ALMAC
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Almac Voice

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The Almac Advantage – Post-Brexit Northern Ireland IVD Landscape

Almac is uniquely placed to act as "one stop shop" with easy access to both the EU and UK for biomarker clinical trial support and CDx development & commercialisation

Dr Stewart McWilliams, Global VP of Quality & Regulatory Affairs
Almac Diagnostic Services

Background

Due to the special status that Northern Ireland has been granted as part of the EU Withdrawal Agreement between EU27 and UK, once the transition period ends (and regardless of whether the EU and UK have concluded a trade agreement by then), Northern Ireland will continue to adhere to EU rules on the regulation of medicinal products, medical devices and the movement of goods. This part of the Withdrawal Agreement is known as the "Northern Ireland Protocol".

This puts Almac in a unique position to allow clients unfettered and flexible access to support their biomarker clinical trial and CDx development in both the UK & European markets.

New MHRA Guidance for Medical Devices

MHRA guidance for regulating medical devices in the UK from the end of the Brexit transition period (31st December 2020), was published on 1st September 2020. Under the terms of the Northern Ireland Protocol, from 1 January 2021, the rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain and will remain aligned with those of the EU.

The Northern Ireland Protocol will offer Northern Ireland-based companies, like Almac, the opportunity to effectively act as if they are still within the EU with respect to compliance with EU In Vitro Diagnostic (IVD) Regulations and EU Clinical Trial Regulations while still being able to easily access the UK market. In other words, the best of both worlds.

As a result, for in vitro diagnostics being used in NI for clinical trials, Almac will remain in compliance with current EU directives and incoming IVD regulations (full compliance to which must be achieved by 26 May 2022 respectively, in line with the EU's implementation timeline.)

The Almac Advantage & Northern Ireland

Almac Group has been working under the current EU directives for many years and Almac Diagnostic Services has been planning for the IVDR for several years. We will be fully compliant with the EU IVDR by the May 2022 deadline. Our customers, who are currently utilising our services, can expect continuity with respect to levels of service and hassle-free regulatory transition for their assays to the new EU regulation.

From the 31st June 2023 for IVD's utilised within the UK a new UKCA mark will replace the CE-mark and will be required to be displayed on all devices. Manufacturers of IVD's, such as Almac, who are located in Northern Ireland, will still be able to register all devices with the MHRA.

As per the current guidance from MHRA, a Northern Ireland-based manufacturer upon registration of an IVD with the MHRA, can then freely supply the device between Northern Ireland and Great Britain with no further registration required.

This is a huge benefit for Almac's customers allowing Almac Diagnostic Services to act effectively as a 'one stop shop' for UK and EU clinical trial support activities such as clinical testing and in vitro diagnostic (IVD) development from our global headquarters based in Craigavon, Northern Ireland.

Further Brexit Information from Almac Group:

About the Author:

Stewart McWilliams leads the Quality Management and In vitro Diagnostic (IVD) Regulatory affairs activities at Almac Diagnostic Services. The team works with pharmaceutical industry clients on the Quality and Regulatory aspects of CDx Development and Commercialisation. They are also responsible for Almac Diagnostic Services' Laboratory Quality Management systems ensuring compliance with ISO13485, CLIA (Federal and New York State CLEP), ISO17025, ISO15189 and the College of American Pathologists (CAP) accreditation requirements.

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An introductory guide to biomarkers, precision, personalised and stratified medicine.

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