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EMEA Indirect Tax | 23 June 2020

Life Sciences & Health Care quarterly newsletter

EMEA Indirect Tax

Second Quarter 2020

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 pursue 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 experience with industry players.

We are pleased to provide you with the Second Quarter 2020 edition of our Life Sciences and Health Care newsletter for Global Trade Advisory and VAT.

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

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EU-Vietnam FTA (EVFTA)

On 30 March 2020, the Council of the European Union adopted a decision on the conclusion of the Free Trade Agreement between the European Union (EU) and Vietnam (EU-Vietnam FTA), clearing the final hurdle on the EU side for the agreement to become operational. On 8 June 2020, Vietnam's National Assembly ratified the Agreement, which is expected to enter into force in July or August 2020 following the approval of all governments.

The goal of the treaty is to eliminate import duties on all trade in goods between the parties. This process will be gradual, and its timeframe will vary depending on the sectors.

In order to benefit from the preferential treatment under the EU-Vietnam FTA, including zero-duty and reduced rates, products must comply with the specific rules of origin outlined in the agreement.

As a rule, to benefit from the preferential treatment, goods must "originate" in the EU or Vietnam, accompanied by a proof of origin, and fulfil certain additional requirements provided for in the FTA. Depending on the type of goods, it can obtain the status of an originating good, either because it is wholly obtained or has undergone "sufficient working or processing" in the EU or Vietnam.

For the LSHC industry, and specifically for the pharmaceutical sector, half of EU pharmaceutical exports will be duty free immediately after the FTA goes into effect, with the other half benefiting from the same relief after seven years.

As for Vietnam, the following aspects are covered in the FTA for pharmaceutical products:

- Vietnam is to recognise and align more closely with international standards, practices and guidelines for pharmaceuticals (e.g. from World Health Organisation (WHO), Organisation for Economic Co-operation and Development (OECD), ICH, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the International Medical Device Regulators Forum (IMDRF)). As a result, EU products will no longer require additional testing and certification in Vietnam;
- Vietnam is to allow foreign pharmaceutical companies to establish foreign-invested companies to import pharmaceuticals that have been authorised to be sold on the Vietnamese market;
- Vietnam is to establish important improvements on intellectual property rights, such as regulatory data protection, improved and extension of patent protection up to a limit of two years, among others;
- Vietnam will simplify its requirements for marketing authorisation, thereby reducing costs and delays in delivering products to the Vietnamese population; and
- Vietnam will accept the "Made in EU" marking of origin for non-agricultural products, with the exception of pharmaceuticals, which are mainly regulated at a national level and with member state-specific markings of origin.

The FTA will provide the Vietnamese population with a secure, fair, and easier access to high-qualitative drugs, and will further expand the EU pharmaceutical sector growth.

Ultimately, the pharmaceutical sector is expected to benefit from the FTA and its overall regulatory improvements.

Please consult the full article here and publications from the European Commission here.

EU-Mexico FTA

On 28 April 2020, the EU and Mexico concluded the negotiations on a new FTA, aiming to replace the current FTA that entered into force in 2001. The treaty should still be ratified with no timing scheduled yet.

The new treaty seeks to progressively eliminate a substantial part of the remaining applicable duties between Mexico and the EU, along with enhancing customs cooperation and easing trade procedures.

The treaty also provides better protection for intellectual property rights and a convergence of standards and regulations, notably for pharmaceutical products.

The next steps include the agreement's legal revision finalisation and translation into all EU languages. The EU Commission proposal will then be transmitted for signature and conclusion to the Council of the European Union and European Parliament.

Please find here the European Commission press release.

Trending topics and the impact on the LSHC industry

CJEU's Pfizer ThermaCare judgment

On 26 March 2020, the Court of Justice of the European Union (CJEU) rendered its judgment in a case involving Pfizer Consumer Healthcare Ltd.

The issue at hand concerns a set of single use self-heating patches and belts imported in the EU by Pfizer under the ThermaCare trademark.

Under Implementing Regulation (EU) 2016/1140, the patches are classified under the Combined Nomenclature (CN) code 3824 90 96 and are subject to an import duty rate of 6.5%. Pfizer challenged this decision in order to re-classify their goods under heading 3005 of the CN, which is subject to an import duty rate of 0%.

The court ruled in favour of Pfizer, arguing that these goods are similar to "wadding, gauze or bandages" and as such, were to be considered as medical products. The products thus fall under heading 3005 of the CN.

The reclassification of these products gives right to a refund claim under the conditions of articles 116, 117 and 120 of the Union Customs Code.

Please find here the Judgment of the Court for Case C–182/19.

Medical Devices Regulation: One-year postponement

On 3 April 2020, the European Commission adopted a proposal to delay the entry into force of the Medical Devices Regulation by one year. This decision was taken in order to avoid potential market disruptions while prioritising efforts against Covid-19.

The Medical Devices Regulation aims to increase patient safety and transparency on medical devices. The proposal means the regulation will enter into force on 26 May 2021, instead of the initial date of 26 May 2020.

Please find here the European Commission's announcement.

Harmonised System 2022

On 29 January 2020, the World Customs Organisation (WCO) officially adopted the seventh version of the Harmonised System Nomenclature. The 351 amendments, covering a wide range of goods moving across borders, will enter into force on 1 January 2022 for the 158 Contracting Parties of the HS Convention. Please find below some examples of changes that will impact the LSHC Industry:

Diagnostic test kits:

A new WCO Explanatory Note 1(ij) is inserted for Chapter 30, indicating Chapter 30 will no longer cover diagnostic reagents of heading 3822.

As a result, subheading 3002.15 will no longer cover the diagnostic test kits, as covered by heading 3822.

Subheading 3002.11 covering malaria diagnostic test kits is replaced by a new subheading 3822.11 and deleted as a subheading. In addition, the heading text for 3822 is revised to explicitly incorporate test kits, as follows:" Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 30.06; certified reference materials."

The following new subheadings are added for diagnostic or laboratory reagents under heading 3822:

- 3822.11 – For malaria;
- 3822.12 – For Zika and other diseases transmitted by mosquitoes of the genus *Aedes*; and
- 3822.13 – For blood-grouping
- 3822.19 – Other
- 3822.90 – Other

Cell Cultures/Products:

The heading text for 3002 is revised to explicitly cover "cell cultures, whether or not modified".

Therefore, for cell cultures, the following new subheadings (2) are added; subheading 3002.51 for cell therapy products and subheading 3002.59 for other cell cultures, whether modified or not.

The cell cultures to be covered under heading 3002 are currently classified as human blood or similar products under subheading 3002.19 or 3002.90.

Products for use as implants in medical, surgical, dental or veterinary sciences:

WCO Explanatory Note 2(a) to Section XV, covering base metals and articles of base metals, is revised to exclude "articles specially designed for use exclusively in implants in medical, surgical, dental or veterinary sciences."

These articles are to be classified in heading 9021, substituting the WCO Explanatory Note 1(f) to Chapter 90 as follows: "[…] however, articles specially designed for use exclusively in implants in medical, surgical, dental or veterinary sciences are to be classified in heading 90.21."

Placebos and blinded (or double-blinded) clinical trial kits:

WCO Explanatory Note 4 (e) covering "Blood-grouping reagents" will be deleted and substituted by "Placebos and blinded (or double-blinded) clinical trial kits for use in recognised clinical trials, put up in measured doses, even if they might contain active medicaments." Subheading 3006.20,

covering blood-grouping reagents, is deleted and a new subheading 3006.93 is inserted to cover the placebos and blinded (or double-blinded) clinical trial kits for a recognised clinical trial.

Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products:

Subheadings 3002.20 and 3002.30 are deleted and substituted to cover vaccines under one subheading 3002.4 to make a clear distinction.

Rubber gloves for medical, surgical, dental or veterinary purposes:

For subheading 4015, covering articles of apparel and clothing accessories (including gloves, mittens and mitts), for all purposes, of vulcanised rubber other than hard rubber, a new subheading 4015.12 is inserted, and subheading 4015.11 is deleted to cover a broader scope, including "gloves, mittens and mitts of a kind used for medical, surgical, dental or veterinary purposes."

A comprehensive list of the new WCO amendments are listed here.

COVID-19 updates

Deloitte resources relating to COVID-19 VAT/GST measures

Over the past months, various countries around the globe have adopted emergency tax measures to help mitigate the COVID-19 pandemic's economic impact on businesses and individuals.

Measures specific to the LSHC industries include relief from import duties and VAT exemption, or reduced rates on imports/acquisition of goods needed to combat the effects of COVID-19, such as medical equipment, supplies, and consumables needed for medical care or prevention.

Details regarding the measures adopted by various governments around the globe to address the COVID-19 pandemic have been centralised and are available via:

- Our global overview of VAT/GST measures in response to Covid-19. Note that the survey is regularly updated.
- Deloitte Tax Atlas COVID-19 Tax and Fiscal Measures microsite: Businesses can sign up for access here.

Significant efforts have been made to gather, compile and centralise these global fiscal measures. However, the information presented reflects matters at the date shown, with developments quickly evolving and measures taken by governments changing at short notice. Accordingly, this information should be considered directional; any decisions made purely on the basis of this information is at the reader's own risk. If you would like more detailed and current

information or advice, please contact your usual engagement team or the Deloitte firm in the country concerned.

Brexit – State of negotiations

On 12 March 2020, Brexit negotiations were brought to a pause by the COVID-19 pandemic. At that time, the Negotiating Parties admitted that it was impossible to have detailed trade talks when unable to physically meet. However, negotiations resumed on 20 April 2020 through video conferencing.

Opposition Parties have already expressed the need for a delay to the December 2020 deadline, in terms of reaching an agreement. By 1 July 2020, the British government needs to decide whether it accepts to extend the current Brexit transition period until 31 December 2021. Such a move is however unlikely as the British government repeatedly expressed its intention to leave the Customs Union by December 2020.

However, on 12 June, the UK government confirmed that it will not seek an extension of the Brexit Transition Period and announced the phased introduction of border controls with effect from 1 January 2021.

The new border controls for imports from the EU into the UK will come into effect in three phases, between 1 January 2021 and 1 July 2021 as follows:

1. From 1 January 2021 – Importers of standard "non-controlled" goods will have up to 6 months after import to submit a customs declaration. Payments of customs duty on these imports will be deferred until submission of the customs declaration. There will be checks on controlled goods such as tobacco and alcohol, and customs declarations for such imports will be required at the border.

2. From 1 April 2021 – In addition to the requirements set out above, importers of Products of Animal Origin and all regulated plants and plant products into the UK will require pre-arrival notification and will need to submit relevant health documentation.

3. 1 July 2021 – Importers of goods into the UK will have to make full customs declarations and pay tariffs at the point of importation, unless they have customs authorisations in place to make electronic supplementary customs declarations (under Customs Freight Simplified Procedures). There will be increased checks on animals, plants and their products.

Please find here a practical guide to importing into the UK from the EU from 1 January 2021.

In addition, on 19 May 2020, the UK published its proposal for an FTA together with 11 separate agreements. This confirms that unlike the EU, the UK does not seek a comprehensive partnership agreement, but is rather aiming for separate agreements, each covering a subject area; similar to those

that the EU has with other countries such as Norway, Canada and Switzerland.

The package of separate agreements includes the Draft UK-EU Comprehensive Free Trade Agreement (CFTA). The CFTA aims at establishing "zero tariff, zero quota" free trade agreement, but it significantly differs from the EU's proposed partnership agreement on several key points.

The EU and UK proposals also differ on the tolerance rule. The Draft CFTA provides for a tolerance of 15% for products and 20% or 25% for sets of goods, while the proposed EU partnership agreement provides for a tolerance of 10% for products and 15% for a set of goods.

Alongside the draft CFTA, HMRC also published the UK Global Tariff (UKGT), which contains the UK's "Most Favoured Nation" (MFN) duty rates for all products. The UKGT is set to apply to all imports (unless an exception applies) into the UK from 1 January 2021, after the Transition Period ends, and will replace the EU's Common External Tariff. This list applies to any country with which the UK does not have a preferential trade deal. This means that the UKGT rates will apply for imports from the EU unless a deal (i.e. a Free Trade Agreement) is reached.

With the UKGT, the UK will eliminate or reduce tariffs on more than half of the 12,000 listed products. Some changes are significant, while others are only rounded down or slightly reduced. The percentage of products that come into the UK, tariff free and on World Trade Organisation (WTO) terms, would increase from 47% to 60%. The weighted average tariff charged on goods imported from the MFN will however only fall from 2.1% to 1.5%.

Goods for which tariffs have not changed are mainly goods produced in the UK or goods subject to the current negotiations. If the parties fail to reach an agreement, these tariffs would be applied to EU products. Severe trade backlashes are expected if no deal is reached. New VAT and customs procedures and requirements could also lead to disruption in supply chains between the EU and UK.

See the full article on the proposal for an FTA and UKGT here.

Import duty and VAT exemption for products that help combat COVID-19

On 3 April 2020, the European Commission adopted Commission Decision (EU) 2020/491 on the relief of duties and VAT exemption on imports, which are granted for goods needed to combat the impact brought by the COVID-19 outbreak. The decisions respond to requests from multiple Member States.

After the COVID-19 outbreak was officially recognised as a pandemic by the World Health Organisation, the European Commission found that the extreme challenges brought by COVID-19 constitute a 'disaster', as defined by Section C of Chapter XVII of Regulation (EC) No 1186/2009 and Chapter 4 of Title VIII of Directive 2009/132/EC. In such a situation, the

EU Customs legislation provides for the possibility to grant duty relief for imports by state organisations or approved (charitable) organisations.

Importing products intended for the free of charge distribution to persons affected by, being at risk from, or combatting the COVID-19 outbreak, are granted with an import duty relief and VAT exemption for the period running from 30 January until 31 July 2020. If, however, the situation has not improved by 31 July 2020, the Commission may decide to extend the period of application, in consultation with Member States.

The Belgian Authorities have published a non-exhaustive list of concerned organisations. More information on the procedure and the conditions to fulfil can be found here.

In addition to the import duty relief, a deduction of VAT is possible for personal protective gears and medical equipment (excluding medicines) donated directly to healthcare institutions between 1 March and 30 June 2020. More information on the procedure and conditions can be found here.

Furthermore, for certain gear that is subject to attestation of conformity with EU standards, certificates from certain non-EU test bodies will be exceptionally accepted, as well as products that comply with non-EU yet internationally recognised standards.

The Entry Summary Declaration

When entering the fiscal territory of the European Union, a carrier of goods must lodge an Entry Summary Declaration (ENS), containing all information on goods entering EU territory. After lodging an ENS, the goods need to be presented to the Customs Authorities. The outlined procedure applies to all goods, including medical, surgical, and laboratory equipment.

However, due to the COVID-19 pandemic, Article 127(7) of the UCC provides for the possibility to use commercial, port or transport documents instead of the ESN, under the condition they are made available within the specified time limit and contain the necessary ENS particulars.

In line with the above, all non-Union medical, surgical and laboratory equipment can be presented to customs for temporary admission by oral declaration, and are not exempt from this obligation.

More information on COVID-19 related customs measures can be found here.

France issues new guidelines for non-EU exporters

The French customs authorities issued new guidelines on 3 March 2020, amending the authorities' position regarding exports from France by non-EU companies. The new rules (see below) were to become effective on 1 May 2020. However, on 27 March 2020, the French customs authorities announced the

extension of the 1 May deadline to 1 October 2020, taking into account severe difficulties encountered by operators during the COVID-19 related lockdown.

From 1 October 2020 (according to the French customs authorities' latest update), a company not established in the EU will no longer be able to act as the exporter of record in France and be reported in box 2 of the SAD. The indirect customs representative will have to be reported both in boxes 2 and 14 of the SAD.

Please consult the full article here.

Contacts

If you have any questions concerning the items in this newsletter, please contact your usual Deloitte tax consultant or:

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