2019 onwards

12-14.03.19

12.03.19: Second meaningful vote on Withdrawal Agreement: defeated by 149 votes.
13.03.19: Commons votes against no-deal Brexit (312 votes to 308).
14.03.19: MPs vote 413 to 202 in favour of asking EU to delay Brexit.

29.03.19

- Withdrawal Agreement defeated for the third time by the House of Commons (344 votes to 286). April will see the Commons cast further votes on possible Brexit options.
- The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 was passed by UK Parliament.

08.04.19

UK Parliament passed the European Union Withdrawal Act 2019 ('The Cooper Bill'), obliging Theresa May to seek an extension from the EU.

10.04.19 & 11.04.19

- UK and EU hold emergency summit to discuss Brexit.
- Early on 11.04.19 the EU and UK agree 'Flextension' to delay Brexit to 31.10.19, but the EU rejected Theresa May's request for an extension to 30.06.19.
- This decision will cease to apply on 31.05.19 if the UK has not held European Parliamentary elections and not ratified the Withdrawal Agreement by 22.05.19. The UK Parliament does not need to approve this flextension despite it being different from 30.06.19.

Life Sciences as of Exit Date:

- **Deadline for (i) UK based applicants to switch to EMA applications; and (ii) UK MAs transfer to EU holders.**
- **MHRA takes over EMA regulatory functions with respect to the UK.**
- **EMA active in Amsterdam.**
- **Contingency Legislation effective.**

23-26.05.19

European Parliamentary elections to take place.

31.10.19

2300 GMT: EXIT DATE

(assuming an earlier Exit Date has not occurred).

04.03.19

MHRA publishes guidance on how to make MHRA submissions on human medicines if there is no-deal.

18-22.03.19

18.03.19: MHRA publishes further guidance notes on a Hard Brexit.
19.03.19: Speaker holds that a third Brexit vote on the Withdrawal Agreement must be 'substantially different' to previous votes.
20.03.19: Theresa May writes to Brussels requesting extension to the negotiating period.
21.03.19: Following EU summit and subject to UK approval, EU agrees to delay Brexit to either the 12.04.19 (No Deal) or 22.05.19 (Deal approved). EMA advises that the deadline of 29 March in all its guidance should be understood to be 12.04.19 until further notice. Note that given the recent changes to Exit Date the EMA now advise that the date should be read as 31.10.19.

01.04.19

- UK Parliament rejects all four Brexit alternatives.
- Annual Fee for converted CAP becomes payable to MHRA.
- Human Medicines (Amendment etc.)(EU Exit) Regulations 2019 and the Medical Devices (Amendment) (EU Exit) Regulations 2019 passed by UK Parliament.

03.05.19*

Deadline for MAH to opt out of automatic CAP Conversion.

22.05.19

Deadline to ratify the Withdrawal Agreement if the UK does not intend to hold EU Parliament Elections.

31.05.19

Flextension expires if the UK has not ratified Withdrawal Act or held European Parliament Elections: resulting in a Hard Brexit on 01.06.19.

(*) These deadlines were updated to reflect an Exit Date of 12 April 2019. Given the recent changes to Exit Date (as defined herein), these dates may be revised further.

General UK Position as of Exit Date:

- No Transition Period if Withdrawal Agreement not ratified by UK Parliament.
- Customs/Trade Tariffs imposed.
- UK becomes Third Country and automatically reverts to trading on WTO terms.
- Contingency Legislation impacting wider UK industry takes effect.
- UK/USA Mutual Recognition Agreement enters into force.
- New trade deals can commence – with the US already stating it is 'ready to deal'

Brexit Scenarios

Hard Brexit Scenarios:

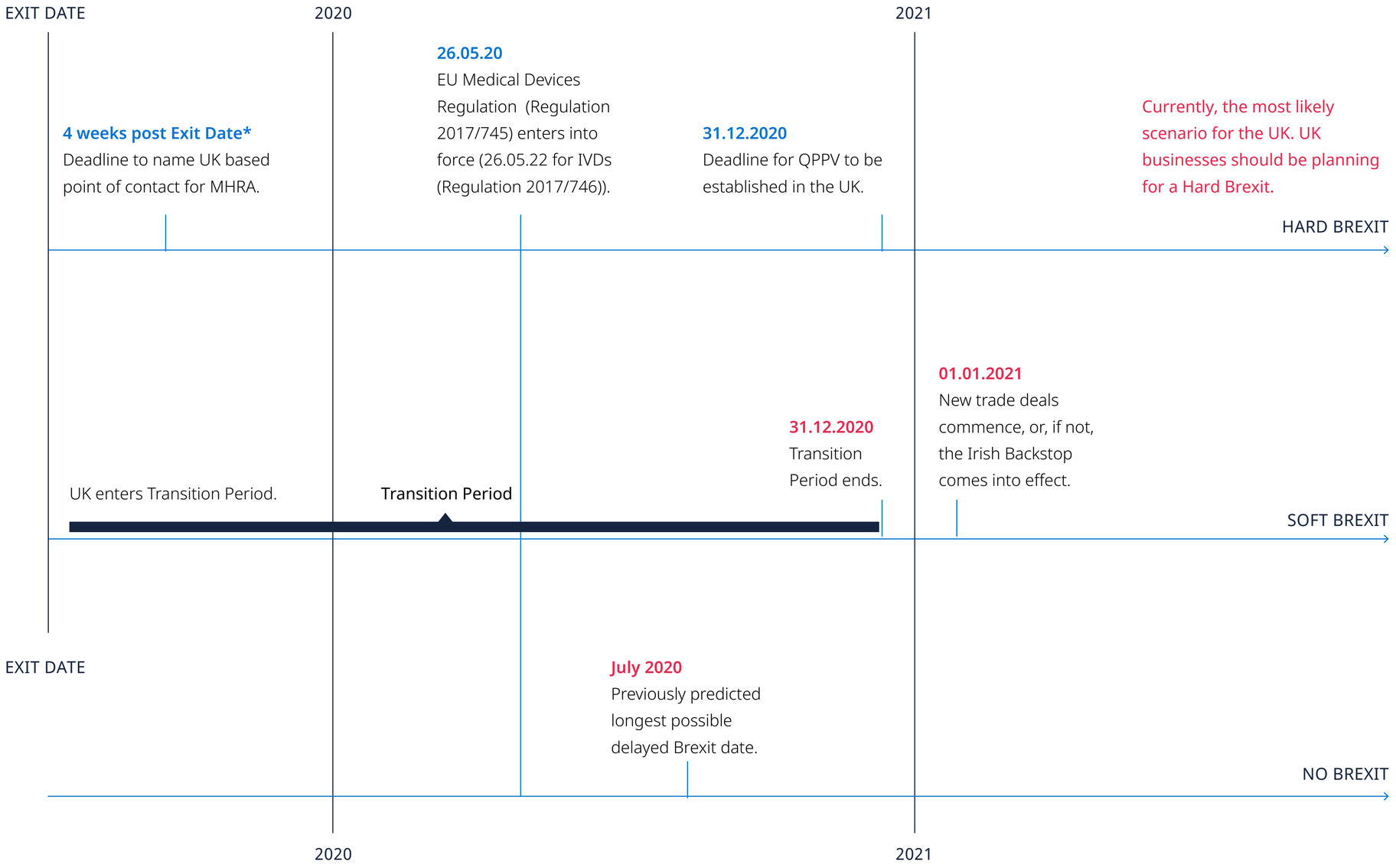
1. Exit Date is 01.06.19
UK Government fails to ratify Withdrawal Agreement before 22.05.19 and does not hold EU Parliament Elections; or
2. Exit Date is 31.10.19
UK Government does hold EU Parliament Elections but fails to ratify the Withdrawal Agreement.

Soft Brexit Scenarios:

1. Exit Date is Pre 22.05.19 if the UK ratifies the Withdrawal Agreement before EU Parliament Elections; or
2. Exit Date is Post 22.05.19 but before 31.10.19
UK Government does hold EU Parliament Elections and subsequently ratifies the Withdrawal Agreement before 31.10.19.

No Brexit

Prior to any Exit Date, the UK revokes Article 50 TFEU. This is most likely to occur if a General Election is won by a political party with a manifesto pledge to remain, or Parliament agrees to legislate for a second referendum. This would require a further long extension.



(*) These deadlines were updated to reflect an Exit Date of 12 April 2019. Given the recent changes to Exit Date (as defined herein), these dates may be revised further.

Medicines

- UK held Marketing Authorisations (MAs) must be transferred to holders established in the EU before Exit Date. UK-based applicants anticipating a MA after Exit Date will need to change to a non-UK based applicant established in the EEA/EU before Exit Date.

- MAs for Centrally Authorised Products (CAPs) will be automatically Grandfathered to UK MAs on Exit Date – unless the MAH has opted out by notifying MHRA in writing before the deadline (as communicated to holders in the November 2018 letter). The deadline has been amended by the Contingency Legislation and is expected to be 21 days from Exit Date). See here for UK Government guidance on CAPs conversion.

- MAHs will have one year from Exit Date to provide MHRA with baseline data for converted CAPs. Two days after submission of this data, the MAH can apply for a Certificate of Pharmaceutical Product which may be required for manufacturers to export medicinal products. Further guidance can be found here.

- Pending CAPs will be assessed depending on what stage of the assessment timetable has been reached:
  - Day 181 – outstanding issues assessed by MHRA in a tailored assessment.
  - Day 120 – either an In-Flight Assessment (Route 1) or Targeted Assessment (Route 2).
  - Pre day 120 – applications in the first phase will need an independent assessment by MHRA.

- More information on pending applications can be found here.

- The abridged procedure for Generic, Abridged Applications for UK MAs will remain in place in the UK; however they will require amending as it will not be possible to rely on European reference data after Brexit. The implication of this is that generics companies must file a complete set of regulatory data in the UK to obtain authorisations in the UK, otherwise generic or biosimilar products will not be available in the UK.

- The deadline for amending administrative details on the packaging and leaflets for medicinal products in the UK to comply with UK requirements is the end of 2021. As stated in MHRA guidance, it is likely that UK companies will not be able to comply with the verification and authentication requirements under the Falsified Medicines Directive and thus these legal obligations would be removed in respect of all actors in the UK Supply Chain. The UK Government is evaluating the options for a future UK falsified medicines regulatory framework. More information can be found here.

- UK MAs based on EU reference products that have been granted/ are pending prior to Exit Date will remain valid after Exit Date.

- For further guidance on regulating medicines click here.

- For information on making submissions to the MHRA, click here.

Legal Presence

- MHRA will continue to need a named individual who can: (i) be contacted in the event of a safety issue; (ii) require independent re-testing of medicines; and (iii) withdraw the medicine from the market if needed.

- A UK MAH must be established in the UK by 31 December 2020:
  - A change of ownership will need to be submitted to MHRA to change from an EU MAH to a UK MAH.

- Companies will be expected to put in place a UK based contact person within 4 weeks of Exit Date:
  - This is a temporary solution until MAH can be changed as above.
  - This individual must be accessible to the licencing authority in respect of any matter in relation to the MA.

- Companies will have until 31 December 2020 to establish a UK based QPPV. Further UK Government guidance can be viewed here. Government guidance on QPPVs can be found here, and on pharmacovigilance procedures here.

Medical Devices

- Following Exit Date, all medical devices, active implantable medical devices, In-Vitro Diagnostics Medical Devices (IVDs) and custom-made devices will need to be registered with the MHRA to be placed on the UK market. There is a grace period for complying with these additional requirements – see 'Registrations' section of Government guidance.

- New devices being placed on the UK and/or EU market following Exit Date should be authorised by an EU Notified Body.

- The UK will give UK Notified Bodies an on-going legal status and continue to recognise certificates granted by UK-based Notified Bodies prior to Exit Date, allowing products authorised by UK Notified Bodies to continue to be placed on the UK market.

- CE marks approved by a UK-based Notified Body will no longer be valid in the EU/EEA on Exit Date, meaning the devices they have certified will no longer be able to be placed on the EU market. UK exporters of CE marked goods to the EU should put measures in place for re-authorisation of such products by a Notified Body in an EU/EEA Member State.

- CE Marks approved by an EU based Notified Body will continue to be recognised in the UK for a limited (unspecified) period: no separate marking by a UK established Notified Body is required.

- The UK will continue to comply with all key elements of the Medical Devices Regulation (MDR) and the In-Vitro Diagnostics Regulations (IVDR) entering into force in the EU from May 2020 and 2022 respectively. The key elements in the MDR and IVDR will be transposed into the Contingency Legislation.

- Under the MDR, from 26 May 2020 there will be increased requirements for clinical evidence, including an expectation for higher risk devices that clinical investigations specific to the device in question are conducted.

- MHRA will continue to perform market surveillance of medical devices on the UK market.

- Formal UK presence at EU committees in respect of devices will cease at the beginning of the Transition Period or following no-deal.

- UK Government guidance on regulating medical devices (updated 19 March 2019) can be found here.

Clinical Trials

- UK clinical trials will continue to be managed nationally by the MHRA. The UK will continue to recognise existing approvals – no need to re-apply.
- MHRA will require trial sponsors to be based in the UK (or on an approved list – to include EU/EEA countries) following Exit Date. Further guidance can be found here and here.
- The current EU position is that from Exit Date, sponsors based in the UK may no longer sponsor trials conducted in the EU. UK sponsors running a trial in the EU must, from Exit Date, ensure that the sponsor or a legal representative is established in the EU27. Further EU guidance can be found here.
- Clinical trials are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004. These regulations will remain in force, albeit amended by Contingency Legislation.
- The new EU Clinical Trials Regulations 536/2014 (CTR) will likely not be in force on Exit Date. Therefore, they will not be incorporated into EU law under the EUWA and will not apply to the UK. UK Government guidance has stated that the UK will align 'where possible' with the new CTR once it enters into force.

Orphan Drugs and Minor Use Minor Species (MUMS)

- Orphan Drug Designations held by a UK entity/individual must be transferred to a sponsor established in the EEA by Exit Date.
- Transfers are free of charge, but a separate application is required for each designation.
- Proof of EEA establishment must be submitted if there is a change of legal entity. This is likely except where a designation is held by an individual and that individual changes residency to remain in the EEA.
- The EMA has provided a checklist for sponsors on the transfer of Orphan Drug Designations, guidelines and templates. Further information can be found here.
- A new UK system for re-assessing the orphan status of rare disease medicinal products at the point of applying for an MA will be in force following Exit Date (using the current EU criteria as a base and adding UK-specifics).
- The UK will offer market exclusivity and full or partial refunds for Marketing Authorisations as incentives to encourage development of medicines in rare diseases.
- The UK Government will consult on the treatment of orphan drugs in the UK. For further information on orphan drugs, click here.
- A MUMS/limited market classification held by a UK sponsor/applicant must be transferred to a sponsor established in the EEA.
- MUMS/limited market classifications attach to a veterinary product/indication, but do not transfer automatically on transfer of the related MA to a new MAH. Original sponsor/applicant must write to the EMA regarding the transfer of the classification of the product and the MUMS/limited market classification to a sponsor/applicant established in the EEA. This letter should state the document reference number of the MUMS outcome letter confirming the MUMS classification.

Manufacturing and Supply

Manufacturing

- Non-UK based device manufacturers must designate a 'UK Responsible Person' to act on its behalf from Exit Date; a new role to be created under the Contingency Legislation. No labelling changes will be required to reflect this new role. Guidance on this role is available here.

- Human medicines manufactured in the UK will continue to require a UK based QP. Human medicines manufactured and directly imported into the UK from a country not on the MHRA QP List (currently this includes all EEA countries: see here) will require a UK based QP to ensure compliance with the MHRA. See also further information under Batch Testing.

- API Certificates authorised by the UK stating that products manufactured in the UK comply with GMP must be transferred to a holder established in the EU.

- Manufacturers placing a medical device on the UK market must first register with the MHRA. The 'UK Responsible Person' can assume the manufacturer's role as the MHRA will only register manufacturers with a registered place of business in the UK.

- UK based authorised representatives for medical devices/IVDs cease to be recognised in the EU post Exit Date. Manufacturers will need to establish a new authorised representative in an EU country.

- The UK-US Mutual Recognition Agreement, signed February 2019 (entering into force on Exit Date) is intended to streamline processes for GMP inspection and monitoring by the FDA and MHRA/Veterinary Medicines Directorate. When in force it will apply to a broad range of human and veterinary pharmaceuticals, biologicals, IMPs, APIs and medicated feeds. Similar MRAs are being agreed with other countries.

Supply Chains

- If EU-UK trade reverts to WTO terms, EU to UK imports will be subject to import tariffs, clearance procedures and delays. The supply risk profile will depend on the nature of the supply chain (UK-EU, UK-third country, UK domestic) and the product being imported and distributed:

    - For example, import logistics for drugs with particular storage conditions and shelf lives (e.g. insulin, highly sensitive to light and hot or cold temperatures) must be managed to account for likely delays that could result in degradation and consequently loss of stock.

    - Existing wholesalers importing QP certified medicines should refer to the Government guidance for details on complying with the licensing regime and assurance system so they can continue to import medicines that have been QP certified in the EU/EEA.

Batch Testing and Parallel Imports

Batch Testing and QP Certification

- Immediately following Exit Date, medicines regulation in the EU will be the same as the UK, and so batch testing for compliance does not need duplication in the UK in respect of imports from the EU, thereby facilitating the movement of medicines into the UK. The UK Government has advised that these measures shall continue until the UK Government considers that further change is necessary. However, the EU has not yet reciprocated these provisions meaning re-testing for compliance may be needed in the EU in respect of imports from the UK to the EU.

- MHRA to set out a list of countries (MHRA QP List). On Exit Date this list will include EEA countries and those countries with whom the EU has a mutual recognition agreement (MRA). The list can be found here. The UK will continue to accept batch testing of human medicines, and batch testing of IMPs carried out in the countries on the MHRA QP list and imported into the UK, without further clarification. An imported device from the EU into the UK will be treated as a new placing on the market so requirements such as registering the device with the MHRA and ensuring there is a UK Responsible Person in place will apply. For government guidance, click here.

- Human medicines manufactured and certified in a third country on the MHRA QP List will be recognised if conducted by a QP based in the listed country, without further clarification.

- Human medicines manufactured and imported into the UK from a country not on the MHRA QP List will require a UK based QP to ensure compliance.

- For products subject to Official Control Authority Batch Release (OCABR) testing (immunological medicinal products or medicinal product derived from human blood or plasma), if the UK ceases to be part of the Official Medicines Control Laboratory (OMCL) network, either a MRA needs to be in place or the UK National Institute for Biological Standards and Control will need to certify batches before the medicine can be placed onto the market. Any products where the OMCL is in the UK will need to change from Exit Date regards OCABR release for the EEA.

Parallel Imports

- Parallel importing from the EU into the UK will remain possible for an initial period, as the UK has agreed to recognise the EU exhaustion regime. However, this position has not been reciprocated, meaning parallel imports from the UK to the EU may not be possible.

- The UK Government are issuing Parallel Import Licences (PILs) as a replacement for Parallel Distribution Notices (PDNs) in case of a Hard Brexit:

  - PDN holders need to opt in to this process; failing to do so means that the product will no longer be licensed in the UK following Exit Date. PDNs holders have 4 weeks (beginning on Exit Date) to opt in. Following this period, a new application for a PIL will be necessary.

  - For PDN holders issued by the EMA in respect of CAPs, where the UK is listed as the destination country, this process will be automatic (subject to the provision of certain information to the MHRA by 21 April 2019). Click here for further guidance.

  - PIL holders will need to be located in the UK by 31 December 2020, and should appoint a contact person within 4 weeks of Exit Date in any event.

Patents, SPCs and PEs

- The UK is a signatory to the European Patent Convention and European Patent Organisation (EPO); EU membership is not a pre-requisite for either.

- The majority of UK patent law will not be effected by Brexit. Applicable EU patent law is already contained in the Patents Act 1977 (as amended) and the Patent Rules 2007. For example:
  - the Bolar exemption (allowing use of a patented product to obtain approval for a generic medicine); and
  - Patenting of biotechnology inventions.

- Additional contingency legislation, the Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801), will amend UK law to create a UK Supplementary Protection Certificate (SPC) system. SPC grant is conditional on having a valid UK patent and a MA allowing sale of the product in the UK; this remains unchanged.

- Granted SPCs will remain in effect/come in to force as normal subject to the above condition and any CAPs being converted to UK MAs. After Exit Date, the duration of SPCs will be based on the first authorisation to place the product on the market in the UK or the EEA. The Unified Patent Court (UPC) (if it comes into force) will have exclusive jurisdiction over SPCs based on patents granted by the EPO. Additional information on patents and SPCs can be found here.

- Equivalent provisions for Paediatric Extensions (PEs) will be introduced into the Human Medicines Regulations 2012. Procedures will essentially remain the same but new applicants will not need to provide evidence of the MA covering the product across EEA. Granted PEs still require this evidence if challenged or, if pending, for grant of the PE.

Trade Marks and Designs

- All existing EU trade marks (EUTMs) and registered community designs will continue to be valid in the EU. On Exit Date, existing EU rights holders will automatically be granted an equivalent UK trade mark or registered design right, though owners can opt out in limited circumstances. Advice on the numbering system for the new UK rights can be found here.

- The equivalent UK rights will be entirely independent from the EU right i.e. they can be disputed before UK courts, or assigned and licensed separately from the corresponding EU rights.

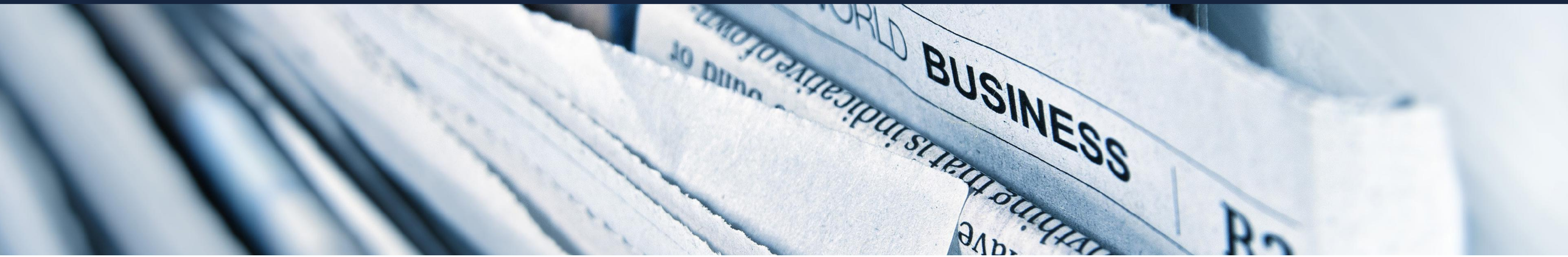
- All pending EUTM applications need to be re-filed with the UK IPO. For a period of 9 months following Exit Date, the UK Government will recognise filing dates, claims to priority and UK seniority in the earlier EU applications. UK applicants will still be able to apply for EU protection under an EU right in the future.

- International trade marks (IRs) designating the EU and pending EU designations of IRs will be treated in materially the same way in the UK as EUTMs and EUTM applications, thus also resulting in equivalent UK rights and the right to file applications claiming priority etc. This includes trade mark registrations protected under the Madrid Protocol.

- Unregistered Community Design rights are an EU right, providing 3 years of protection and completely distinct to the UK Design Right. The UK Government is creating a new 'Supplementary Unregistered Design Right'. This will mirror the characteristics of the existing EU right and all existing disclosed EU unregistered designs will continue to be protected in the UK for the remaining period of protection. No action is needed by rights holders, providing the unregistered design is disclosed in the UK.

- The UK will remain a member of the Madrid and Hague Systems, enabling international protection of trade marks and industrial designs. Note that design registrations under the Hague system will be treated as registered community designs and granted an equivalent UK right.

- Detailed government guidance on these changes can be found here.



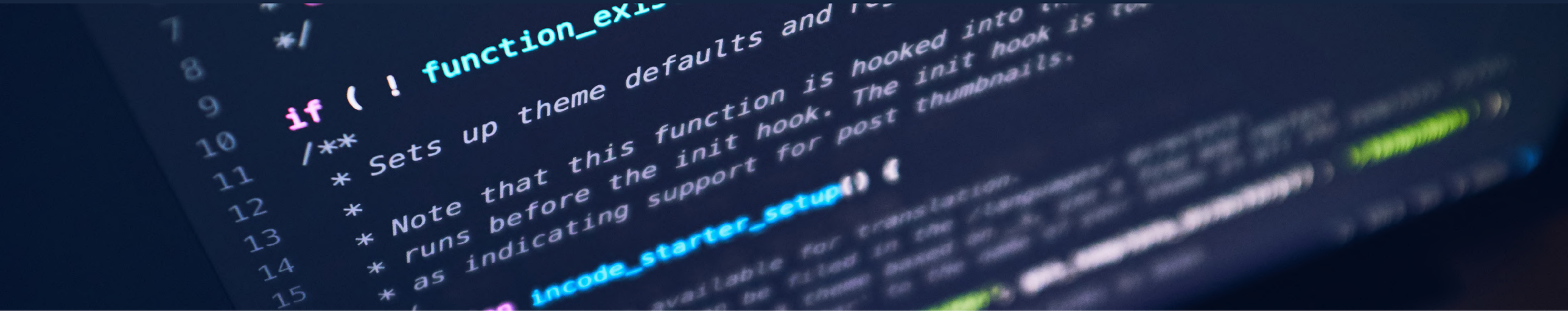
Copyright and Database Rights

- The UK and EU are parties to the main international copyright treaties – the Berne Convention and WIPO treaties. The rules therein underpin copyright legislation in all Member States and will be unaffected by Brexit.

- There are certain unique EU rights where UK users will lose reciprocal protection in the EU, but these mainly affect the media sector and are unlikely to be relevant in a life sciences context (e.g. portability of online audio-visual content).

- Sui generis database rights:
  - under a Hard Brexit:
    - EU-wide right only arises for database makers established in the EU (which will cease to include the UK);
    - UK-established database makers will have database right protection for UK only;
  - under the Withdrawal Agreement, the EU-wide database right shall be extended to cover the UK following Exit Date, and UK-established database makers shall benefit from that 'EU + UK' database right.
  - In event of a Hard Brexit, UK database owners should plan alternative strategies to continue enforcing/protecting rights in their databases in the EU: e.g. restrictive licences, trade secret protection, and copyright where applicable.

- Further government guidance on copyright and database rights can be found here.



Data Protection and Privacy

- In a Soft Brexit, the Withdrawal Agreement maintains the status quo for the duration of the Transition Period. During transition:
  - GDPR directly applicable in the UK and the UK treated as a Member State for the purposes of GDPR.
  - No restrictions on the transfer of personal data from the EU to the UK (or *vice versa*).
  - ICO (UK data protection regulator) continues to be a competent supervisory authority.
- A Hard Brexit will have the following consequences from Exit Date:
  - Immediate restrictions on the transfer of personal data from the EU to the UK (although **not** *vice versa*) – practical consequence is the need for businesses to adopt an appropriate safeguard in respect of these transfers, which will often mean 're-papering' existing contractual arrangements to incorporate the standard contractual clauses.
  - ICO no longer a competent supervisory authority (for example, for lead supervisory authority purposes). This also means businesses lose the benefit of the 'one-stop-shop' regime for cross-border processing, and face dual UK/EU oversight on data protection.
- In the immediate term, the data protection legal framework will remain materially the same in the UK as in the EU – the UK will transpose the GDPR into national law, making certain technical changes in order to create a 'UK GDPR' (to work in conjunction with the Data Protection Act 2018) which closely mirrors the EU GDPR, but which recognises that the UK will no longer be a Member State of the EU (for example, references to 'EU or Member State law' are changed to 'UK law').

People and Movement

- UK nationals in the EU:
  The Withdrawal Agreement provides for continued freedom of movement for UK nationals in the EU until the end of the Transition Period. After which, the rights to remain are regulated. Importantly, the rights to remain are regulated at the national level and it will therefore be for each Member State to decide on UK nationals' rights to remain. In the event of a Hard Brexit, the rules of each Member State will apply from that date.

- Key dates and implications for EU/EEA and Swiss nationals in the UK:
  - For EU nationals who are resident in the UK by 31 December 2020, rights and status will remain the same until 30 June 2021 if the UK leaves the EU with a deal.
  - A new EU Settlement Scheme is open for applications until 30 June 2021 if there is a deal, or 31 December 2020 if there is a Hard Brexit.
  - This scheme will allow EU nationals already in the UK, or those who start living in the UK by 31 December 2020 (or, if there is a Hard Brexit, Exit Date) and have 5 years' continuous residence in the UK to claim 'settled status' and remain in the UK indefinitely, or 'pre-settled status' if they do not have 5 years' continuous residence.
  - Applicants with pre-settled status can remain in the UK and apply for settled status once they achieve 5 years' continuous residence.
  - For applicants arriving in the UK after Exit Date:
    - Permission to enter and remain will be required if wishing to stay for longer than 3 months;
    - Subject to checks, leave to remain will be granted for 36 months, including permission to work and study; and
    - After 36 months, EU citizens must apply under the new skills-based immigration regime if they wish to remain in the UK.
  - Post 31 December 2020, a new UK skills-based immigration regime will apply regardless of whether there is a deal or a Hard Brexit, to any individuals wishing to come to live and work in the UK for the first time from 1 January 2021.
  - Family members will have different rights to live in the UK and rights will also differ depending on whether the UK leaves with a deal or there is a Hard Brexit:
    - If there is a deal, under the EU Settlement Scheme, EU citizens with pre-settled and settled status, who are already in the UK may be joined by close family members up to 31 December 2020 and beyond, provided the relationship began before this date and still exists at time of application.
    - If there is a Hard Brexit, EU citizens with pre-settled and settled status will be able to be joined by close family members until the deadline of 29 March 2022, provided the relationship existed before Exit Date and continues to exist when the family member applies. If a relationship with an EU citizen with settled status comes into existence after Exit Date, the deadline is 31 December 2020. After these deadlines, the new UK skills-based immigration regime will apply.
    - Visa-free travel: Regulation (EU) 2019/592 of the EU Parliament and Council has now been published in the Official Journal to grant UK nationals visa-free travel to the EU following Exit Date for short stays of up to 90 days in any 180 day period. This is conditional on the UK granting reciprocal and non-discriminatory visa-free travel for all EU citizens. This will apply from the day following that on which Union Law ceases to apply in the UK. More information is available here.
    - For further guidance on the EU Settlement Scheme Statement of Intent (21 June 2018) see the Policy paper on citizens' rights in the event of a no-deal Brexit (issued 6 Dec 2018, updated 28 March 2019). See here.

UK Government Support

- In December 2017 and 2018 the UK Government published the Life Sciences Sector Deals 1 & 2 respectively, demonstrating its commitment to the life sciences sector:
  - The UK Government to increase public investment to £12.5 billion for 2021/22.
  - Continued commitment to increase investment in R&D to 2.4% of GDP by 2027.
  - The life sciences sector is named as the UK's flagship sector following Brexit.
- Deal 1 included close to £500 million of UK Government support for major new research programmes and over £1 billion of new industry investment.
- A world first – commitment to sequence 1 million whole genomes in the UK in the next 5 years, and provision of whole genome sequencing as part of routine clinical care for NHS patients with rare diseases and cancer.
- £79 million commitment by the UK Government to the new 'Accelerating detection of disease' challenge.
- The Wellcome Trust has committed £250 million to their Leap Fund for high risk, high reward pioneering science.
- SMEs based in the UK may still access financial and administrative assistance under SME Regulation (Commission Regulation (EC) No 2049/2005) as a non-EEA based company.
- EMA SME guidance (see here and here) for non-EEA based companies suggests establishing a legal entity in the EEA or indirectly benefiting through an EEA established SME regulatory consultancy as solutions.

Further ahead

- The UK Life Sciences industry is consistently ranked in the top global life science hubs, alongside Boston and San Francisco.
- Investment in the UK Life Sciences sector remains upbeat, with Astrazeneca and GSK committing to the UK, with the former in the midst of developing its £500+ million global headquarters and R&D hub in Cambridge. Other UK Government industry partners such as GW Pharmaceuticals, Roche, Celgen, IQVIA Ltd and Oxford Biomedica have committed over £200 million of new investment.
- A forecasted weakening of the pound coupled with attractive private and public sectors may be a positive draw for foreign investors when deciding whether to enter the UK market or enlarge an existing footprint.
- The UK position on Brexit is pragmatic, with the UK Government committing to minimising disruption to ensure 'business as usual'.
- All challenges create opportunities and DLA Piper has the combination of political policy and legal know-how, as well as global coverage, to provide the highest level Brexit and trade advice.

Glossary of Terms (1)

API(s): Active Pharmaceutical Ingredient(s).

Brexit: The United Kingdom's departure from the European Union, to take place on Exit Date.

CAP(s): Centrally Authorised Product(s): benefit from a single MA authorised by the EMA that is valid in all Member States, Iceland, Liechtenstein and Norway.

Contingency Legislation: Legislation passed by powers granted under the EUWA to amend current UK law to reflect that the UK ceases to be a member of the EU. For Life Sciences, three key pieces are: Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/775); The Medical Devices (Amendment) (EU Exit) Regulations 2019 (SI 2019/791); and The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (SI 2019/774).

EEA: The European Economic Area made up of EU countries and Iceland, Liechtenstein and Norway.

EMA: European Medicines Agency. See here for EMA's Brexit website. Note: 29 March deadline in EMA guidance now refers to 31 October 2019.

EU: The European Union.

European Parliament: The parliamentary institution of the EU that has a significant role in the EU budget and legislation. Elections are due to be held on 23-26 May 2019.

EUWA: The European Union (Withdrawal) Act 2018.

Exit Date: 31 October 2019 at 23:00 GMT or possibly earlier, depending on which scenario occurs as set out on page 9 of this guide.

GDPR: General Data Protection Regulation 2016 (Regulation (EU) 2016/679).

Generic/Abridged Applications: Application for a MA for generics/ hybrid abridged/biosimilars which does not require full pre-clinical or clinical studies.

GMP: Good Manufacturing Practice; the minimum standard that a medicines manufacturer must meet in its production process.

Grandfathered: The automatic conversion of MAs for CAPs into UK MAs on Exit Date.

Hard Brexit: The UK leaves the EU with no trade deal and becomes a Third Country on Exit Date.

ICO: Information Commissioner's Office (UK).

IMPs: Investigational Medicinal Products.

MA(s): Marketing Authorisation.

MAH: A Marketing Authorisation Holder is a company, firm or non-profit organisation that has been granted a Marketing Authorisation.

Member State(s): The individual 28 nations making up the EU, currently Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and (currently) the UK.

MHRA: Medicines and Healthcare products Regulatory Agency. See here for MHRA's guidance on a Hard Brexit.

Notified Body: An organisation designated by an EU country to assess the conformity of certain products before being placed on the market.

Paediatric Extension (PE): A 6 month extension that can be added to SPCs under current EU legislation.

Glossary of Terms (2)

QP: Qualified Person who is legally responsible for quality assurance of medicines and GMP.

QPPV: Qualified Person for Pharmacovigilance. The individual (typically employed by a pharmaceutical company) who is personally responsible for the safety of the human pharmaceutical products marketed by that company in the EU.

Soft Brexit: Where the UK and the EU negotiate and agree a deal (as described on page 9 of this guide) and the UK enters a Transition Period.

SPC(s): Supplementary Protection Certificate(s) – a form of intellectual property that extends the protection of patented active ingredients present in pharmaceutical or plant protection products.

TFEU: The Treaty on the Functioning of the European Union (Consolidated version 2016 OJ C 202, 7.6.2016).

Third Country: A country not a member of the EU and not subject to its rules or the jurisdiction of the European Court of Justice.

Transition Period: From Exit Date to 31 December 2020 (or later agreed date if Exit Date is delayed) whereby the UK remains in the EU and EU laws continue to apply.

Withdrawal Agreement: The deal agreed with the European Union that governs the terms of the UK's departure from the EU (published on 14 November 2018). It is still in draft as it is yet to be agreed by the UK Parliament.

Further Useful Links

DLA Piper's dedicated Brexit site: https://www.dlapiper.com/en/uk/focus/brexit-legal-impact/overview/

EMA Brexit Guidance: https://www.ema.europa.eu/en/about-us/uks-withdrawal-eu/brexit-related-guidance-companies

IP and Brexit: https://www.gov.uk/government/publications/ip-and-brexit-the-facts/ip-and-brexit

MHRA Guidance and Publications on a no-deal Brexit: https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario

Contingency Legislation covering regulation of medicines and medical devices: https://www.gov.uk/government/news/contingency-legislation-covering-regulation-of-medicines-and-medical-devices-in-a-no-deal-scenario