Hogan Lovells

Brexit -

What next for Life Sciences companies?

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1. Introduction – Background information

2. Potential consequences for pharmaceutical companies

3. Potential consequences for medical devices companies

4. Q&A – Conclusions

Background Information

What happened?

- 23 June 2016: UK referendum
- 13 March 2017: agreement of the UK Parliament to the withdrawal Bill
- 16 March 2017: Royal Assent from Her Majesty The Queen
- 16 March 2017: the Bill became an Act of Parliament
- 29 March 2017: UK notification letter to the European Council in accordance with Article 50(2) of the EU
- 30 March 2017: White Paper "Legislating for the UK's withdrawal from the EU" from the UK Department for Exiting the EU"
- 31 March 2017: European Council's draft guidelines following the UK's notification under Article 50 TEU
- 5 April 2017: Parliament adopted a resolution laying down the EU Parliament's key principles and conditions for its approval of the UK's withdrawal agreement
- 29 April 2017: Special European Council adopted guidelines following the UK's withdrawal agreement
- 3 May 2017: European Commission presents to the European Council a recommendation for a Council decision on the Brexit negotiations

The UK's 29 March notification letter

- Proposed principles for negotiation with the EU
  - We should engage with one another constructively and respectfully, in a spirit of sincere cooperation

    "*We know that we will lose influence over the rules that affect the European Economy*"
  - We should always put our citizens first
  - We should work towards securing a comprehensive agreement

    "It is necessary to agree the terms of our future partnership alongside those of our withdrawal"
  - We should work together to minimise disruption and give as much certainty as possible

    "people and businesses in both the UK and the EU would benefit from ***implementation periods*** *to adjust in a smooth and orderly way to new arrangements. It would help both sides to minimise unnecessary disruption if we agree this principle early in the process"*

The UK's 29 March notification letter

- Proposed principles for negotiation with the EU (continued)
  - We must pay attention to the UK's unique relationship with the Republic of Ireland and the importance of the peace process in Northern Ireland
  - *We should begin technical talks on detailed policy areas as soon as possible but we should prioritise the biggest challenge*

    "we should also propose a bold and ambitious Free Trade Agreement between the UK and the EU"
  - We should continue to work together to advance and protect our shared European value

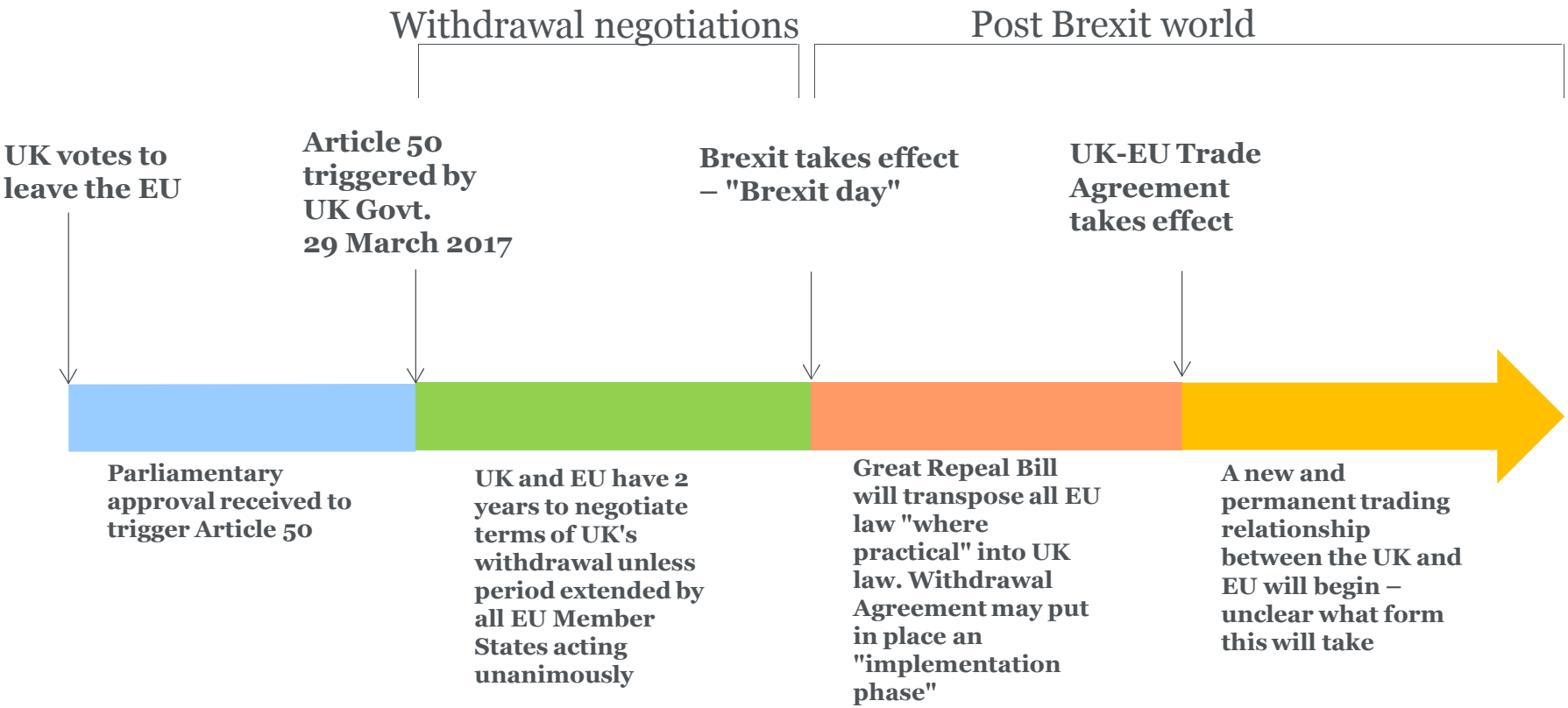
The UK's 30 March White Paper

- Guiding principles for the Great Repeal Bill
  - *"The Government's overall approach is to convert the body of existing EU law into domestic law"*
  - *"This ensures that, as a general rule, the same rules and laws will apply after we leave the EU as they did before"*
  - *"Simply incorporating EU law into UK law is not enough, however. A significant amount of EU derived law, even when converted into domestic law, will not achieve its desired legal effect in the UK once we have left the EU"*
  - *"We have also been clear that no deal for the UK is better than a bad deal for the UK"*

Special European Council guidelines 29 April 2017

- The guidelines define the framework for negotiations under Article 50 TEU and set out the overall positions and principles that the EU will pursue throughout the negotiation:
  - Any agreement with the United Kingdom will have to be based on a balance of rights and obligations, and ensure a level-playing field;
  - Preserving the integrity of the Single Market excludes participation based on a sector-by-sector approach;
  - A non-member of the Union, which does not have the same obligations as a member, cannot have the same rights and enjoy the same benefits as a member;
  - Participation in the Single Market requires the acceptance of all four freedoms;
  - Under Article 50 TEU will be conducted in transparency and as a single package – individual items cannot be settled separately;
  - To the extent necessary and legally possible, the negotiations may also seek to determine transitional arrangements which are in the interest of the Union and, as appropriate, to provide for bridges towards the foreseeable framework for the future relationship.

The Process

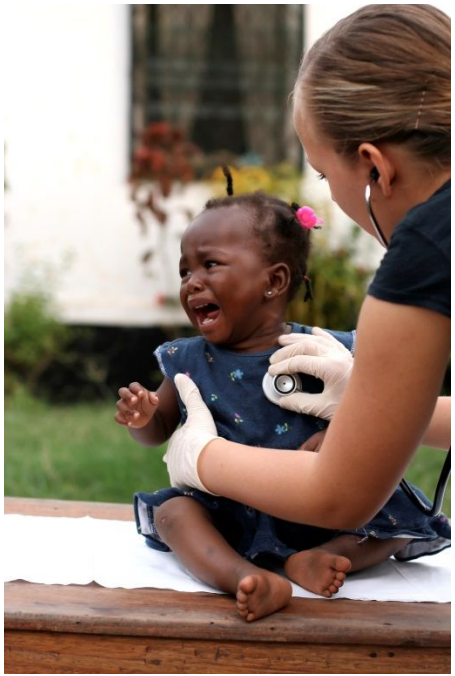

Withdrawal negotiations
Post Brexit world
UK votes to leave the EU
Article 50 triggered by UK Govt. 29 March 2017
Brexit takes effect – "Brexit day"
UK-EU Trade Agreement takes effect
Parliamentary approval received to trigger Article 50
UK and EU have 2 years to negotiate terms of UK's withdrawal unless period extended by all EU Member States acting unanimously
Great Repeal Bill will transpose all EU law "where practical" into UK law. Withdrawal Agreement may put in place an "implementation phase"
A new and permanent trading relationship between the UK and EU will begin – unclear what form this will take

Brexit – what's next?

Where are we now and what's next?

Here we stand: Theresa May has triggered Article 50

Doctor, please help me !



Potential consequences for pharmaceutical companies

Regulation of medicinal products

- Guidelines following the United Kingdom's notification under Article 50 TEU
- Limited details concerning substance. However, the Guidelines include the statement:
  - *"To the extent necessary and legally possible, the negotiations may also seek to determine transitional arrangements which are in the interest of the Union and, as appropriate, to provide for bridges towards the foreseeable framework for the future relationship."*

Regulation of medicinal products – related checks

- For marketing authorisation holders established in the UK:
  - How many of your products are based on centralised marketing authorisations granted by the European Commission?
  - Where are your third party manufacturers based?
  - Do you have third party suppliers? If so where are they based?
  - Do you have supply agreements for your authorised medicinal products with sites in other EU Member States?

Regulation of medicinal products – related checks

- For all marketing authorisation holders:
  - How many medicinal products for which you have a marketing authorisation and which are currently available on the EU market:
    - Rely on a marketing authorisation granted nationally by the MHRA?
    - Rely on a marketing authorisation granted through a decentralised procedure for which the MHRA was the Reference Member State authority?
    - Rely on a marketing authorisation granted by the MHRA on the basis of mutual recognition of a marketing authorisation granted by another EU Member State?

European Commission's and EMA's perspective (1)

On 2 May 2017, the European Commission and the European Medicines Agency published a notice to marketing authorisation holders (MAHs) of centrally authorised medicinal products concerning the MHAs legal obligations while preparing for Brexit.

"marketing authorisation holders of centrally authorised medicinal products for human and veterinary use are reminded of certain legal repercussions, which need to be considered:

- *EU law requires that marketing authorisation holders are established in the EU (or EEA);*
- *Some activities must be performed in the EU (or EEA), related for example to pharmacovigilance, batch release etc"*

European Commission's and EMA's perspective (2)

In the notice it was also pointed out that:

- The MHAs may be required to adapt processes and to consider changes to the terms of the marketing authorisations to ensure its continuous validity and exploitation, once Brexit becomes a reality;
- The MHAs will need to act sufficiently in advance to avoid any impact on the continuous supply of human or veterinary medicinal products within EU;
- The MHAs are expected to prepare and proactively screen authorisations they hold for the need for any changes. The necessary transfer or variation requests will need to be submitted in due time considering the procedural timelines foreseen in the regulatory framework.

EMA's collaboration with national authorities

General principles for workload distribution will include:

- ensuring business continuity;
- maintaining the quality and robustness of the scientific assessment;
- continuing to comply with legal timelines;
- ensuring knowledge retention, either by building on existing knowledge, or through knowledge transfer;
- assuring an easy implementation and medium- and long-term sustainability.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/04/news_detail_002738.jsp&mid=WC0b01ac058004d5c1

Potential consequences for Medical Device companies

Different Regulatory systems

- Compliance with EU requirements and UK requirements applicable to medical devices
  - When? In theory from 2019
  - In the EU: compliance with the medical device Directives and from 2020 the new MDR/from 2022 the new IVDR
  - In the UK: which rules will apply?
- How similar will the two regulatory systems be?
  - Gap analysis
  - Creation/update of new SOP
  - Implementation of the practical changes: e.g. labeling, IFU, authorised representative, importer, distributor
  - Internal resources/team size
  - Financial resources

Authorised Representatives

- UK medical devices manufacturers:
  - May be required to appoint a European Authorised Representative established within an EU Member State
  - May decide to completely relocate their activities in the EU
- EU medical device manufacturers:
  - May be required to appoint an authorised representative in the UK
- Non- EU and non-UK manufacturers:
  - May not be able to continue to rely on Authorised Representatives established in the UK to continue the placing of their medical devices on the EU market
    - Authorised Representatives established in the UK may have to stop their activities
    - UK has the largest number of Authorised Representatives established in the EU
    - Towards a penury of authorised representative?

Notified bodies

- Currently 5 notified bodies in the UK
  - BSI, SGS United Kingdom Limited, Lloyd's Register Quality Assurance Ltd., Amtac Certification Services LTD, UL International (UK) Ltd.
- UK notified bodies may lose their right to conduct conformity assessment procedures
- Manufacturers working with UK notified bodies may be required to appoint a new notified body established in an EU Member State.
  - This will require a new conformity assessment to permit the continued CE marking of their medical devices in the EU
  - notified bodies are already refusing clients due to workload. What will be the effect of the Brexit on new requests? Will manufacturers have to face delays in conformity assessment procedures? What will be the impact for patients?
  - Some UK notified bodies such as SGS and BSI have already other offices in another EU Member State: this may be the solution to maintain relationship with manufacturers

Preparing the potential consequences of Brexit

- For non-EU manufacturers:
  - How many of your devices are marketed in the EU with an appointed UK Authorised Representative?
- For legal manufacturers established in the UK:
  - Have you identified an experienced Authorised Representative established within an EU Member State which could serve as your local representative?
  - How many of your devices would require an update of the labelling, outer packages and Instructions for use in order to include the details of an Authorised Representative and benefit from access to EU markets?
  - How many of your devices will need to be re-registered as a result of the appointment of a new Authorised Representative?
- For all medical device manufacturers:
  - How many of your devices rely on CE Certificates of Conformity granted by a UK notified body?

Clinical investigations

- What about clinical studies that will begin in the next two years or will continue after this period?
  - Related questions of governing law
- Will informed consent previously given by UK patients remain valid?
- UK sites will not benefit from the multi-centre approval process provided in the new MDR
- UK sponsors will be required to appoint an authorised representative in the EU
- UK sponsors will be required to appoint Data Protection Representatives in all EU Member States where sites are based

On-going participation in EU research programs

- Participation in 7FP/Horizon 2020 is open to third country sites
- Funding is available only to EU sites
- What are the consequences for on-going projects for which UK sites have received funding from 7FP/Horizon 2020?
- What are the consequences for pending applications for Horizon 2020 that include UK participants?

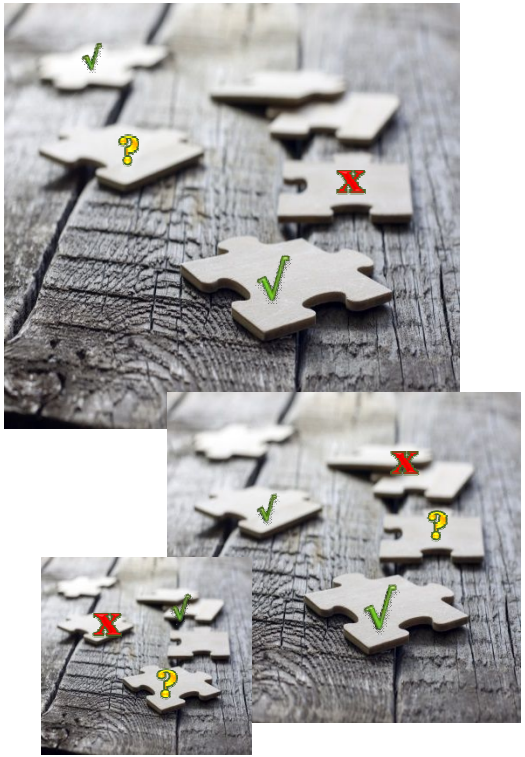
Commercial considerations

The transitional period

The “Great Repeal Bill”

- **There will not be a comprehensive New World on Brexit Day:**
  - There will need to be transitional arrangements between the UK and the EU
  - There will also need to be a UK domestic law transition

- UK's intention is to **transpose all EU law "where practical" into domestic law on Brexit Day** via a **Great Repeal Bill**:
  - White paper issued
  - What does this mean in a life sciences context?
  - The process of review and reform post-Brexit is a mammoth task
  - Much legislation relevant in the Life Sciences industry will refer to EU institutions and will require amending (and in some cases EU27 agreement) to be ready for Brexit day



Commercial considerations

What matters to the Life Sciences industry

- What else to consider besides the impact on regulation?
- People
- Commercial and trade
- Patient safety

Commercial considerations

Supply chain impact

- Using up old stock?
- Are active ingredients, components, bulk or finished products transported to and from the UK as part of your supply chain?
- Lead times for new packaging?
- How much existing stock do you hold? Where is it located?
- Import/export of products and component to and from UK and EU
- Who is responsible for complying with any additional border control requirements?
- Border control requirements

Commercial considerations

Contract Healthcheck

- Incoterms and payment clause:
  - who is responsible for any new tariffs that may apply post-Brexit?
  - what about the costs of delays?
  - mechanism for currency fluctuation?
- Territory definition: will contracts continue to cover the UK post-Brexit?
  - have you reviewed your key licences, distribution arrangements and collaborations?
- Will Brexit trigger:
  - a price change, or
  - a termination event?
- Are there any implications to interpretation due to changes in legislation and/or the UK's status within the EU?
  - do your definitions still work (e.g. cGMP)?
  - will equivalent new UK laws be caught?

Parallel import business between UK and EU

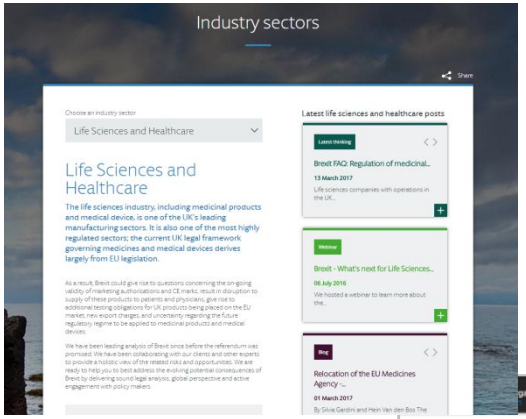
Possibility of three scenarios:

- The "Norwegian model"
- The "Swiss model"
- The "hard" Brexit – leaving the European Single Market and trading with the EU as if the UK were any other country not part of the EU

http://hoganlovellsbrexit.com/blog/69/brexit-the-end-of-parallel-imports-from-the-uk-

Sources for further information

- Access our resources at
  - www.hoganlovells.com/brexit
  - http://maps.hoganlovells.com/europe/
  - http://hoganlovellsbrexit.com/industries?type=Life+Sciences+and+Healthcare
- Contact us at brexit@hoganlovells.com



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