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Life Sciences & Health Care Newsletter

Indirect Tax

June 2017

The continuous growth of the Life Sciences and Healthcare 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 on 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 June 2017 edition of our Life Sciences and Healthcare 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, Stryker (read more)*
- *ECJ, C-497/16, Juraj Sokáč (read more)*
- *ECJ, C-412/15, TMD Gesellschaft für transfusionsmedizinische Dienste mbH (read more)*
- *ECJ, C-573/15 Etat Belge vs Oxycure Belgium SA (read more)*

Indirect tax Regulatory updates in the LSHC industry:
- *Pharmaceuticals and the 2017 Harmonised System reform (read more)*
- *New amendment in Explanatory Notes for orthopaedic appliances (read more)*
- *EU GMP Annex 21: Possible change of the importation of medicinal products in EEA (read more)*

Regulatory updates in the LSHC industry:
- *Regulation (EU) 2017/746 and Regulation 2017/745 (EU) on medical and on in vitro diagnostic medical devices (read more)*

Trending topics in the LSHC industry:
- *Blockchain: a disruptive technology? (read more)*

European Court of Justice Decisions related to the LSHC industry

ECJ, C-51/16, Stryker - New requirements for classification of medical implant screws

In the case at hand, the ECJ was asked to provide a preliminary ruling on the conditions for medical screws to fall under CN heading 9021. Following the publication of Regulation No 1212/2014, the Dutch Customs repealed the three Binding Tariff Information (BTI's) issued to Stryker, on the ground that a screw intended for use in surgery due to its objective characteristics and properties, are classified as 'part of general use', under heading 8108 (7% duty rates).

The ECJ was asked whether implant screws, which are solely intended to be implanted in the human body, can be classified under CN heading 9021. In its judgment, the ECJ observed that the criteria for consideration are not only the objective characteristics and properties of the product, but more importantly:

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

Therefore, the above objective characteristics distinguish them from ordinary tools, as medical implant screws can only be inserted in the human body by means of specific medical tools.

Consequently, this judgment is to be welcomed for companies dealing with similar goods, since the applicable import duty rate for goods falling under heading 9021 is 0%.

The classification of screws for medical purposes is currently also under discussion at the WCO HS Committee. It seems that the WCO will classify such screws under the heading 9021. This would force the European Commission to withdraw the regulations of 2014, which were subject of the aforementioned case.

ECJ, C-497/16, Juraj Sokáč - Ephedrine and pseudoephedrine, found in medicine not subject to intra-Union controls

In the case at hand, the ECJ was asked to provide clarification on whether medicinal products, which contain scheduled substances, such as ephedrine and pseudoephedrine, remain excluded from the scope of Regulation No 273/2004 and amending Regulation No 1258/2013. These Regulations lay down the rules for intra-Union controls on certain substances, used for illicit manufacture of narcotic drugs or psychotropic substances.

The ECJ highlights the fact that although the amending Regulations No 1258/2013 and No 1259/2013 share the same objective, their application differs since the former applies to Intra-Union trade controls and the latter to Extra-Union trade controls.

As a result, the intention of the Union legislature, when creating the amending Regulation No 1259/2013 for Extra-Union control, was to strengthen the control of trade in medicinal products containing scheduled substances, such as ephedrine or pseudoephedrine. The Union legislature's aim was never to impede legitimate trade in those products.

Consequently, the amending Regulation No 1259/2013 cannot influence the interpretation for medicinal products, outlined in Regulation No 273/2004, which means scheduled substances, such as ephedrine and pseudoephedrine, remain excluded from Intra-Union trade controls of certain substances as indicated in the Regulation.

ECJ, C-412/15, TMD – Supply of blood plasma

The Court was asked to judge whether the exemption for the supply of human blood also applies to the supply of blood plasma obtained from human blood. And if so, whether the exemption also applies to blood plasma that is not intended to be used directly for therapeutic purposes, but exclusively for manufacturing medical products.

The Court drew a clear distinction between blood plasma actually intended for direct therapeutic use and blood plasma solely intended for pharmaceutical purposes. The first type of plasma qualifies for the exemption. However, the supply of plasma obtained from human blood to exclusively manufacture medicinal products, and not to use for direct therapeutic purposes, is subject to VAT.

ECJ, C-573/15 Oxycure Belgium SA

The Court had to determine whether EU law precludes national legislation which provides the application of the standard VAT

rate to the supply or rental of oxygen concentrators, even if a reduced VAT rate is applied to similar supplies, namely of oxygen cylinders and medical liquid oxygen tanks.

In its decision, the Court acknowledges that oxygen concentrators are perceived by the consumer as being similar to medical oxygen cylinders and medical liquid oxygen tanks, two products with reduced VAT rates. Nevertheless, the principle of neutrality does not preclude national legislation which provides that the standard VAT rate is applicable to the supply or rental of oxygen concentrators. The rationale of this decision lies in the fact that it does not appear to be proven that the concentrators are for the exclusive and personal use of disabled persons.

Customs and VAT regulatory updates in the LSHC industry

Pharmaceuticals and the 2017 Harmonised System reform

In January 1 2017 a reform of the WCO HS took place. Chapters 29 (organic chemicals) and 30 (pharmaceutical products) were particularly impacted.

In this respect, companies dealing in the trade or production of API should have a closer look at the numerous additions made in Chapter 29 to see the heading under which chemicals now fall. On the other hand, those dealing with pharmaceuticals need to re-read the codes of Chapter 30. This is especially important for manufacturers of bio-medication, as Heading 3002 has been completely overhauled.

Given the substantial changes in these Chapters, note that not all 207 countries and territories using the HS codes have taken the time to incorporate the HS 2017 changes into their local tariff schedules. Likewise, preferential origin rules and rates may also still refer to codes which are now defunct.

Economic Operators are advised to carefully review the applicable local legislation to ensure that requirements in both the country of departure and country of arrival are met, as six-digit divergences could occur. Additionally, holders of customs licenses/authorisation, which are tied to classification codes impacted by the Harmonised System's reform, need to ensure that their authorisations are updated as soon as possible.

New amendment in Explanatory Notes for orthopaedic appliances

In order to clarify the product classification of an orthopaedic appliance, the Explanatory Notes are amended for the CN subheading 9021 10 10. This subheading classifies the orthopaedic appliances specifically designed for a particular orthopaedic purpose, and described as follows:

"The orthopaedic appliances must completely prevent a specific movement of the defective or disabled part of the body (for example, joints, ligaments or tendons) in order to

exclude further injuries or (an aggravation of) bodily deformities."

The above described orthopaedic appliances are distinct from ordinary products, such as wrist orthoses, lumbar support belts, elbow supports and knee supports.

For these ordinary products, classified under a different CN in Chapters 61, 62 and 63 as 'parts of general use', no zero duty rate applies, in contrast to orthopaedic appliances, which benefit from a zero duty rate. Therefore, it is important for a company to have a look at its current classification to determine if potential savings could be made.

EU GMP Annex 21: Possible change of medicinal products import into the EEA

Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes. The same standard has to be applied on goods entering the European Economic Area (EEA). The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonising GMP activities at EEA level. EMA also provides EU GMP guidelines which are documents providing guidance on the scientific or regulatory aspects of the development of medicines and applications for marketing authorisation. Although guidelines are not legally binding, applicants need to provide justification for any deviations.

In this respect, EMA is working on a new Annex 21. The document is expected to be in public consultation during the last quarter of 2017 and will be integrated in the EU GMP Guidelines at a later stage. It is expected that this Annex should clarify and modify the term "import" of medicinal products. The modification would possibly operate a switch from the import concept based on the flow of goods to an import based on the financial flow. The EEA party will likely be considered as the importer. In such a case, it would multiply the licenses needed and potentially require smaller to medium size businesses to change the structure of their supply chain in order to match the new policy.

Such change will trigger indirect tax related consequences. Deloitte is closely monitoring the upcoming Annex 21 and advises all companies involved in the affected market to carefully follow the next steps.

Regulatory updates in the LSHC industry

A new Medical Device Regulations (MDR) and In Vitro Diagnostic Regulations (IVDR)

With over 500,000 types of medical devices and in-vitro diagnostic medical devices on the EU market, alongside problems with divergences in the interpretation and application of the now replaced rules, the EU highlighted the need to revise the three Directives for Medical Devices within the EU.

In April 2017, the three Medical Directives were replaced by two new Regulations: the Regulation on Medical Devices (MDR) and the Regulation on in vitro diagnostic medical devices (IVDR). In order for manufacturers and authorities to review their existing products and procedures for compliance with the new regulations, the new rules will only apply after a Transitional period, namely 3 years after publication for the MDR and 5 years after publication for the IVDR.

These two new regulations need to establish a modernised and more robust EU legislative framework to ensure a more consistently high level of health and safety protection for EU citizens using these medical devices.

To address this, the new regulations improve and strengthen:

1) market surveillance and traceability;
2) quality, safety and reliability of medical devices and;
3) transparency of information for consumers.

Companies active in this market will face higher regulatory compliance and a potential increase of costs. This will be brought by tighter checks by the authorities on, for example, high-risk devices and checks on clinical trials, as they will require stricter preclinical and clinical evaluation of the new medical devices. The above only highlight some of the potential impacts of the new regulation, as this list is not exhaustive.

Trending topics in the LSHC industry

Blockchain: a disruptive technology?

Companies active in the life science market are actively monitoring blockchain, a disruptive technology with the potential to change their supply chain organisation. Blockchain is an emerging forward-looking tool, which is a record or ledger of digital events. The specific event is distributed between many different parties. Blockchain can only be updated after consensus is reached by a majority of system participants. Once entered, information can never be erased. Every single transaction is contained in a certain and verifiable record.

Blockchain has the potential to meet industry demands in innovation, regulatory compliance, care delivery, costs and in addressing key challenges for both the life sciences and health care sectors. For example, Blockchain may be of substantial interest to the pharmaceutical industry for giving their products greater traceability after they are dispatched. At times, there is a lack of information on transportation route, delivery time and transport conditions. Blockchain technology could allow manufacturers to establish a drug’s supply chain footprint. By having intermediaries add product status updates, a retailer would be able to authenticate the drug and finalise the drug’s supply chain footprint.

An audit trail and a holistic view of the supply chain journey can be created on Blockchain. However, this emerging technology presents many more potential developments for

the life sciences and healthcare sectors. Several LSHC industry players are currently considering the opportunity to embark on a Blockchain journey. As the LSHC industry is one of the most regulated, Blockchain may become the next solution. Companies should use it as way to gather and sometimes replace legally required documentation, such as proof of transport or customs documentation. This technology can therefore potentially be used to fulfil various regulatory steps required in the life science sector.

Deloitte is at the cutting edge of this emerging technology and is equipped and readily available to provide LSHC companies with forward-looking opportunities.

More info on disruptive technologies?

Contacts

If you have any questions concerning the items in this alert, please contact your usual tax consultant at our Deloitte office in Belgium or:

- Liesbet Nevelsteen, lnevelsteen@deloitte.com, + 32 2 600 66 53
- Hadrien Janne, hjanne@deloitte.com, +32 2 302 25 38

For general inquiries, please contact:
bedeloittetax@deloitte.com, + 32 2 600 60 00

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