THE UK'S WITHDRAWAL FROM THE EU

THE REGULATORY IMPACT ON PHARMA

The UK's prospective withdrawal from the EU ("Brexit") is the subject of Q&As and practical guidance issued by the European Medicines Agency. These publications provide valuable references for the pharma and biopharma industries and they acknowledge the **"considerable uncertainties, in particular concerning the content of a possible withdrawal agreement"**[1].

It is not only the depth of uncertainties but also their breadth that counts; the UK has been at the heart of EU medicines regulation for decades and relevant legislation covers the life cycle of medicinal products from their inception through to post-marketing.

At PharmaLex, we are at the cutting edge of industry best practices in this unprecedented situation. As your external partner, we will address your requirements systematically and rationally with our impartial perspective. Our solutions are also, above all, practical.

[1] Practical guidance for procedures related to Brexit for medicinal products for human and veterinary use within the framework of the centralised procedure – EMA/478309/2017 Rev. 11, 29 January 2018.

PHARMA'S PREDICAMENT

Pharma's predicament is the uncertainty and the sheer magnitude of the task that Brexit faces it with. The prospect of the UK becoming a so-called "third country", after so many years of immersion in our EU regulatory system for pharma, is daunting. Pharma has a lot to prepare for and reconfigure to ensure the on-going validity of its Marketing Authorisations, the compliance of its supply chain, manufacturing and procurement, as well as in many cases, the integrity of its orphan medicinal product designations and SME registrations. The stakes are very high indeed.

TO ACT NOW OR WAIT?

Within the uncertainty, there are reasons to be optimistic that change may not prove to be as profound as it could be and industry has been granted some breathing space with the agreement on the transitional phase which runs to 31 December 2020. The UK Prime Minister has spoken about a desire to explore with the EU, the terms on which the UK could remain part of EU agencies such as the European Medicines Agency; there are many who regard the fragmentation of pharma regulation in Europe as unthinkable and consider that the life science sector and pharma industry should be subject to a special deal in Brexit negotiations.

However, within the uncertainty, **PharmaLex fully endorses the position of regulators that concerted action should be taken to plan for the "third country" outcomes in order to avoid medicines supply disruption both inside and outside the UK.** The EMA has launched a survey to determine the level of Brexit-readiness. The time to start acting was yesterday.

HOW DOES PHARMALEX HELP?

PharmaLex is perfectly positioned to support industry in **proactively** managing the impact of Brexit because our expertise covers all aspects of regulation, pharmacovigilance, supply chain and compliance. With offices in the EU27 and the UK, we are keeping abreast of developments in relation to both future EU and UK regulatory intelligence for a post-withdrawal era. All bases are covered.

You are not alone. Whether you have yet to **take action**, or you are actively preparing for the UK's withdrawal from the EU and would like an independent review of your Brexit-readiness plan, our team offers **expert guidance and practical advice that will lead to the most robust plan for the continued supply of your medicinal products in the EU27 and the UK.** We work with you to navigate the considerable complexity surrounding the inter-relationships of the impacted areas.

PharmaLex helps companies through:

1	2	3	4
Brexit Impact Assessment	**Brexit-prepardness**	**Stakeholder Reassurance**	**Sharing the Burden**

1. **Let us lead your Brexit Impact Assessment** or coach your team how to lead it effectively.

2. **Let us examine your Brexit-preparedness** strategy and tactical action plan. We will identify the gaps and make practical and constructive recommendations for optimisation.

3. Execution of your Brexit-preparedness programme requires expert governance. **Reassure your stakeholders** that your steering committee has PharmaLex's industry-leading cross-functional expertise on its panel.

4. The enormous volume of work to realign operations, reconfigure supply chains and update your Marketing Authorisations risks distracting your operations from other day-to-day activities and special projects that underpin compliance and commercial progress. **Invite PharmaLex to take on or share your burden.** It is what we are here for.

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

PHARMALEX IN NUMBERS

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS

30,000+
SUCCESSFUL PROJECTS COMPLETED

60% OF OUR CUSTOMER BASE REPRESENT SMALL TO MID-SIZED ENTERPRIZES (SMEs)

50+%
OF OUR PROJECTS ARE GLOBAL

UNDERTAKE
50+
ANNUAL INDUSTRY "EXPERTISE" WORKSHOPS
ON KEY OR NEW INDUSTRY DEVELOPMENTS AND REGULATIONS

1000+
EXPERTS WORKING IN COUNTRIES ACROSS THE GLOBE

25+ YEARS
OF INDUSTRY EXPERIENCE

LEAD 40+
HEALTH AGENCY MEETINGS ANNUALLY WITH EMA/FDA/PMDA

200+
EXPERIENCED AND CERTIFIED LOCAL REPRESENTATIVES SUPPORTING OUR GLOBAL COVERAGE

CONTACT US TO FIND OUT MORE >>

To discuss how PharmaLex can help, contact our Brexit Taskforce leaders:

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