

New rules in CEE countries regarding exports of medical equipment and medicinal products – as per 25/03/2020

Country	Rule	Exemptions	Sanctions
EU	<p>Equipment:</p> <ul style="list-style-type: none"> • EU-restrictions on export: export authorisation shall be required for the export outside the Union of personal protective equipment listed in Annex I Reg (EU) 2020/402, whether originating in the Union or not; • European standards for medical supplies made freely available to facilitate increase of production (read here); • COM Recommendation on conformity assessment and market surveillance (read here): <ul style="list-style-type: none"> ➢ opening the EU market to protective equipment manufactured in accordance with WHO recommendations; ➢ for medical devices, that MS should use their discretion to authorise derogations from EU conformity assessment procedures (development/changes in Austria are rumored to be expected); ➢ that for a limited period, market surveillance authorities allow the circulation of protective equipment or medical devices for which conformity assessment procedures, including the affixing of CE marking, have not been fully finalised, provided that the products are otherwise safe in accordance with EU law; and ➢ that MS take appropriate measures to ensure that protective equipment or medical devices not bearing the CE marking are only made available to healthcare workers. 		
Austria	Limited prescription-only medicinal products may be affected by export bans entering into force on 01/04. See here for details.		
Bulgaria	<p>8/03: shipment of personal protective equipment banned. Ban was notified to the European Commission (see here). This ban is based on Article 36 TFEU and Article 10 of Regulation (EU) 2015/479.</p> <p>It pertains to exports of the existing stocks of personal protective equipment (disposable coverall suits, respiratory masks, surgical masks, eye protection, latex/nitrile gloves and overshoes) which have been produced or are in the possession of or distributed by natural and legal persons, until the needs within the territory of the country have been met.</p>		Although no explicit sanctions are discussed in the decision of the Council of Ministers, such goods have already been confiscated at the border.

Croatia	No ban on exports of equipment and products imposed yet.		
Czech Republic	4/03: MoH prohibited the export of respirators FFP3.		Up to CZK 3m (approx. EUR 110k).
	06/03: MoH prohibited the export of hand disinfection products, except for a small quantity for personal use.		
	17/03: Govt decision to prohibit export of medicaments (export of medical devices or equipment should still be allowed).		Up to CZK 5m (approx. EUR 200k).
Hungary	24/03: Export ban for medicinal products: (i) containing the active substance of hydroxychloroquine-sulfat and (ii) which are manufactured with the use of hydroxychloroquine-sulfat.	Exemption possible upon request by either the Government or the national Healthcare Services Center.	<ul style="list-style-type: none"> • Withdrawal of authorization. • Fine of up to EUR 1.4m imprisonment of up to 3 years.

Poland	<p>16/03: MoH announcement regarding an updated "anti-export list": list of medicinal products, foodstuffs and medical devices with risk of lack of availability (Preparations of ibuprofen, metamizole and paracetamol remained on the anti-export list, while there are currently no drugs used in the symptomatic treatment of bacterial and viral infections. Masks and other medical devices intended to counteract the coronavirus pandemic have also been removed).</p> <p>Reportedly, gloves, surgical gloves, surgical drapes, surgical masks, surgical gowns and non-woven gowns have been included into the latest update of the "anti-export list".</p> <p>17/03: Further update of "anti-export list" announced by MoH, now including caps, thermometers, gloves, masks, surgical drapes, surgical masks, surgical gowns and non-woven gowns.</p>	<p>Intention to export items on the "anti-export list" must be reported, with a possibility of an official rejection within 30 days.</p>	<p>Violating the reporting obligation: fine from PLN 10k – 50 k (approx. EUR 2k – 10k)</p> <p>Export against the objection or before the objection deadline has passed: imprisonment of up to 2 years. In the case of a medicinal product, imprisonment between 3 months and 5 years.</p>
	<p>13/03: MoH announcement on epidemic threat:</p> <ul style="list-style-type: none"> • Prohibition to export respirators and cardio monitors until further notice. • Reporting obligation 24 hours in advance if one intends to export: protective goggles, coveralls type TYVEK, masks type FFP2/FFP3, surgery masks, shoe covers, latex gloves, nitrile gloves, hand, surface and room disinfectants. <p>Entities not performing medical activities were asked to report type and number of respirators and cardio monitors on stock by 17/03.</p>		<p>Violating the prohibition ban should trigger the same fines as above.</p>
Romania	<p>12/03: MoH imposed, for six months, (i) an export ban on selected medical devices and sanitary materials (See here for the list) and (ii) suspension of export of certain medication.</p>	<p>No exemption possible.</p>	<p>Fine RON 50k – 100k (approx. EUR 10k-20k); for repeat offenders within 3 months: withdrawal of authorisation.</p> <p>Risk of confiscation of goods.</p>
	<p>17/03: Institution of emergency, restricting right of economic liberty.</p>		<p>Violations of the MoH ban might be declared a criminal act in the future</p>
	<p>18/03: minister of internal affairs issued the military ordinance no. 1/2020, which came into force the same day, prohibiting during the emergency state the export of (i) medical devices and sanitary materials ensuring the prevention and treatment of medical conditions associated with COVID – 19 and (ii) export of certain medication.</p>	<p>Export of ensembles and sub – ensembles of medical equipment, made in Romania, for external beneficiaries</p>	<p>No specific sanction. However, infringement of obligations provided under the ordinance may trigger the disciplinary, civil, contravention or criminal liability, as the case may be, in</p>

			accordance with the general laws.
	21/03: issuance and entry into force of military ordinance no. 2/2020 which amended the ordinance no. 1/2020, in the sense that other exemptions from the medical equipment / medicines export ban shall be established through orders issued by the MoH.	Through orders of MoH	No specific sanction. However, infringement of obligations provided under the ordinance may trigger the disciplinary, civil, contravention or criminal liability, as the case may be, in accordance with the general laws.

Serbia	16/03: Export ban for medicinal drugs for 30 days.	Medicines: <ul style="list-style-type: none"> intended for foreign markets (i.e. that have not been registered in Serbia), and dispatched from the Serbian customs territory by a foreign person as part of transit operations. 	No specific penalty, but general customs laws apply. Possibility of declaring violations to be criminal acts cannot be ruled out.
	14/03: Export ban for certain essential goods for 30 days: plastic, rubber, surgical and other gloves, plastic face masks with textile filters, paper face masks, surgical textile covers, surgical suits, adult and child diapers, protective glasses, medicinal alcohol and all other disinfectants.	Goods purchased by a domestic person in a foreign state, provided that such goods are shipped outside Serbia following customs clearance.	
Slovakia	No ban on shipments of medical equipment imposed yet. However, state of emergency (applicable mainly to hospitals and other medical facilities) has been declared.		
Slovenia	13/03: MoH prohibited the sale of protective equipment (such as protective gloves, protective clothes, protective masks, disinfectants, etc.) inside and outside the territory of Slovenia (except for the needs of medical service providers, the police, the Slovenian armed forces and the protection, rescue and help forces in Slovenia). This ban was lifted on 15/03.		
	14/03: Govt set maximum prices for safety, protective and other medical equipment for a period of three months: protective masks (FFP2 and FFP3 types), surgical masks, protective glasses, tyvek protective clothing, waterproof protective clothing, nitrile or latex protective gloves, disinfectants (50 ml, 200 ml and 500 ml), intensive care ventilators, portable oxygen systems, and non-contact body temperature meters. Maximum price is set as a maximum retail price in force on 14 March.		Min EUR 6k; responsible person can be fined min EUR 1.1k.

If you have any questions, please feel free to contact our legal experts across CEE:

Austria



Christoph Haid
Partner
T: +43 1 534 37 50 119
c.haid@schoenherr.eu



Franz Urlesberger
Partner
T: +43 1 534 37 50196
f.urlesberger@schoenherr.eu



Volker Weiss
Partner
T: +32 2 743 40 44
v.weiss@schoenherr.eu



Hanno Wollmann
Partner
T: +43 1 534 37 50152
h.wollmann@schoenherr.eu

Bulgaria



Galina Petkova
Attorney at Law
T: +359 2 93310 83
g.petkova@schoenherr.eu

Czech Republic



Claudia Bock
Attorney at Law
T: +420 225 996 500
c.bock@schoenherr.eu

Hungary



Anna Turi
Counsel
T: +36 1 8700 707
a.turi@schoenherr.eu

Poland



Paweł Halwa
Partner
T: +48 22 223 09 11
p.halwa@schoenherr.eu

Romania



Georgiana Bădescu
Partner
T: +40 21 319 67 90
g.badescu@schoenherr.eu

Serbia



Srđana Petronijević
Partner
T: +381 11 3202 600
s.petronijevic@schoenherr.rs

Slovenia



Eva Škufca
Partner
T: +386 1 200 09 82
e.skufca@schoenherr.eu

Turkey



Levent Çelepci
Partner
T: +90 212 230 17 00
l.celepci@schoenherr.eu