



Customs toolkit for IMP VAT requirements in the EU

With an understanding of IMP valuation, customs tax updates and optimization of duties and VAT we have compiled an overview of the considerations per EU country.

Country	Is VAT registration required for a pharma company for the transfer of IMP from one EU country to another, during the course of a clinical trial?	What IMP value has to be considered?	What are the applicable VAT rates?
Austria	YES	VAT basis is considered to be the production cost or purchase price	20% - Basic rate 10% - Medicinal products according to the Austrian Medicines Act; sanitary protection products (since 1 Jan 2021)
Belgium	YES , however a simplification exists with regard to the transfer of IMP, whereby under certain conditions the registration obligation can be avoided	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	21% - Basic rate 6% - Medicines for human or animal consumption; blood and blood products (red blood cells, white blood cells, plasma, platelets, blood containing anticoagulants, etc.); condoms; Band-Aid and similar products; injection and similar medical products; products used for sanitary protection (Royal Decree N°20, Table A, categories XVII and XXIII) 0% - COVID-19 vaccines and in vitro diagnostic medical devices, and related services
Bulgaria	YES , if the value of the goods per calendar year exceeds EUR 10,000	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	20% - Basic rate 9% Supply of baby diapers and similar baby hygiene items (until 21 Jan 2021)
Croatia	YES	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	25% - Basic rate 5% - Medicines which have the approval of the competent authority
Cyprus	YES , provided that the value of the goods exceed the registration threshold of EUR 10,262	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	5% - Basic rate

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Czech Republic	YES	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	21% - Basic rate 10% - Selected pharmaceutical products: Radiopharmaceuticals, vaccines, medicaments, contrast agents for X-ray examinations, diagnostic reagents intended for administration to patients, chemical contraceptives on a hormonal basis - intended for medical and veterinary services, disease prevention and treatment for medical and veterinary purposes. 15% - Radiopharmaceuticals (excl. those subject to the second reduced rate of 10%) sorbitol for diabetics, aspartame, saccharin and its salts, antibiotics, pharmaceutical products - intended for medical services, disease prevention and treatment for medical purposes only
Denmark	YES	Complex topic; ruling request is recommended	25% - Basic rate
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	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)	20% - Basic rate 9% - Applicable to medicinal products within the meaning of Medicinal Products Act; food for special medical purposes within the meaning of the Food Act; oxygen for medical inhalation; radioactive chemical elements and isotopes and their compounds used for the treatment and diagnosis of diseases on importation by a person authorised to provide health care or on sale to that person; antisera prepared from animal blood; modified immunological products, including those obtained by means of biotechnological processes; toxins and other vaccines, and products similar to those in the presence of microorganisms (humans, animals and plant viruses and antiviruses, bacteriophage patterns); contraceptives.
Finland	YES	Transfer of own goods: purchase value or a probable lower price of supply. Self-manufactured goods: direct and indirect manufacturing costs	24% - Basic rate 10% - Restricted to medicines in the meaning of the Medicines Act. Including herbal medicinal products and homeopathic preparations in so far they, according to the registration due to the Medicines Act may be sold only at pharmacies. Also including clinical foodstuffs as well as basic creams and ointments in so far they are eligible for reimbursement in accordance with the The Health Insurance Act. 24% - Products used for sanitary protection and contraception, other than medicinal products.

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France	YES with regard to the deemed intra-community acquisition	Production costs	<p>20% - Basic rate</p> <p>10% Non-reimbursed pharmaceutical products, namely pharmacy and pharmaceutical drugs or products for use in human medicine and subject to the authorisation provided for in Article L. 5121-8 of the Code of public health.</p> <p>5.5% - Sanitary protection for women</p> <p>2.1% - Reimbursed pharmaceutical products, namely medicines, drugs or pharmaceutical products defined in Article L. 5121-8 of Code of public health, which fulfil the conditions of Article L. 162-17 of the French social security code, or which are approved in accordance with Articles L. 5123-2 and L. 5123-3 of the Code of public health and on the products referred to in 1°, 3°, 4° and 5° of Article L. 1221-8 of the Code of public health and medicinal products subject to temporary authorisation for use referred to in Article L. 5121-12 of the Code of public health.</p>
Germany	In general, yes. However, a deviant practice is observed recently	Purchase price plus incidental costs or (if not available) cost price	<p>19% - Basic rate</p> <p>7% - Only for products used for sanitary protection</p>
Greece	YES	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	<p>24% - If not specified under 6% or 13%</p> <p>13% - the following pharmaceutical goods: (a) sterile surgical catgut and sterile tissue adhesives for surgical wound closure; (b) sterile laminaria and sterile laminaria tents; (c) sterile absorbable surgical or dental haemostatics; sterile surgical or dental adhesion barriers; (d) opacifying preparations for X-ray examinations and diagnostic reagents designed to be administered to the patient; (e) blood grouping reagents; (f) dental cements and other dental fillings; bone reconstruction cements; (g) first-aid boxes and kits; (h) chemical contraceptive preparations based on hormones, on other products of heading 2937 or on spermicides; (i) gel preparations designed to be used in human or veterinary medicine as a lubricant; (j) waste pharmaceuticals; and (k) appliances identifiable for ostomy use</p> <p>6% - Especially for tariff headings 3002, 3003 and 3004 (as referred to in the Commission Implementing Regulation (EU) No 1101/2014 of 16 October 2014). Medicaments for human medicine of tariff heading and vaccines and immunological products for human medicine of tariff heading</p>
Hungary	YES	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	<p>27% - Basic rate</p> <p>27% - Products for veterinary purposes</p> <p>5% - Human medical products; radioactive medical isotopes, dietary foods for special medical purposes, medical oxygen (max. 10 or respectively 20 litre capacity, 150 or respectively 200 bar pressure cylinders or formulated in a liquid form, only pharmaceutical grade product)</p>

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Ireland	YES , once the threshold of EUR 41,000 calendar year has been reached	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	23% - Basic rate 21% - Non-oral pharmaceutical products used for human or animal consumption such as injections, infusions, liniments and ointments. 0% - Oral pharmaceutical products used for human or animal consumption, excluding medicine which is packaged, sold or otherwise designated for the use of dogs, cats, cage birds or domestic pets. Oral Contraception and sanitary products. 13,5% non-oral contraceptive products; menstrual cups, menstrual sponges and period pants
Italy	YES	As a general rule, the production or purchase costs should be considered	22% - Basic rate 10% - Medicines for human and veterinary use, including homeopathic products; pharmaceutical substances and medication items the provision of which is compulsory for pharmacies in accordance with the official pharmacopoeia 5% - Products for feminine sanitary protection which are compostable or washable and menstrual cup
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	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	21% - Basic rate 12% - Medicinal products: a) registered in accordance with the registration procedure of the European Agency for the Evaluation of Medicinal Products; b) included in the list of medicinal products registered in the Republic of Latvia; c) for which the relevant permit of the State Agency of Medicines is issued; d) the registration of which is not necessary in accordance with the laws and regulations in the field of pharmacy
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	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	21% - Basic rate 5% Medicaments and medical aids fully or partially compensated by the Compulsory Health Insurance Fund (at the moment of acquisition) as well as for all non-compensated prescribed medicines - Pharmaceutical preparations (entered into the Lithuanian or EU register of prescribed medications)
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	There is no specific rule and currently no official guidance in Luxembourg concerning this matter	3% proprietary medicinal products, ready made medicinal products and medicinal products, as defined in Article 1 of the law of 11 April 1983 regulating the publicity and marketing of pharmaceutical products - Veterinary medical products as defined in Article 1 of the law of 18 December 1985 concerning veterinary medical products - Pharmaceutical preparations - Products used for contraception; Products used for sanitary protection: sanitary towels (pads), tampons, panty liners, period panties, menstrual cups, menstrual sponges and similar feminine hygiene products 17% basic rate

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Malta	YES	The Maltese VAT Act does not provide detailed rules for this but the cost to the entity should be a good basis	0%
Netherlands	YES	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	21% - Basic rate 9% - Drugs as defined in Article 1, paragraph b of the Medicines Act, contraception, infusion and inhaled gases intended for medical purposes; veterinary medicine, with the exception of veterinary medicinal products for in vitro use; cotton wool, bandages, gauze, adhesive, bandages, tampons, splints and similar setting items which are clearly intended for medical purposes, as well stocked first aid kits, sanitary napkins, maternity mattresses and incontinence products
Poland	YES	Normally production costs are the basis for VAT calculation for free-of-charge supplies reportable by hospitals	8% - Basic rate 5% - Sanitary towels and tampons, napkins and similar articles of any material 0% - COVID-19 vaccines : a) admitted to trading in the territory of Poland in accordance with the provisions of the Act of 6 September 2001 - Pharmaceutical Law, b) that have obtained a permit issued by the Council of the European Union or the European Commission
Portugal	YES	Market price, and if that is not possible production cost	23% - e.g. veterinarian services and vitamins 6% - Pharmaceutical or similar products and the respective active substances indicated below: a) Medication, pharmaceutical specialities and other pharmaceutical products intended exclusively for therapeutic and prophylactic ends; b) Condoms; c) Pastes, gauzes, cotton wool, foil and adhesive dressings and other similar aids impregnated or coated in any substances, for hygienic, medicinal or surgical; d) Medicinal plants, roots and tubers; e) Glycaemia, glycerine and acetone strips, needles, syringes and pens for the administration of insulin used in the prevention and treatment of diabetes
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	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	19% - Basic rate
Slovakia	YES	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	20% - Basic rate

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Slovenia	YES	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	22% - Basic rate 9.5% - Antiserums, other fractions of blood and modified immunological products used for treatment; vaccines; toxins; microbiological cultures (except yeasts); human, animal and plant viruses, antiviral drugs and bacteriophages; diagnostic reagents; intrauterine contraceptive device; disposable diapers and cloth diapers, but not sanitary towels and tampons
Spain	YES. If only transfers of own goods to Spain are made, simplified registration for statistical purposes would be required	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	21% - Basic rate 10% - Medical products for veterinary uses; napkins, tampons, panty liners, condoms and other non-medical contraception 4% - Medicinal products for human use, pharmaceutical forms, pharmaceutical compounding products and officinal preparations
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	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)	25% - Basic rate 0% Medicine supplied on prescription or sold to hospitals or imported into the country to be supplied on prescription or sold to hospitals
United Kingdom	YES	The costs of the goods is applicable	20%

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