

Annex 4. Application of Article 23: Wholesalers to decommission on behalf of persons authorised or entitled to supply medicines to the public

MS	Persons authorised to supply outside health care institutions and pharmacies	Veterinarians and retailers of veterinary products	Dental practitioners	Optometrists and opticians	Paramedics and emergency medical practitioners	Armed forces	Police	Other governmental institutions	Universities and other higher education establishments	Prisons	Schools	Hospices	Nursing homes	Decision adopted
AT	No	Yes, if human medicinal products are concerned to be supplied to the public in a veterinarian's office pharmacy	No	No	Yes, if medicinal products containing substances under control are concerned	Yes	Yes	Yes	Yes	Yes	No	No	No	Entered into force on 07.02.2019
BE					Yes, for supply to emergency medical supplies on ships	Yes, all products		Vaccination centres : vaccines						Royal Decree of 3 February 2019.
BG														No, currently it is under discussion. Adoption of Amendment to the Medicines Act and Ordinance of Minister of Health is expected in Q4 2018 or at the beginning of 2019

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EE	Persons who are not retailers, but are entitled to dispense MPs to the general public without retailing activity (for example vaccines)	Yes, all human products for vet use	No. Dentist don't have right to make wholesale purchases of medicinal products in Estonia	No. Optometrists and opticians don't have right to make wholesale purchases of medicinal products in Estonia	Yes	No. All medicines for army go via special pharmacy	No. Police don't have right to make wholesale purchases of medicinal products in Estonia	Yes	Yes, certain universities which need medicines for science	No. All medicines for prisons go via special pharmacy.	It is special degree of the Ministry of Social Affairs about schools, hospices and nursing homes which have right to make wholesale purchases of medicinal products in Estonia. Wholesalers have to verify and decommission medicines before selling to these entities.			Yes, national legislation was adopted on 12 Dec 2018
EL														
ES	Yes, only for some medicinal products	Yes, only for some medicinal products	Yes, only for some medicinal products	No	No	Yes, except medicinal products supplied to military pharmacies	No	Governmental institutions for civil protection, e.g. vaccination programmes	No	No	No	No	No	No, Royal Decree currently under consultation. Adoption expected Q2 2019

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FI	No	Yes, all products for veterinary use	No	No	No	Yes	No	Yes, for vaccines used by vaccination centers from the National Institute for Health and Welfare according to the national immunoprophylaxis programme (specifically for seasonal influenza) for the purposes of civil protection and disaster control. [Decision currently being prepared.]	Yes, all products for research purposes	No	No	No	No	Adopted 23.02.2019
FR	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes, legislation published on 16 June 2019 (décret n° 2019-592 du 14 juin 2019).

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HR	Yes, all products	Yes, all products	Yes, all products	No	Yes, all products	Yes, all products	No	Vaccination centres: vaccines	Yes, all products for research purposes	Yes all products , if there is no pharmacy supplying the medicines to prison	No	Yes, all products	Yes, all products	No, currently under consultation. Final decision will be made by the Ministry of Health.
HU	Yes, for dialysis centres (until 09.02.2021).	No	No	No	Yes, all products	Yes, all products (via special pharmacy)	No	Vaccines: used for national immunoprophylaxis program (until 09.02.2021). Certain products: supplied to National Healthcare Services Center (for the purposes of civil protection and disaster control).	No	No	No	No	No	Yes, minor amendments to Decree No. 53/2004 (VI.2.) on Wholesale and Parallel Import Activity related to Medicines
IE	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, national legislation was adopted on 8 February 2019

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IS														
IT														
LI	No	No	No	n.a.	No	n.a.	n.a.	n.a.	n.a.	No	n.a.	No	No	Adopted decision not before 2020
LT	Yes, only legal entities, providing the following types of healthcare services: health rehabilitation; family medicine (general practitioners); forensic medicine The exemption applies to a very small amount of medicinal products that are used for healthcare in these legal entities, such as just first aid kits and others as needed.	No	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Vaccination centres: Exemption applies only to vaccines used according to national immunoprophylaxis programme	Yes, all products for research purposes	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, Order of the Minister of Health No V-1182 /31.10.2018; Order of the Minister of Health No V-166 /07.07.2019 (amendments to Order No V-1182)

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LU	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Yes, depending on the decision of the MoH	Grand-Ducal Regulation of 13 January 2019. (Official Journal No 51 of 1st February 2019)
LV	Yes, in principle possible, but according to national law restricted to vaccines only if they are supplied to general practitioners in private practice, if decommissioning is not done by them	Yes, all products	No	No	Yes, all products – supplied to State Emergency Medical Service	Yes, for the purpose of civil protection and disaster control	No	Yes, all products – supplied to State Emergency Medical Service (for the purposes of civil protection and disaster control)	Yes, all products for research purposes (according to Pharmaceutical law the above mentioned institutions have to obtain permission from State Agency of Medicines)	Yes, all products	Yes, all product (according to Pharmaceutical law the above mentioned institutions have to obtain permission from State Agency of Medicines)	Yes, all products (hospices and nursing homes must be registered as social care institutions in accordance to national law)		Yes, Regulation of Cabinet of Ministers no. 38/15.01.2019 (in force from 18/01/2019)
MT	No	Yes, all products	Yes, only anaesthetics	No	Yes, all products	Yes, all products	Yes, all products	Yes, all products	Yes, all products for research purposes	Yes, all products	Yes, only vaccines	Yes, all products	Yes, all products	No, currently under consultation
NL	Yes	Yes	Yes	No	No	Yes, where not via a pharmacy	No	No	No	No	No	No	No	Published 14.01.2019

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PT	Yes	NA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NA	Yes	Yes	<p>Legislation published 24 April 2018 – INFARMED, I.P. prepared and published a directory listing of all entities on behalf of whom wholesalers have to verify UI's in continental Portugal. List made public on the NCA website. Listings prepared by regulators of Azores and Madeira can also be found on INFARMED, I.P. website. Link below: http://www.infarmed.pt/web/infarmed/entities/licenciamentos/aquisicao-direta-de-medicamentos</p>

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RO	Yes for dialysis centres (until 10.02.2021) and for units performing clinical studies	No	Yes	No	Yes, unless they have a pharmacy in their structure	Yes (until 10.02.2021)			No	Yes (until 10.02.2021)	No	No	No	Yes, Ministry of Health Order no. 985/06.08.2018
SE	No	No	No	No	No	All products	All products	All products	No	No	No	No	No	Adopted 29.11.2018
SI	No	No	No	No	No	Yes, all products	No	No	No	No	No	No	No	No, currently under consultation adoption expected
SK	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion	Under discussion - decision planned Q4, our intention is to ensure that the supply would be as smooth as possible and "vulnerable" supply chains burdened as little as possible, wholesalers can expect to be responsible for decommissioning (reg. art. 23)

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UK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Entered into force 9.02.2019.