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Life Sciences & Health Care Newsletter

Indirect Tax

October 2018

The continuous growth of the Life Sciences and Health Care Industry (LSHC) comes with a fast changing and very specific Indirect tax landscape. A proper management of what are often sector specific requirements is not only crucial for Indirect tax compliance, but also to guarantee minimal lead times in your supply chain, among other benefits.

In that respect, a cross-disciplinary and international Community has been established within Deloitte for LSHC. Several Indirect tax initiatives have been launched, such as newsletters, webinars and seminars. Our LSHC Community is eager to share its knowledge and experiences with industry players.

We are pleased to provide you with the October 2018 edition of our Life Sciences and Health Care Newsletter for Customs & Global Trade and VAT.

The purpose of this quarterly newsletter is to keep you informed about trending issues and regulations in the indirect tax area of the LSHC industry.

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Customs and VAT regulatory updates in the LSHC industry

Extended collaboration on medicine manufacturer inspections between EU and Japan

The EU and Japan already have a Mutual Recognition Agreement (MRA) in place since 2004. MRA allows regulators in both countries to rely on Good Manufacturing Practice (GMP) inspection, to wave batch testing of medicines entering Japan from the EU and vice versa, and to share information on inspection and quality defects. The purpose is to reduce double inspections in both countries.

In July 2018, the EU and Japan decided to extend the agreement's scope to cover *inter alia* chemical pharmaceuticals, homeopathic products, vitamins and herbal medicines, as well as APIs for any of the medicines falling under the agreement. While in the EU, inspections of manufacturing sites are performed by national competent authorities, GMP inspections in Japan are conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

The purpose of an MRA is to facilitate market access and improve the harmonisation of compliance standards, while reducing costs for manufacturers by waiving the re-testing of products upon import. This extended collaboration with Japan relates to the signature of the biggest Free Trade Agreement ever negotiated by the European Union.

The Netherlands: Increase of reduced VAT rate

The Dutch reduced VAT rate will be increased from 6% to 9%, with effect from 1 January 2019. One of the consequences is a potential increase in the cost of medicines and other daily necessities (i.e. refreshments, books, etc.).

The Government stated that it will not include any additional legislation for transitional situations, thus confirming the

earlier statement by the State Secretary for Finance. Services to be performed in 2019 do not require a correction to the new 9% VAT rate if they have been paid before 1 January 2019.

Trending topics in the LSHC industry

Blockchain - A leading pharmaceutical company working with Deloitte on a Blockchain Proof of Concept (POC)

Blockchain has gone far beyond being a tech buzzword. Concrete applications are coming to life in different industries, notably in the LSHC sector. The distributed ledger technology (DLT) is a critical enabler to realise digital supply chain networks.

Deloitte has recently been working with a leading pharmaceutical company on the development of a PoC for the clinical supply chain, narrowing down the use case to the tracking of supply chain events between six stakeholders. In this first test solution, different features of Blockchain are explored, such as the smart contract functionality, record keeping, digital identity, provenance and the multi-party aggregation. Drugs are shipped by the inventory manager with an end destination to the hospital nurse that will administer the drugs to the patient. Several events are captured in Blockchain, such as stock status, shipments requests, approvals etc. The short-term benefits of this solution are improvements to the visibility, transparency and efficiency of the client's internal clinical supply chain. The long-term goal would be to further develop the Blockchain solution to an industry application where the client can integrate a broader group of stakeholders to enhance collaboration and increase transparency.

EU Clinical Trial Regulation - Building a successful program

The new Clinical Trial Regulation (CTR) is set to revolutionise clinical trial processes across Europe, impacting all European Union (EU) Member States and companies that plan to run clinical trials across European territory. It is applicable to Investigational Medicinal Products (IMP) for human use and does not apply to non-interventional trials or trials without medicinal products such as devices, surgery, etc. The regulation seeks to provide a single, unified portal and database for both trial sponsors and regulatory agencies in each Member State. For sponsors, the portal will be the main platform to submit applications and notifications allowing regulators to conduct their assessments and supervise the trial.

The implementation of the new CTR will provide a unified portal and database for trial sponsors and regulatory agencies across EU Member States, promising to bring greater regulatory convergence and efficiency to the clinical trial application process.

Deloitte UK developed a paper providing a synopsis of the new regulation, including insights on timing, the advantages of

preparedness and the impact that Brexit may have. It also provides guidance on how companies can set up a successful CTR program.

Second annual Real-World Evidence (RWE) Benchmarking Survey

In 2018, Deloitte released its second RWE Benchmarking survey on the life sciences industry capabilities. Real-world data refers to healthcare data gathered from a variety of sources, outside of randomised controlled clinical trials. These data sources can include electronic medical records (EMRs), health insurance claims, genomic data, and data from health apps, wearables, and other biometric devices. Real-world evidence refers to insights generated from the data.

Deloitte conducted its second annual real-world evidence (RWE) survey to explore the perceived value, capabilities, and barriers to utilising RWE.

Our survey results reveal that:

- RWE is being used to achieve key strategic priorities across the product life cycle.
- Companies are investing in people, data, and technology (including machine learning) to build internal capabilities.
- Increased use of non-traditional data sources will likely require external strategic partnerships.
- Internal and external barriers threaten the success of RWE initiatives.

Pharma.be releases Pharma Figures for 2017: "Now more than ever, Belgium is a pharma valley"

A report was recently published by Belgian pharmaceutical association Pharma.be (*Association Générale de l'Industrie du Médicament - Algemene Vereniging van de Geneesmiddelenindustrie*) outlining the Belgian biopharmaceutical sector's performance in 2017.

Home to nearly 200 biopharmaceutical companies (of which 130 are pharma.be members), at least 15 general headquarters, 14 research and development sites, 31 production sites and 14 bio-incubators, Belgium holds a prominent position in the worldwide biopharmaceutical industry.

The figures for 2017 speak for themselves. In terms of employment, the industry continued to see its total workforce increase, and is now providing almost 36,000 direct jobs. 2017 also proved to be a record year in terms of Research and Development investments: EUR 3.5 billion (E) were invested in research for innovative therapies. This amount has virtually doubled since 2010.

In 2017, the total value of biopharmaceutical products exported from Belgium across the globe stood at EUR 40.5 billion. About half of biopharmaceutical medicines and vaccines export is destined to countries outside the EU, which underlines the vital role that Belgium plays in the global supply of biopharmaceutical medicines and vaccines.

Contacts

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