A Guide to VAT for Clinical Trials in Europe

Overview for 28 European Member States in 2018

pwc

www.pwc.ch

Content

Foreword

Dear Madam and dear Sir

Clinical Trials in Europe and VAT – a complex topic with 28 different local VAT regulations.

This Guide to VAT for Clinical Trials in Europe aims at:

- providing you a first high level overview of the regulations in 28 EU Member States
- helping you assess the VAT implications and reporting obligations (e.g. VAT registration obligation, VAT return, EC Sales Listing and Intrastat reporting)
- assisting you answering some questions related to the trends in the pharma sector for clinical trials and precision medicines.

We are pleased to invite you to have a closer look at the countries of your interest and are looking forward to discuss your specific VAT hot topics.

In case of any questions, please do not hesitate to contact us.

Sincerely yours

Michaela Merz
Partner
Leader VAT Switzerland

Dr. Sandra Ragaz
Partner
Leader Pharma & Life Sciences VAT Switzerland

1

Would a VAT registration be required for the pharmaceutical company related to the transfer of Investigational Medicines Products (“IMP”) from one European country in the European country of arrival in the course of a Clinical Trial?

Austria	Yes
Belgium	Yes, however a simplification exists with regard to the transfer of IMP, whereby under certain conditions the registration obligation can be avoided
Bulgaria	Yes, if the value of the goods per calendar year exceeds EUR 10,000
Croatia	Yes
Cyprus	Yes, provided that the value of the goods exceed the registration threshold of EUR 10,262
Czech Republic	Yes
Denmark	Yes
Estonia	No, if the conditions for a tax exempt deemed intra-community acquisition are met, otherwise VAT registration as a limited liability taxable person arises as of the date of the intra-community acquisition of goods
Finland	Yes
France	Yes with regard to the deemed intra-community acquisition
Germany	In general, yes. However, a deviant practice is observed recently
Greece	Yes
Hungary	Yes
Ireland	Yes, once the threshold of EUR 41,000 calendar year has been breached
Italy	Yes
Latvia	Yes, for a domestically taxable person, if the total value of the intra-community acquisition of goods in Latvia in a current calendar year reaches or exceeds EUR 10,000. However, an EU taxable person should register for Latvian VAT purposes prior to performing domestically taxable transaction(s) irrespective of the value of the transaction
Lithuania	No, since the VAT exemption applies to the acquisition of goods from the EU on condition that a foreign taxable person would have a right to recover this VAT based on requirements for foreign taxable persons (e.g. no taxable activity in Lithuania) had this VAT been paid
Luxembourg	VAT registration is in principle required in Luxembourg for intra-community acquisitions of goods. There is no specific rule and currently no official guidance in Luxembourg concerning this matter
Malta	Yes
Netherlands	Yes
Poland	Yes
Portugal	Yes
Romania	No if only VAT-exempt import/intra-community acquisition of goods in Romania is undertaken. Otherwise, a taxable person that is not established or registered for VAT purposes in Romania must apply for VAT registration prior to performing intra-community acquisition of goods that is deemed taxable
Slovakia	Yes
Slovenia	Yes
Spain	Yes. If only transfers of own goods to Spain are made, simplified registration for statistical purposes would be required
Sweden	Yes, a transfer of IMPs to Sweden for the purpose of being used in clinical trials will in certain cases be deemed an intra-community acquisition for VAT purposes in Sweden. Should an intra-community acquisition be VAT liable, the taxable person needs to register for VAT purposes. Also the taxable person needs to register for VAT purposes should the intra-community acquisition be exempt from VAT but the taxable person has a right to reclaim VAT according to certain provisions in the Swedish VAT Act
United Kingdom*	No, if the goods are in trial ready state i.e. the packets are already filled and labelled no UK VAT registration requirement should exist

*Please note the answers as provided within this report for the UK are based on current legislation and issued guidance. Once the UK exits the EU the answers provided will need to be reviewed and updated accordingly.

2

Upcoming possible new European VAT rules in 2020/2022 – Is there sufficient insight at this stage on the new rules for 2020/2022 on the arrival of own goods in your country that might change the above provided input?

Austria	No clear rules are known yet
Belgium	No
Bulgaria	No clear rules are known at present
Croatia	No
Cyprus	No clear rules exist regarding the new rules for 2020/2022
Czech Republic	Not known at the moment
Denmark	No
Estonia	No
Finland	No
France	No
Germany	No
Greece	No
Hungary	No
Ireland	No
Italy	No
Latvia	No
Lithuania	No
Luxembourg	No
Malta	No
Netherlands	No
Poland	No
Portugal	No
Romania	No
Slovakia	No
Slovenia	No
Spain	No
Sweden	No
United Kingdom*	No

*Please note the answers as provided within this report for the UK are based on current legislation and issued guidance. Once the UK exits the EU the answers provided will need to be reviewed and updated accordingly.

3

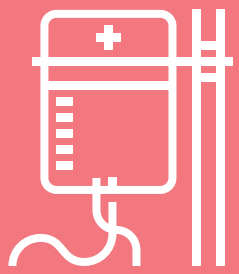
If the transfer of clinical trial material/IMP has to be taxed/declared in the VAT reporting obligations in your country, what value has to be considered?

Austria	VAT basis is considered to be the production cost or purchase price
Belgium	No specific guidance with regard to the valuation of clinical trial products exists. Hence general rules are to be applied: purchase price of the goods or similar goods or, if there is no purchase price, the cost price calculated at the time of the transfer
Bulgaria	For intra-community acquisition purposes, the taxable base is equal to the tax base of the corresponding intra-community supply in the country of dispatch. Normally this is the purchase/import/production cost
Croatia	According to the provisions of the Croatian VAT Act, for the transfer of goods to another Member State the taxable amount shall be the purchase price of those and similar goods, and, if that price is unknown, the amount of production costs determined at the moment of the transfer of goods
Cyprus	The taxable amount shall be the amount payable by the supplier for the purchase of (a) identical goods, including of the same age and condition as the goods referred to, or, if this cannot be applied, then (b) similar goods, or if neither (a) and (b) can be applied the production cost
Czech Republic	Provided the person is entitled to full input VAT refund, the intra-community acquisition of goods is VAT exempt and no taxation/ declaration is required
Denmark	Complex topic; ruling request is recommended
Estonia	In the case of deemed intra-community acquisition of goods the acquisition cost or in the absence thereof the cost price of the goods or other similar goods. In the case of imported goods the customs value of the goods according to the Customs Code and all duties payable upon import, as well as other costs related to the carriage of the goods to their destination (incl. commission, packing, transportation and insurance costs which have not been included in the customs value up to the first place of destination in the territory of Estonia)
Finland	Transfer of own goods: purchase value or a probable lower price of supply. Self-manufactured goods: direct and indirect manufacturing costs
France	Production costs
Germany	Purchase price plus incidental costs or (if not available) cost price
Greece	The taxable value would be the current purchase price of the goods or of similar goods or, in the absence of a purchase price, the costs of the goods at the time of the chargeable event
Hungary	The taxable amount shall be the purchase price of the goods or of similar goods determined at the time the transfer takes place or, in the absence of a purchase price, the cost price, determined at the time when the chargeable event occurs
Ireland	The taxable value for the movement of own goods (i.e. intra-Community supplies) to Ireland is the cost of the goods to the person making the supply or, in the absence of such a cost, the cost price of similar goods in Ireland
Italy	As a general rule, the production or purchase costs should be considered
Latvia	In the case of deemed intra-community supply/acquisition of goods, a taxable value is the acquisition value of the relevant goods or of similar goods or, in the absence of an acquisition value, the cost price of manufacture of goods, determined at the time of supply
Lithuania	Not applicable, since the VAT exemption applies to acquisition of goods from the EU on condition that a foreign taxable person would have a right to recover this VAT based on requirements to foreign taxable persons (e.g. no taxable activity in Lithuania), had this VAT been paid
Luxembourg	There is no specific rule and currently no official guidance in Luxembourg concerning this matter
Malta	The Maltese VAT Act does not provide detailed rules for this but the cost to the entity should be a good basis
Netherlands	The purchase price of the goods or similar goods or, if there is no purchase price, the cost price, calculated at the moment of the transfer of own goods
Poland	Normally production costs are the basis for VAT calculation for free-of-charge supplies reportable by hospitals
Portugal	Market price, and if that is not possible production cost
Romania	The taxable base for a deemed taxable intra-community acquisition consists of the purchase price of the goods or of similar goods or, in the absence of a purchase price, the cost price, determined at the time the transfer takes place. The taxable base also includes taxes and fees, as well as transport costs. Note that, the costs of transport or other ancillary costs, such as insurance or packing, shall be included in the taxable amount of goods acquired from the EU only if they fall under the seller's responsibility under the contract concluded between the parties
Slovakia	Tax base for own goods should be the cost of their acquisition/creation which we understand can be hard to define in case of clinical goods
Slovenia	The value that has to be considered is the purchase price of the goods or of similar goods or the cost price determined at the time the transfer takes place
Spain	Yes, the transfer of clinical trials should be declared within the intra-community Sales and Acquisition Listing form (form 349). Please note that, if the goods have not been processed, the tax base amount will be the value established when the goods were acquired. Furthermore, if the goods delivered have been processed or processed by the transferor or on their behalf, the taxable base will be the cost of the goods or services used by the taxpayer to obtain the goods referred to, including personnel expenses incurred for the same purpose. Finally, if the value of the goods has been modified because of usage, damage, revaluation, etc., the taxable base will be the value of the goods at the moment when they are transferred
Sweden	In the case of a transfer of goods from another EU country, without transfer of ownership of the goods, which is considered an intra-community acquisition, the taxable basis should be either the purchase price of the goods or similar goods or, if there is no such price, the cost price of the goods (e.g. production costs)
United Kingdom*	Not applicable, since IMP has not to be taxed. However, for Intrastat purposes the costs of the goods is applicable

*Please note the answers as provided within this report for the UK are based on current legislation and issued guidance. Once the UK exits the EU the answers provided will need to be reviewed and updated accordingly.

4

In case the clinical trial material/IMP consists of modified blood/tissue samples of a patient (e.g. precision medicines topics) would you add additional comments to your above outlined answers?



Austria	No
Belgium	Specific VAT exemption exists in connection with human blood/organs. However attention is to be given to the recent EU Case Law, where the exemption was limited to the use for therapeutic purposes
Bulgaria	Normally, these items are VAT exempt
Croatia	Generally no. However, please note that this is a complex issue; confirmation with the Croatian VAT authorities recommended
Cyprus	Yes, as this type of material could be subject to exemption from VAT subject to the fulfilment of certain conditions and provided that the approval of the Tax Commissioner is obtained beforehand (where applicable)
Czech Republic	No
Denmark	No
Estonia	According to the VAT Act, the supply of an organ or tissue of human origin, human blood or blood product made from human blood and breast milk (which are specified in the list approved by a regulation of the minister responsible for the area) are tax exempt in any case
Finland	Finnish VAT Act: tax is not payable on the sale of human blood and tissues. No VAT deduction is permitted if the purchases have been made for VAT-exempt activities
France	No
Germany	Complex topic, a possible tax exemption should be examined in detail
Greece	There is no explicit provision/guidance in this respect
Hungary	Modified blood or tissue samples are exempt from VAT
Ireland	Yes: the supply of certain blood products are VAT exempt in Ireland
Italy	There is no particular guidance in this respect
Latvia	No
Lithuania	No
Luxembourg	No
Malta	No
Netherlands	A Dutch VAT exemption applies to the supply, intra-community acquisition and importation of human organs and human blood
Poland	No
Portugal	No, but please note that the supply of human blood is exempt
Romania	Certain categories of therapeutic substances and reagents may also be subject to VAT exemption, provided that these goods are intended for institutions and laboratories authorised by the Ministry of Public Health and used exclusively for non-commercial medical or scientific purposes. In this regard, please find below the respective categories of goods: – therapeutic substances of human origin (human blood and derivatives thereof – whole human blood, dry human plasma, human albumin and human plasma protein binding proteins, human immunoglobulin and human fibrinogen) – blood-grouping reagents (all reagents of human, animal, plant or other origin, used for blood grouping and for blood incompatibilities) – reagents for the determination of tissue types (all reagents of human, animal, vegetal or other origin, used for the determination of human tissue types) As such, both intra-community acquisitions and imports of the categories of therapeutic substances and reagents will qualify as VAT exempt operations, provided that the conditions previously mentioned are met
Slovakia	Supplies of human blood/tissue are VAT exempt. VAT treatment of clinical trial materials consisting of it should be considered on a case-by-case basis
Slovenia	The supply of blood and blood products, mother's milk and human organs for transplantation shall be exempt from VAT
Spain	No, however, please note that the delivery of modified blood/tissue samples will be exempt from Spanish VAT
Sweden	No, but there is an exemption in the Swedish VAT Act for supplies of human blood and organs. However, the Swedish Tax Agency has stated in their official guideline that this exemption is only applicable should the human blood or organ be used for therapeutic purposes (e.g. to cure or prevent a disease or provide a diagnosis). Supplies to a pharmaceutical company of e.g. plasma would not be exempt through this provision, according to the Swedish Tax Agency
United Kingdom*	If a business makes only exempt or partly exempt supplies its VAT recovery will be impacted accordingly. Acquisition VAT accounting is further only needed where the goods themselves are subject to VAT (i.e. not VAT exempt)

*Please note the answers as provided within this report for the UK are based on current legislation and issued guidance. Once the UK exits the EU the answers provided will need to be reviewed and updated accordingly.

Contacts

Michaela Merz
Partner
Leader VAT Switzerland
+41 58 792 44 29
michaela.merz@ch.pwc.com

Dr. Sandra Ragaz
Partner
Leader Pharma & Life Sciences
VAT Switzerland
+41 58 792 44 69
sandra.ragaz@ch.pwc.com

Keep updated with the recent pharma-related news
www.pharmabusinessblog.ch

and our Pharma Experts
www.pwc.ch/vatexperts