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Life Sciences & Health Care quarterly newsletter

EMEA Indirect Tax

First Quarter 2021

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 First Quarter 2021 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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EMEA Customs & VAT updates

A new version of the EU Combined Nomenclature

On 23 October 2020, an annual CN update was published by the European Commission. The updated version (CN 2021) entered into force on 1 January 2021.

The CN is based on the WCO's Harmonized System (HS) and forms the basis for the declaration of goods:

- Imported into or exported from the EU;
- Transferred between EU Member States and subject to intra-Union trade statistics.

See Commission Implementing Regulation (EU) 2020/1577 of 21 September 2020.

What is new in the CN 2021?

The CN 2021 introduces changes to the classification of goods, mostly by deleting, modifying or adding CN codes. These changes relate to the last two digits of the 8-digit CN codes.

The CN 2021 holds some changes for the LSHC sector. The following changes might be of interest with respect to Chapter 28, 29 and other:

- A change in Chapter 28 concerning 'Phosphorus'. The CN code for 'phosphorus' changed from 2804 70 10 to 2804 70 90, to make a clear distinction between Red phosphorus and others for monitoring purposes;

- Change in the TARIC code for substance '1,1,1-trifluoroethane' (HFC-143a). This product was previously classified under TARIC code 2903 39 29 25, but will now be classified under 2903 39 24 90;

- A new TARIC code is introduced for protective face shields/visors under subheading 3926 90, as follows:
  - 3926 90 60 - Protective face shields/visors

- New TARIC codes are introduced for protective face masks:
  - 6307 90 93 - Filtering facepieces (FFP) according to EN149, and other masks filtering at least 80 % of 0,3-micron particles; and
  - 6307 90 95 - other protective face masks

- New TARIC codes are introduced within subheading 9019 20 - Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus, as follows:
  - 9019 20 10 - Mechanical ventilation apparatus, capable of providing invasive ventilation
  - 9019 20 20 - Mechanical ventilation apparatus, non-invasive
  - 9019 20 90 - Other, including parts and accessories

- New TARIC codes are introduced within heading 9020 - Other breathing appliances and gas masks, excluding protective masks having neither mechanical parts nor replaceable filters, as follows:
  - 9020 00 10 - Gas masks
  - 9020 00 90 - Other, including parts and accessories

- The classification of some substances in the list of non-proprietary names of pharmaceutical substances is also amended in Annex 3 of Part Three (Tariff Annexes) of Annex I to Regulation (EEC) No 2658/87 and in the list of pharmaceutical intermediates in Annex 6 of Part Three (Tariff Annexes) of Annex I to that Regulation.

Please read the full alert here.

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Clarification of ‘goods that have been used’ in the context of a customs debt cancellation (CJEU C-476/19)

On 8 October 2020, the Court of Justice of the European Union (‘CJEU’) issued a preliminary decision (C 476/19) on the interpretation of ‘goods that have been used’.

In short, the CJEU ruled that this must be interpreted as meaning the use of goods going beyond their use in accordance with the customs procedure authorisation under which they have been placed (such as the ‘inward processing procedure’).

This CJEU decision provides importers with much-needed clarification on the concept of ‘goods that have been used’. In practice, we often see that with the inward processing procedure, a customs debt occurs through non-compliance with administrative requirements. This case could serve as a solid basis to argue for cancelling such customs debts if the goods were used in accordance with the inward processing authorisation and were subsequently re-exported from the EU.

Please read the full alert here.

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Fee for Exclusive Distribution Agreement is part of customs value (CJEU C-775/19)

On 19 November 2020, the Court of Justice of the European Union published their decision in case C-775/19, in which they decided that the fee for an Exclusive Distribution Agreement is part of the goods' customs value.

Please read the full alert here.

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New guidelines by VAT Committee on when VAT ID number is not indicated with intra-Community supply

After the introduction of the quick fix that requires acquirers to indicate a VAT identification number to apply the exemption of an intra-Community supply of goods, several practical issues remain unclarified in the Explanatory Notes to the quick fixes or by the VAT Committee.

Consequently, the EU Commission asked the VAT Committee for its opinion in a new Working Paper on the following cases:

- When the acquirer, either by negligence or ignorance, did not communicate the VAT identification number to the supplier;
- When the VAT identification number has been requested but not attributed to the acquirer; and
- When the supplier stops their activity before the acquirer receives their own VAT identification number

From the recently published VAT Committee Guidelines, it appears that a large majority (between 18 and 23) of EU Member States agrees that a supplier is allowed to correct the initial invoice and apply the VAT zero-rate on intra-Community supply of goods, if the acquirer communicates their VAT ID number at a later stage and there is no reason to suspect any fraudulent intention.

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Dutch Court confirmed that paid discounts to health insurance companies result in a VAT refund for the pharmaceutical company

A Dutch Court in Gelderland recently ruled in a case regarding a pharmaceutical company that was obliged to pay discounts to health insurance companies based on a financial arrangement in the Netherlands.

Based on the fact that the CJEU ruled that no additional VAT can be due on top of the amount finally received, and based on similarities with the Boehringer case, the Dutch Court ruled that the pharmaceutical company is entitled to take into account the discount paid to health insurers when calculating the VAT taxable amount, in essence resulting in a VAT refund for the pharmaceutical company.

Before submitting a VAT refund request, it is recommended to compare the present facts and circumstances with those of the Dutch Court case.

Please read the full alert here.

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The Belgian Act on medical devices

The Belgian Act of 22 December 2020 on medical devices was recently published in the Belgian Official Journal, completing and implementing provisions from the Medical Device Regulation 2017/745 ('MDR'), including rules on sanctions, damage compensation and clinical research. Apart from chapter 4 on notified bodies, the Act does not apply to in vitro diagnostic medical devices within the meaning of the In Vitro Diagnostic Medical Device Regulation 2017/746 ('IVDR').

As we move closer to the MDR's full application (on 26 May 2021), the adoption of this new law constitutes an important milestone for medical device companies aiming to do business in Belgium. Some takeaways are as follows:

- As for all clinical studies in Belgium, the Act confirms that sponsors of clinical studies with medical devices within the meaning of the MDR have a no-fault liability towards participants in such a study. They must take out adequate insurance before initiating a clinical study.
- Monitoring compliance with the new regulation will primarily be the responsibility of the Belgian Federal Agency for Medicines and Health Products (FAMHP) and its inspectors.
- Infringements on the new regulations are, depending on severity, punishable by a penalty ranging from level 1 to level 5:
  - Level 1: a fine of EUR 208-4,000
  - Level 2: a fine of EUR 400-40,000 and/or a prison sentence of eight days to a month
  - Level 3: a fine of EUR 1,600-400,000 and/or a prison sentence of one month to a year
  - Level 4: a fine of EUR 8,000-800,000 and/or a prison sentence of one to three years
  - Level 5: a fine of EUR 16,000-1,600,000 and/or a prison sentence of two to five years

    The fees have already been indexed.

As previously stated, the new law constitutes another step towards the full implementation of the MDR as governments and agencies try to cover all necessities before the 26 May 2021.

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German VAT rate back at 19% and 7% since January 2021

In July 2020 and as part of its COVID-19 measures, Germany lowered its standard and reduced VAT rates until the end of 2020. In this regard, it should be noted that the reduced tax rates (i.e. 16% and 5%) have increased back to 19% and 7% as of 1 January 2021. Deloitte Germany is unaware of any intention by the German government to extend the temporarily reduced VAT

rates' period of validity. Companies should therefore make sure to readjust the VAT rates in their ERP systems.

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Brexit

Since 1 January 2021, the UK began operating its own independent trade policy, including the application of UK tariff rates as set out in the UK Global Tariff, and a UK-specific trade remedies regime.

If there are any questions regarding changes brought by Brexit, the below listed contacts are readily available to help.

UK-Japan Trade Agreement (CEPA)

On 23 October 2020, the UK-Japan Comprehensive Economic Partnership Agreement (CEPA) was signed and entered into force on 1 January 2021. The CEPA is based on the Economic Partnership Agreement (EPA) between the European Union (EU) and Japan. However, the CEPA contains some enhanced provisions in areas such as rules of origin, financial services, and digital (trade) matters, and eliminates certain tariff lines earlier than the EPA.

Following the CEPA's entry into force, UK exports to Japan will benefit from the preferential tariff treatment provided for in the Agreement, exclusively on the basis of 'importer's knowledge', as importers have to make the claim for preferential treatment. Exporters have to produce a statement on origin that the products being traded are originating.

Regarding the rules of origin, it has been agreed that component material produced in both countries will be recognised as "originating". This however will also be extended to components made in the EU (known as extended cumulation). This is a significant outcome for businesses where supply chains cross the EU, Japan and the UK. However, any business with integrated supply chains linked to the EU, and hoping to continue exporting to the EU, will need to follow the rules laid down in the 24 December 2020 agreement (the TCA) between the EU and the UK (addressed next).

Furthermore, under the CEPA, the importing party will be allowed to set the statement of origin's validity for longer than the 12 months set out in the EU-Japan agreement.

The Agreement can be found here. More information on the importer's knowledge criterion can be found here.

Please read the full alert.

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EU-UK Trade and Cooperation Agreement (TCA)

On 24 December 2020, the European Union and the United Kingdom concluded their negotiations and announced their Trade and Cooperation Agreement ("EU-UK Trade and Cooperation Agreement" or "the TCA").

What are the highlights of the TCA?

- The Free Trade Agreement eliminates all customs duties on goods that originate in the other party's territory - representing the most extensive trade agreement on tariffs that the EU has ever reached.

- As with all EU Free Trade Agreements, the TCA provides comprehensive Rules of Origin to determine when and how goods originate in the UK or the EU.

- There is a provision for 'full' bilateral cumulation of origin, which allows traders to include the value of originating components and the processing undertaken in either the UK or the EU when determining origin for the purposes of the FTA, thereby increasing the likelihood of qualification. However, the TCA does not authorise diagonal cumulation with other partners in common to both. Thus, even though both the UK and the EU have concluded a free trade agreement with Japan, Japanese components will be considered as non-originating material when applying the TCA's specific origin rules to products in which they have been incorporated. The same applies under the Pan Euro Mediterranean (PEM) Convention, where the specific nature of the TCA makes future integration with the PEM Convention rather unlikely. Note that this will not impact UK FTAs that do allow EU content.

- The FTA contains features typical of the EU's FTAs, but these features are generally set at a liberal level. This increases the likelihood of bestowing origin qualification on several borderline goods, and provides more generous terms than under many other FTAs.

- Exporters will be able to self-certify the origin of goods through a statement, such as on an invoice, thereby making it easier for importers to prove the origin of their products. Importers may also be able to claim preference based on their own knowledge or information. A statement of origin can cover multiple identical shipments in a 12-month period.

- To make statements on origin upon import into the UK, EU exporters are generally required to be registered in the REX system. However, for consignments with the value of less than EUR 6,000, REX-registration is not required. Upon importation into the EU, UK exporters need to submit a statement on origin referring to their UK EORI numbers.

- Given the short period of time, it is difficult for some suppliers to provide all relevant declarations in time for exporters to produce statements on origin based on said declarations as of 1 January 2021. Therefore on 29 December 2020, the Commission published the Commission Implementing Regulation (EU) 2020/2254 on producing statements on origin based on supplier declarations for preferential exports to the United Kingdom during a transitory period.

- Importers will have up to three years from import date to claim preferential tariff treatment.

- The TCA does not contain a specific prohibition on the use of duty drawback or inward processing schemes in combination with preferential tariff treatment ("no-drawback rule").

To facilitate the supply of medical products and chemicals between the EU and UK, the following is agreed upon in the TCA:

1) Medical products:

- A recognition of results from inspections carried out by authorities of the other Party in manufacturing facilities located in the issuing authority's jurisdiction. This will avoid unnecessary duplication of inspections of medicinal product manufacturers to assess their compliance with Good Manufacturing Practice requirements.

- A possibility for each Party to unilaterally extend such recognition for manufacturing facilities located outside the issuing authority's jurisdiction, under specific terms and conditions.

2) Chemicals:

- Regulatory cooperation, while respecting each Party's right to regulate, both bilaterally and in relevant international fora, on the assessment of hazards and risks of chemicals, and formats for documenting the results of such assessments.

- Both Parties' commitment to implementing the United Nations Globally Harmonized System of Classification and Labelling of Chemicals, as well as any scientific and technical guidelines issued by relevant international organisations and bodies.

- Transparent procedures for the classification of substances and the possibility to exchange non-confidential information.

In relation to the above, please reach out to your local Deloitte tax consultant for further information or refer to the contacts section.

Please read the series of alerts. A Brexit blog is also available for more information.

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EU Council adopts VAT Directive regarding the identification of taxable persons in Northern Ireland post-transition period

Since the transition period ended on 1 January 2021, EU VAT legislation in principle no longer applies to the United Kingdom. However, Northern Ireland will remain part of the EU VAT system with respect to goods. As Northern Ireland will remain part of the UK VAT regime as well, businesses should be able to distinguish transactions with the EU that are subject to the Northern Ireland protocol (i.e. intra-community dispatches and acquisitions between the EU and Northern Ireland) from other transactions with or from the rest of the UK (i.e. Great Britain, comprising the England, Scotland and Wales territories).

Against this backdrop, the Council adopted a proposal amending the VAT Directive for the use of a 'XI-prefix' on VAT identification numbers for Northern Ireland. The measure is effective since 1 January 2021. This means that VAT identification numbers should be issued by HMRC (the UK tax authorities) for businesses trading under the Northern Ireland protocol, containing the prefix 'XI', provided that these businesses are already in possession of a GB VAT identification number. As there is no specific guidance from an EU perspective in relation to European Sales Listing and/or Intrastat, the assumption is that 'XI-

VAT identification numbers' should be reported. For Intrastat purposes, it could be that both the XI- and GB-prefix will have to be used until the end of 2021.

However, HMRC recently stated that there is no need to apply for a new VAT number if a taxable person is already identified for Northern Ireland VAT purposes. According to recently updated UK guidance, businesses are responsible for identifying whether certain transactions are subject to EU VAT rules. If such transactions are completed, the current UK VAT number with prefix XI should be communicated with suppliers or customers (instead of GB). Furthermore, VAT identification numbers containing the new XI-prefix will be included in the VIES database. We expect HMRC to soon provide more clarity on the practical implications.

We strongly advise to consider whether the Northern Ireland protocol can apply to your business activities and monitor any additional guidance that may be published. If this is the case, it is recommended to analyse this VAT Directive amendment's impact on the supply chain and ERP-setup, when trading with both Northern Ireland and the 'rest of the UK'.

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COVID-19 updates

EU Commission prolongs customs and VAT relief for medical equipment during pandemic

On 28 October 2020, the European Commission adopted further measures in the area of taxation and customs to tackle the ongoing COVID-19 pandemic. The measures take a two-step approach to support the provision of medical equipment, protective equipment, vaccines and testing kits:

The current temporary waiver of customs duties and VAT on imports of medical devices and protective equipment will be extended to help tackle the pandemic. The Decision will prolong the exemption on imports to EU Member States until the end of April 2021. The extension came after consultation with Member States and as a response to an increased number of coronavirus cases reported across the entire EU. For the UK, this exemption ended on 31 December 2020.

Protective face masks are the most imported among these goods by far, accounting for almost 50% in value of all imported goods under the Decision. This is why, for these goods, the Commission established more detailed customs tariff codes to enhance the monitoring and quality controls of imported masks, thereby safeguarding the protection of healthcare workers and citizens. In addition and in order to enhance the quality controls of imported masks, the Commission has also informed Member States of the possibility to share, with the support of EU funding, existing analytical capacity within the Customs Laboratories European Network.

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EU Directive renders temporary VAT measures applicable to COVID-19 vaccines and in vitro diagnostic medical devices

On 7 December 2020, The European Commission welcomed the adoption of important new measures that will enable Member States to relieve EU hospitals, medical practitioners and individuals of VAT when acquiring coronavirus vaccines and testing kits.

The measures will allow EU Member States to provide a temporary VAT exemption for vaccines and testing kits being sold to hospitals, doctors and individuals, as well as for closely related services. Member States were only previously able to apply reduced VAT rates on sales of vaccines and not a zero rate, while testing kits could not benefit from reduced rates. Under this amended Directive, Member States will be able to apply either reduced or zero rates to both vaccines and testing kits if they so choose. To allow an immediate response within Member States, the rules will apply the day after they are published in the Official Journal of the European Union. They will remain in place until the end of 2022, or until an agreement is reached on the Commission's pending proposal for new rules on VAT rates, if the latter occurs earlier.

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Contacts

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

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