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Life Sciences & Health Care Newsletter
Indirect Tax

October 2017

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 2017 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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European Court of Justice Decisions related to the LSHC industry

ECJ, C-51/16, Boehringer Ingelheim case: Advocate-General opinion on rebates paid to insurers or health bodies

On Tuesday 11 July 2017, the Advocate-General's ("A-G") opinion in the Boehringer Ingelheim case was issued. The question addressed by this opinion is whether mandatory rebates granted to private health insurers should be treated as a discount for VAT purposes.

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 Advocate General opined favourably for the taxpayers' possibility to adjust their output tax (when granting a rebate to both private and public insurers).

This position will prevent the tax authorities from charging an amount exceeding the actual tax paid by a consumer. At EU level, this reopens the discussion on how businesses approach rebates.

It is important to note that this is only an A-G opinion at this stage. However, should the CJEU follow this opinion the impact on businesses operating in certain countries with private insurers will be considerable.

Customs and VAT regulatory updates in the LSHC industry

Russia: Federal law on introduction of VAT exemption for lease of medical devices

A new federal law has been signed on 18 July 2017 introducing a VAT exemption with respect to the lease of medical devices. The supply of said devices is exempt from VAT in accordance with the list established by Government Resolution.

Under the previous version of the law, a VAT exemption was only applied to the sale of essential medical devices, while their financial lease was VAT taxable under the general rules.

The Federal Law will enter into force on 1 October 2017.

Switzerland: decrease of Swiss VAT rates

The temporary increase of the Swiss VAT rates (agreed in 2011 for a period of 7 years) will expire by the end of 2017. On 24 September 2017, the Swiss population rejected the 2020 Old-Age and Survivors reform. The direct effect of this decision is a slight decrease of the standard VAT rate (currently 8%) and the special rate (currently 3.8%). On 1 January 2018, the following rates will apply:

- Standard rate: 7.7%
- Special rate: 3.7%
- Reduced VAT rate would remain at 2.5%

Medicine and related goods will not be impacted by the change in rates applicable as of 1 January 2018.

GCC VAT update specific to LSHC industry

United Arab Emirates (UAE)

The UAE VAT Law came to light on 27 August 2017. A VAT system will be implemented as of 1 January 2018.

According to UAE law, VAT will be applicable on all imports. The local supply of goods and services will be subject to the standard VAT rate of 5%, with a few exceptions granted to the supply of goods and services related to certain sectors.

Health care services and related supply of goods will be one of these exceptions and will be subject to a zero rate. Subjecting health care services to a zero rate means that businesses active in this market will be able to recover input VAT.

Kingdom of Saudi Arabia (KSA)

The KSA has published its final VAT law on 27 July 2017 and the final Implementing Regulations on 29 August 2017. VAT will be implemented in KSA on 1 January 2018 and will be applicable to all imports and local supply of goods and services at the standard rate of 5%, with a few exceptions.

Through its article 35, the final Implementing Regulations specify that "*the Supply of any Qualifying Medicines or Qualifying Medical Goods is zero-rated*". The KSA will apply a similar regime to the one implemented by the UAE, meaning that input VAT on medicines or on qualifying medical goods will be recoverable.

Regulatory updates in the LSHC industry

EU-Japan Economic Partnership Agreement

A breakthrough has been announced during the EU-Japan summit held in Brussels on 6 July 2017. The EU and Japan have reached a political agreement, in principle, on an Economic Partnership. It aims to set global trade rules and facilitate commercial exchanges.

After the partnership's entry into force, tariffs on more than 90% of the EU's exports to Japan will be eliminated. Once the agreement is fully implemented, Japan will have scrapped customs duties on 97% of goods imported from the EU.

The partnership aims to ensure that standards and technical regulations are based on international standards. It should be combined with provisions on non-tariff measures, which can be regarded as good news for pharmaceutical companies.

The EU-Japan Economic Partnership Agreement will foster new opportunities on one of the biggest markets for pharmaceutical products and medical devices.

Trending topics in the LSHC industry

Managing Indirect tax in a complex regulatory landscape

The life sciences industry operates in one of the world's most regulated environments. Nowadays, organisations of all sizes deal with a highly complex, changing set of laws and directives. There are several kinds of industry specific rules and regulations that affect a company's operations, from a sourcing, production, warehousing and distribution perspective.

For example, one may think of product specific restrictions on the movement of controlled substances such as narcotics. Depending on the product in question, different requirements may apply when moving these products. When dealing with the regulatory license obligations, it is key to check these against the requirements from a customs, VAT and corporate tax perspective, since these can change at any time.

Developments in the area of industry-specific laws and directives may also have an effect on indirect tax. An example is the new definition of an importer in the EU GMP. This will potentially increase the administrative burden and licence requirements.

Import as well as export control regulations need to be complied with when exporting controlled products and technology or know-how. Before exporting, the proper analysis and checks need to be made to ensure that the necessary clearance can be obtained from the competent governing authorities.

Failure to comply with these regulations may lead to supply chain disruptions, fines, penalties, brand damage, loss of customs and/or VAT related privileges or authorisations, prison sentences, etc. A key take-away is that one should take a proactive approach to tracking and monitoring regulatory and export control related developments, and understanding their individual and combined impacts on indirect tax matters.

Read the full thought piece on this topic published by Deloitte Belgium.

The connected patient – How digital technology is enabling patient centricity

With over 260,000 health apps worldwide and 70% of patient groups using at least one app to manage their condition, it is clear that a digital ecosystem has developed within health care. Deloitte UK released a new report which explores how digital technology can help pharmaceutical companies embrace patient centricity and remain relevant, profitable, and deliver better health outcomes.

Russian Pharmaceutical Market Trends in 2017

The 5th annual “Russian Pharmaceutical Market Trends” survey has been published. It provides a comprehensive study on the Russian pharmaceutical industry. The survey also underlines priority areas of development that could shape the future of the Russian market. This publication is a must-read for companies already operating in Russia or considering a market entry there.

Contacts

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