BREXIT SERVICES

WE CAN HELP YOU TO PREPARE FOR THE 30TH OF MARCH 2019

Cilatus
BIOPHARMA CONSULTING

ORPHAN DRUG
CONSULTING

BREXIT

The Brexit negotiations are ongoing and the outcome of these is still uncertain.

According to the current timeline the UK will become a third country as of **30 March 2019**, unless a ratified withdrawal agreement establishes another date.

Companies have been advised by the EMA to ensure they are prepared for this outcome.

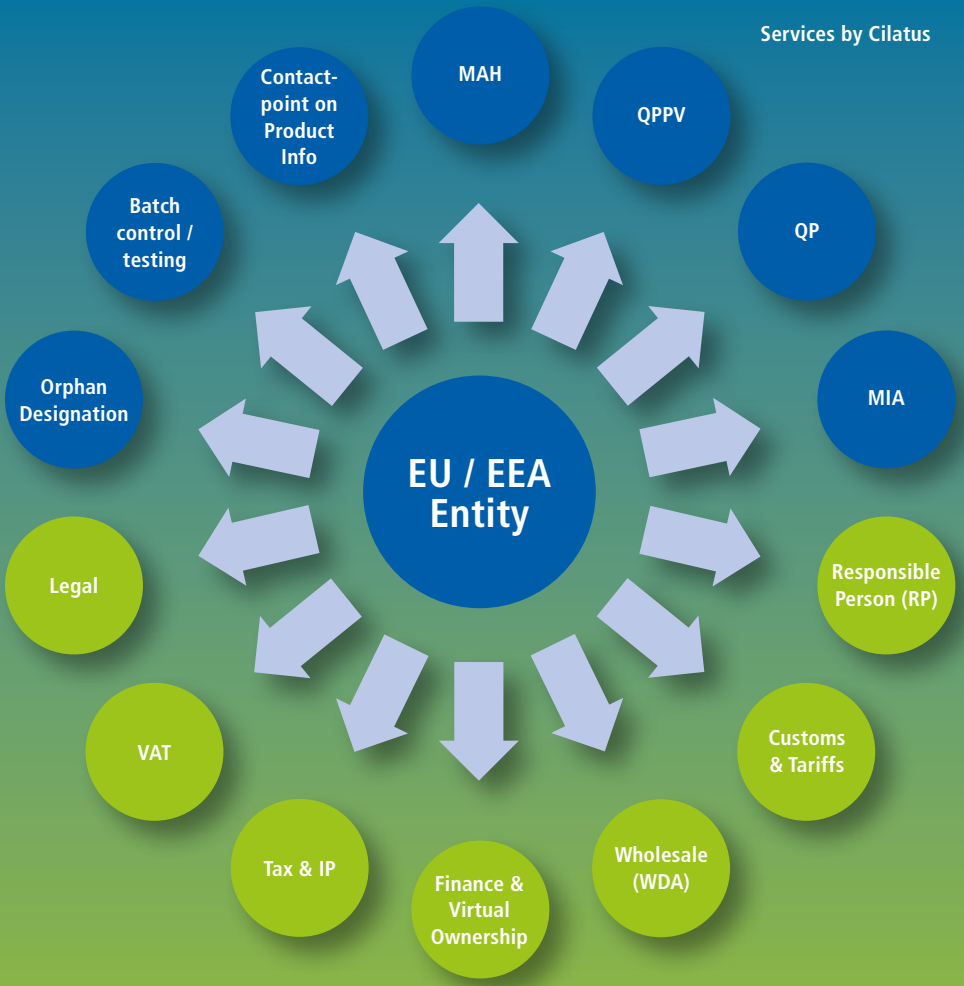
The UK government have asked companies to stockpile 6 weeks drug supply.

SOME IMPLICATIONS OF UK BECOMING A 3RD COUNTRY

- UK Entity cannot hold Marketing Authorisations.
- UK Entity cannot be the official contact point with EU Regulators.
- UK Entity cannot QP release to EU/EEA countries.
- UK Entity cannot wholesale to EU/EEA countries.
- Products manufactured in UK need to be imported to EU/EEA including batch control testing.
- UK will no longer be part of (over 50) EU free trade agreements with non-EU countries.
- Greater administrative burdens and costs will become a reality from a supply chain and VAT perspective including potential working capital implications.
- Intellectual property protection, including patents and trademarks may lapse after Brexit.

ACTIVITIES THAT MUST BE PERFORMED IN THE EU/EEA

Services by Cilatus



Services by Orphan Drug Consulting

ARE YOU BREXIT READY?

Marketing Authorisation

- Are your MA's registered to an address in the UK?
- Have you identified an alternative EU location & EU based personnel?
- Do you have dual packs including UK labelling?
- Is your Orphan or other designations held in UK?

MIA

- Does your supply chain include the UK?
- Is your QP located in the UK?
- Do you have a site of importation within the EU?

Wholesaling & Distribution

- Are you planning to move your financial ownership of products out of UK?
- Do you have the required Wholesale Distribution Authorisation (WDA) in an EU country?
- Do you have a RP located in the EU who understands your supply chain?
- Are there changes required to your existing WDA to support financial flow changes?

Customs

- Does your supply chain 'import' into UK?
- Will potential tariff/import changes impact your supply chain?
- Have you personnel to manage the administrative burden of trading with the UK?

Finance & VAT

- Is your EU entity equipped to manage tax and financial changes?
- Does it have the structure to own medicinal products?
- Is your EU entity registered for VAT in the countries you hold product in?

HOW CAN WE HELP YOU MAINTAIN PATIENT ACCESS TO YOUR DRUGS IN EUROPE?

Expertise & Services

- We can help you develop and implement a Brexit strategy.
- We can help you set up an office in Ireland.
- We can transfer your UK based Regulatory Filings/designations to an EU/EEA entity. We can manage these for you post transfer and act as you contact point with the EMA/EU Agencies.
- We have a fully qualified team who can act as Qualified Person (QP) and Responsible Person (RP).
- Our team are named on licenses on behalf of clients and have the experience to provide a smooth transition of responsibilities.

Locations

- We have IMP and commercial MIA's available with an EU location for importation, testing and QP release of all products.
- We can provide a location for your WDA licenses.
- We can ensure that your company locations are fully compliant and meet all EU obligations.

Technical Support

- Our teams can provide support on requirements such as VAT, Customs and artwork/packaging needs.
- We can manage any technical or financial flows transfer needs and interact directly with vendors to complete these activities.
- We can set up the network you require to manage license obligations from a MA, MIA and WDA perspective.

Advice

- We can provide links to legal, financial and tax support.

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Cilatus is a consultancy and service company specializing in CMC development, manufacturing, quality, QP and regulatory.

Our office in Dublin is licensed by the Irish Regulatory Authority to provide QP Release services for clinical and commercial product.

Our office is in Dublin, Ireland with consultants in Ireland, Germany, Switzerland and USA.

Orphan Drug Consulting

Orphan Drug Consulting specializes in setting up structures and processes to enable organizations to supply products from a European Office. We provide expertise in Supply Chain, Customs, VAT, packaging, artwork and multiple launch models, from early access programmes to commercial sales.

Our offices are located in Dublin, Ireland.

Through our collaboration we can provide an End to End service for companies seeking Brexit support.

Cilatus
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ORPHAN DRUG
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