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Life Sciences & Health Care Newsletter

Indirect Tax

March 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 March 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.

Content

European Court of Justice Decisions related to the LSHC industry

ECJ, C-51/16, Boehringer Ingelheim case

German legislation on health care requires pharmaceutical manufacturers to grant 'rebates' on products, to both private and public health insurers. While the German VAT authorities accept that a rebate granted to a public health insurer qualifies as a rebate, a different view is taken for 'rebates' paid to private insurers. As such, German VAT included in the 'rebate' paid to private insurers remains irrecoverable for pharmaceutical companies.

The CJEU has ruled that the two situations should not be treated differently.

The Court followed the AG's Opinion, which was covered in this Newsletter's previous issue, and decided that a pharmaceutical company should be allowed to adjust its output tax in relation to rebates paid to private health insurance companies.

However, the CJEU decided that Boehringer should not account for VAT on more consideration than it actually received. The judgment means that it should be possible to

adjust VAT on rebates which have to be paid to third parties by law. Pharmaceutical companies, having a statutory obligation to refund parties, should start investigating potential opportunities.

The above topic was also covered in the 12 January 2018 VAT alert.

Customs and VAT regulatory updates in the LSHC industry

UAE VAT update specific to LSHC industry

The Ministry of Finance in the United Arab Emirates (UAE) published its final version of the Value Added Tax (VAT) executive regulations.

Healthcare-related services and goods are mainly zero-rated if they are generally accepted in the medical profession as being necessary for the patient's treatment (including preventive treatment such as vaccination). Other healthcare services that are not for treatment and not preventative, such as cosmetic, beautification, etc. are subject to the standard 5% VAT rate.

On 28 December 2017, the UAE Tax administration published a Cabinet Decision on Medications and Medical Equipment Subject to Tax at Zero Rate. LSHC companies active in the UAE should carefully examine the VAT treatment applicable to their products and if these products are listed as medication and medical equipment, which are registered with the Ministry of Health and Prevention.

New combined Nomenclature 2018

A new version of the Combined Nomenclature (CN) entered into force since 1 January 2018. The CN forms the basis for the declaration of goods upon import or export, and when goods are subject to intra-Union trade statistics. The CN determines which customs duty rate applies and how the goods are treated for statistical and commercial purposes. The CN is thus a vital working tool for businesses and EU Member States' customs and VAT administrations.

The new version of the CN introduces new codes for products, including chemical products, machinery and parts thereof, as well as foodstuffs. It also includes classification codes for new products. From 1 January 2018, an organisation trading products with new or amended classification codes will have to use these new codes for customs and VAT declarations.

Annex 1 and Annex 2 list the new codes or amending descriptions. It should also be noted that additional changes to the CN can occur during the year.

Classification of medical screws: Regulation (EU) 1212/2014 repealed

Implementing Regulation (EU) No 1212/2014 (Regulation 1212/2014 hereafter) classified medical or implant screws

under CN code 8108 90 90. The reasoning behind this classification was that due to their objective characteristics and properties, the screws should be considered as being of "general use". The CJEU needed to consider whether implant screws, which are solely intended for implant in the human body, can be classified under CN heading 9021.

In the Stryker case, which was covered in a previous issue of this newletter, the CJEU observed that the criteria for consideration are not limited to the product's objective characteristics and properties, but include more importantly:

- The quality of their manufacture
- Their high degree of precision
- Their method of manufacture
- The specificity of their purpose

The CJEU judgment thus opposes Regulation 1212/2014. Consequently, Regulation 1212/2014 is repealed by Implementing Regulation (EU) 2017/2243 of 30 November 2017.

Therefore, surgical screws can no longer be classified under CN heading 8108, for which a 7% duty rate is due. For companies dealing with medical implant screws classified under CN heading 8108, a refund procedure on the grounds of Reg. 2017/2243 should be considered.

Update on EU-Japan Economic Partnership Agreement (EPA)

Following the political agreement reached in July 2017, which was covered in this newsletter's previous issue, the EU Trade Commissioner and the Japanese Foreign Minister announced the successful conclusion of remaining negotiations for the EPA on 8 December 2017. Both parties can now start their internal ratification procedures, finalising the biggest bilateral agreement ever negotiated by the EU, with a planned entry into force before 2019.

Along with the progressive removal of almost all customs duties for import of goods on both sides, the EU and Japan agreed to open the services market to service providers of the other party. Regarding intellectual property rights, the agreement recognises both the Japanese and European protection systems but brings them under a single set of provisions.

Economic operators from EU and Japan will be given a tool to optimise their supply chains and increase business opportunities between the two parties. The benefits at stake are a combination of financial savings, increased competitiveness and ease of doing business with one of the biggest markets for pharmaceutical products and medical devices. This agreement will make it easier to export pharmaceuticals and medical devices by considerably reducing certification costs of EU products exported to Japan. The pharmaceuticals and medical devices sector is expected to be among those to benefit most from the Japan-EU EPA.

The above topic was also covered by the 22 December 2017 Customs Flash.

Regulatory updates in the LSHC industry

Brexit: EMA relocates to Amsterdam

As a direct effect of Brexit, the European Medicines Agency (EMA) will relocate to Amsterdam in the Netherlands, a decision made by the EU27 Member States (EU Member State collective excluding the UK). The Agency will launch its operations in Amsterdam on 30 March 2019 at the latest.

This relocation may stimulate the development of the Dutch pharmaceutical market.

Brexit: Regulatory guidance for pharmaceutical companies

The EMA and the European Commission have published regulatory guidance to help pharmaceutical companies prepare for the UK's withdrawal from the EU. This guidance is an update of the initial Q&A published at the end of May 2017. Updates include additional information on how Brexit will affect marketing applications and authorisations for different medical products, such as generic, biosimilar and hybrid medicines.

The guidance stresses the importance for pharmaceutical firms to be prepared ahead of the UK's withdrawal from the EU on 29 March 2019, in order to avoid any impact on the continuous supply of medicines for human and veterinary use within the EU.

Furthermore, in November 2017, the EMA also published practical guidance for procedures related to Brexit for medicinal products within the framework of the centralised procedure. This relates to practical and simplified requirements that LSHC firms should follow to ensure all necessary changes to their marketing authorisations (i.e. the approval to market a medicine in one, several or all Member States of the EU) are made by the end of March 2019.

Modified-release paracetamol-containing products to be suspended from EU market

Following a recommendation from the Pharmacovigilance Risk Assessment Committee (PRAC), the marketing authorisations for medicines containing modified-release paracetamol, isolated or combined with the opioid tramadol, will be suspended. The modified – or prolonged – release products containing paracetamol are designed to slowly release paracetamol over a longer period, in contrast to the common immediate-release products.

The withdrawal of modified-release products from the EU market is due to the lack of a feasible and standardised way to adapt overdose management across the EU, to cover both immediate and modified-release paracetamol products. As it is

difficult to determine if the overdose is due to immediate or modified-release products, deciding how the overdose should be managed is complicated due to differing treatments.

It should be noted that this decision has no implication on immediate-release paracetamol products. Furthermore, the EMA stressed that patients can continue treatment with modified-release paracetamol products when used in accordance with product guidelines, before switching to an appropriate alternative once their supply runs out.

Trending topics in the LSHC industry

Poland: The evolving definition of fixed establishment for VAT purposes

The approach of tax authorities in Poland concerning the definition of fixed establishment is further evolving and has been made evident in two recent court cases.

In the first case, a foreign company entered into a cooperation agreement with a Polish based company which had a production site in Poland. Following the agreement, the Polish manufacturer produced goods for the foreign company. Although the foreign company did not have any technical and/or personal resources in Poland, the authorities concluded in the binding ruling that the foreign company has a fixed establishment for VAT purposes in Poland, on the grounds that it exerts control over the Polish manufacturer. As such, the Polish production site meets the criteria of fixed establishment of the foreign taxpayer.

The second case presents a similar context, where a manufacturing agreement concluded between a foreign company and a Polish manufacturer, for an indefinite period of time. Based on this agreement, the Polish company provided auxiliary services of warehousing and logistics in relation to the finished products, in addition to producing goods exclusively for the foreign company. Referring to CJEU case law, the Court concluded that fixed establishment for the foreign company occurs as it is in possession (via the Polish manufacturer) of the technical and personnel resources. Therefore, all services rendered by the Polish manufacturer to the foreign company will be subject to VAT in Poland.

The above case law confirms the approach of both the tax authorities and administrative courts with respect to the evolving definition of fixed establishment in Poland. These cases are not limited to pure toll manufacturing but can also further relate to contract manufacturing and other cases where some of the functions are handled in Poland by a Polish based entity (including logistics/warehousing services.

Italy: Mandatory e-invoicing from 2019

The Italian 2018 Budget Law confirms that Italy will introduce mandatory e-invoicing from 1 January 2019 via the Interchange System (SDI or “Sistema di interscambio”) using either XML or the “FatturaPA” format. According to current draft guidelines, all taxpayers with VAT registration in Italy

would be required to comply with this obligation. The above mentioned guidelines are only draft and subject to further amendments in due course until the final legislation is published.

The e-invoicing mandate will gradually be implemented using a pilot group (i.e. oil industry) of taxpayers, who will be obliged to issue invoices electronically from July 2018.

As this requirement already affected companies' invoicing to governmental bodies, it could potentially already impact LSHC companies.

2018 Global health care outlook: The evolution of smart health care

The ever-evolving policies, processes and capabilities are challenging the delivery of smart health care, given the magnitude and complexity of the global health care market. Among all of this, technological advances currently shaping the sector continue to have a dramatic impact on the health and wellbeing of consumers around the world.

This 2018 outlook reviews the current state of the global health care sector and explores trends and issues impacting health care providers, governments, other payers, and patients. It also lays out suggestions for providers, payers, governments and consumers that are constantly looking for innovative and cost-effective ways to deliver patient-centred, technology-enabled "smart" health care, both inside and outside hospital walls.

The future awakens – Life sciences and health care predictions 2022

This Deloitte Centre for Health Solutions' 2017 report builds on its 2014 report - "Healthcare and Life Sciences Predictions 2020: A bold future?" Three years later, the pace and scale of innovation has meant that some of these original predictions are already a reality, while some are still distant and several others may never occur.

The report evaluates evidence in 2017 and provides six new predictions of what the life sciences and health care industries may look like in 2022. Deloitte identifies major trends across industries, key constraints that will need to be overcome and currently available evidence to enable its forecast of the future. Also identified are case examples that illustrate the changing role of the patient and the importance of patient experience, as well as how innovations and new business models are already transforming services and processes.

Measuring the return from pharmaceutical innovation 2017

For the past seven years, Deloitte has been releasing an annual report exploring the performance of the pharmaceutical industry and its ability to generate returns from annual investment in new product innovation. The 2017 analysis is based on the return on investment of 16 biopharma companies

(including Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lily, GSK, J&J, Merck, Novartis, Pfizer, Roche, Sanofi, Takeda, Biogen, AbbVie, Celgene, Gilead) and the strategies being used to maximise performance. The report also addresses emerging technologies that will likely and dramatically influence the future of R&D.

Contacts

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