

Brexit Update:

The UK Government Cabinet and European Leaders have formally agreed the plan for the departure of the UK from the European Union; The Withdrawal Agreement, a summary of which is attached for information. However until the plan is agreed by members of the UK Parliament (scheduled around 12th December), there still remains uncertainty over the future of the relationship between the UK and Europe post 29th March 2019.



PCI Pharma Services is committed to ensuring that irrespective of the outcome, the security of supply chain and management of your products is maintained. As a result, regardless of potential trade agreements, PCI Pharma Services continues to plan for a hard Brexit.

WHAT DOES THIS ACTUALLY MEAN AND WHAT IS PCI PHARMA SERVICES DOING?

As part of our global expansion program, PCI acquired an EU based pharmaceutical outsourcing supplier (Millmount Healthcare) in September 2017 located near Dublin, Ireland, to ensure a PCI continued presence within the EU single market. This strategic acquisition provided the foundation for PCI's post-Brexit plans and the commitment to ensure continuity of European supply for all existing and potential new customers, irrespective of the trade agreement that is reached. As a result of this planning, PCI will continue supply as per present arrangements utilizing our EU and UK sites as appropriate.

For PCI Clinical Services customers, in the event of a hard Brexit or no deal, PCI has completed the construction of a clinical storage and distribution facility at the Dublin site that will serve as our EU clinical supplies depot to secure your clinical supply chain for EU investigational sites. This EU S&D depot is now available for audit and we recommend including this site on any new CTA filings. Attached you will find a factsheet which gives advice on how best to structure EU Clinical Trial Applications and list PCI Dublin as an alternative site of EU batch release. Should you need to discuss this further, please contact the PCI Brexit team at brexit@pciservices.com.

In addition, PCI has developed an expansion plan for this EU S&D depot which is dependent on the final outcome of the Withdrawal Agreement. Once the Withdrawal Agreement is confirmed, PCI will then initiate these expansion plans, if required.

For PCI Pharma Services Manufacturing and Commercial Packaging customers, in the event of a hard Brexit or no deal, it is anticipated that commercial products QP released within the UK will not be recognized by the European Union and will therefore require release testing within an EU facility to allow QP release for use within EU member states.

In this instance, the following will be required:

- EU finished product testing on EU importation for commercial products;
- EU QP release for EU supplies;
- UK QP release for UK supplies;
- Regulatory authority approvals in place for QP release, testing and distribution activities.

As a result, a project to deliver a full analytical release testing laboratory within the PCI Pharma Services EU facility, located in Ireland is underway in preparation for transfer of methods from January 2019 onwards.

A second factsheet is attached outlining the suggested approach to commercial activities to ensure the ongoing release of commercial supplies for both the UK and EU.

WHAT IS THE PCI PHARMA SERVICES PLAN MOVING FORWARD?

As the above outlines, the PCI Pharma Services Brexit Plan is progressing at pace, however, on receipt of further guidance or information relating to policies between the UK government and European Union in relation to pharmaceutical trade and supply, this plan will be updated accordingly. Any changes in the PCI plan will then be communicated to you as an existing customer ensuring total transparency.

Whilst there are still unknowns regarding the UK and EU trading negotiations at the present time, PCI would like to assure you that we are working to ensure a seamless transition and continuity of supply for you and your products.

For further information in relation to your specific project(s) with PCI, and to discuss the best way to mitigate the uncertainties of Brexit, please contact your local Business Development Manager or Project Management Team who are on hand to assist with the planning, audit process and execution of any required transfer to our Ireland facility.