Overview of the implementation of Article 81 of Directive 2001/83 EC and the status of full-service healthcare distributors in the European Union Member States

Introduction

As the European Commission started the process of revising the European Union general EU pharmaceutical legislation, GIRP produced an overview with a set of key strategic findings on the implementation of Article 81 of Directive 2001/83 EC[1] of the existing pharmaceutical legislation on the obligation of adequate and continuous supply of wholesale distributors of medicinal products.

The present paper present the measures of national transposition of Article 81 of Directive 2001/83 as well as the different regimes existing for full-service healthcare distributors. For the purposes, the paper focuses on three key issues:

- The existence of a **Public Service Obligation** (PSO) on full-service healthcare distributors (as wholesale distributors) to deliver medicines;

- The **right to be supplied for full-service healthcare distributors**, i.e. the obligation on the manufacturer or marketing authorisation holder of medicinal products to deliver medicinal products to the full-service healthcare distributor;

- The existence of a **separate licensing system** for wholesalers of medicinal products and **full-line wholesaler of medicinal products**.

Indeed, in a significant number of European Union Member States, full-service healthcare distributors are bound by a Public Service Obligation to deliver medicinal products to pharmacies without a right to be supplied or right to claim supplies from marketing authorisation holders. Full-service healthcare distributors are thus exposed to a failure to comply with national law and to put at risk the life of patients, not because of their operations, but because of upstream suppliers that do not provide, sometimes on purpose and through supply quotas, the necessary medicines for patients in Europe. The discrepancy between the existence of a Public Service Obligation and the absence of a right to be supplied is highlighted in this overview.

In addition, GIRP provides an overview of the national legislation that recognise the special status of full-service healthcare distributors, in particular but not exclusively when bound by Public Service Obligations, as opposed to traditional wholesalers of medicinal products. This phenomenon takes the form of a separate licensing system for full-line wholesalers of medicinal products.

This paper first comprises an overview with graph that summarises the state of play of the three key issues identified hereinabove. This is followed by a complete and detailed overview per Member State of the legislation in force, with the provision being reproduced in their original version accompanied with an English translation provided by GIRP.

---

[1] Consolidated text: Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311, Article 81.

GIRP
European Healthcare Distribution Association Brussels, April 2022

European Healthcare Distribution Association (GIRP) (website)

GIRP, the European Healthcare Distribution Association, is the umbrella organisation for pharmaceutical full-line wholesalers and distributors of healthcare products and services in Europe. It represents the national associations of over 750 pharmaceutical wholesalers serving 34 European countries, as well as major international and pan-European healthcare distribution companies. GIRP members employ over 140,000 people and distribute around 15 billion packs of medicines as well as a wide range of healthcare products per year. As the vital link in healthcare, they are committed to developing and providing innovative and efficient healthcare products and services to improve health and wellbeing of patients across Europe.

Table of contents

Overview

Figure 1: Overview of Public Service Obligations, right to be supplied and separate licensing system for full-line wholesalers of medicinal products in EU Member States (see below)

Figure 1 presents in one chart the summary of the national legislation in the European Union on the transposition of Article 81 of Directive 2001/83 EC.

The first four columns grouped under the label 'Public Service Obligation' present the existence or the absence of a Public Service Obligation in the respective Member States. GIRP identified four categories upon which it based its analysis:

- **No transposition**: no transposition of Article 81 was identified
- **Partial transposition**: the transposition measure does not encompass the totality of the obligation arising from Article 81 para 2.
- **Transposition**: the transposition measure adopted by the Member State is a literal transposition and a copy of Article 81 para 2.
- **PSO**: the Member State established a public service obligation regime more stringent than the requirements of Article 81 para 2 or a pre-or post-dating E national PSO .

The fifth column presents the existence or the absence of a right to be supplied for full-line wholesalers.

The sixth column presents the existence or the absence of a separate licensing system for full-line wholesalers as opposed to regular wholesalers.

COUNTRY	Public Service Obligation				Right to be supplied	Different Licensing System
	No transposition	Partial Transposition	Transposition	PSO		
Austria (AT)						
Belgium (BE)						
Bulgaria (BG)						
Croatia (HR)						
Cyprus (CY)						
Czechia (CZ)						
Denmark (DK)						
Estonia (EE)						
France (FR)						
Finland (FI)						
Germany (DE)						
Greece (EL)						
Hungary (HU)						
Italy (IT)						
Ireland (IE)						
Latvia (LV)						
Lithuania (LT)						
Luxembourg (LU)						
Malta (MT)						
Netherlands (NL)						
Poland (PL)						
Portugal (PT)						

Romania (RO)						
Slovakia (SK)						
Slovenia (SI)						
Spain (ES)						
Sweden (SE)						

Figure 1: Overview of Public Service Obligations, right to be supplied and separate licensing system for full-line wholesalers of medicinal products in EU Member States

Overview of EU Member States legislation

Austria (AT)

	Original version	EN translation
PSO	**Arzneimittelgesetz, §57a :** « Sicherstellung der Versorgung (1) Der Zulassungsinhaber oder der Inhaber einer Registrierung einer Arzneispezialität und die Arzneimittel-Großhändler und Arzneimittel-Vollgroßhändler, die diese tatsächlich in Verkehr gebrachte Arzneispezialität vertreiben, haben im Rahmen ihrer jeweiligen Verantwortung eine angemessene und kontinuierliche Bereitstellung der Arzneispezialität für die Abgabe durch Apotheke**n** oder für sonst zur Abgabe gemäß § 59 Berechtigte sicherzustellen, damit der Bedarf der Patienten im Inland gedeckt ist. » **Arzneimittelgesetz, §2 :** « (3) „Arzneimittel-Vollgroßhändler" ist ein Arzneimittel-Großhändler, der zufolge ausreichender Lagerhaltung, einer entsprechenden Sortimentgestaltung sowie einer entsprechenden Versorgungsbereitschaft, -regelmäßigkeit und -intensität, in der Lage ist, die Arzneimittelversorgung im Sinne des § 57 in einem bestimmten Gebiet sicherzustellen. »	**Medicines Act, §57a:** "Securing the supply (1) The marketing authorization holder or the holder of a registration for a medicinal product and the medicinal product wholesalers and full-service wholesalers who sell this medicinal product that has actually been placed on the market shall, as part of their respective responsibilities, ensure that the medicinal product is made available appropriately and continuously for dispensing by pharmacies or for those who are otherwise entitled to dispense in accordance with Section 59, so that the needs of patients in the national territory are covered." **Medicines Act, §2:** " (3) "[Full-line] Pharmaceutical wholesaler" is a pharmaceutical wholesaler who is able to ensure the supply of pharmaceuticals within the meaning of Section 57 in a specific area as a result of sufficient warehousing, a corresponding assortment design and a corresponding supply readiness, regularity and intensity."
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	**Arzneimittelgesetz, §2 :** « (2) „Arzneimittel-Großhändler" ist ein Gewerbetreibender, der auf Grund der Gewerbeordnung 1994, BGBl. Nr. 194, zum Großhandel mit Arzneimitteln berechtigt ist und über eine entsprechende Bewilligung gemäß § 63 Abs. 1 verfügt, sowie ein pharmazeutischer Unternehmer einer	**Medicines Act, §2:** "(2) "Pharmaceuticals wholesaler" is a trader who is authorized to wholesale pharmaceuticals on the basis of the Trade Regulations Act 1994, Federal Law Gazette No. 194 and has a corresponding license in accordance with Article 63 Paragraph 1, as well as a pharmaceutical

	anderen Vertragspartei des Abkommens über den Europäischen Wirtschaftsraum, der berechtigt ist, Großhandel mit Arzneimitteln zu treiben. (3) „Arzneimittel-Vollgroßhändler" ist ein Arzneimittel-Großhändler, der zufolge ausreichender Lagerhaltung, einer entsprechenden Sortimentgestaltung sowie einer entsprechenden Versorgungsbereitschaft, -regelmäßigkeit und -intensität, in der Lage ist, die Arzneimittelversorgung im Sinne des § 57 in einem bestimmten Gebiet sicherzustellen. »	entrepreneur of another Contracting party to the Agreement on the European Economic Area, authorized to wholesale medicines. (3) "[Ful-line] Pharmaceutical wholesaler" is a pharmaceutical wholesaler who is able to ensure the supply of pharmaceuticals within the meaning of Section 57 in a specific area as a result of sufficient warehousing, a corresponding assortment design and a corresponding supply readiness, regularity and intensity."

Belgium (BE)

	Original version	EN translation
PSO	**Loi du 25 Mars 1964 sur les médicaments, Article 1(19)** « " Obligation de service public " : l'obligation faite aux distributeurs en gros de garantir en permanence un assortiment de médicaments capables de répondre aux exigences d'un territoire géographiquement déterminé et d'assurer la livraison des commandes demandées dans de très brefs délais sur l'ensemble dudit territoire; »	**Law of 25 March 1964 on medicines, Article 1(19)** "Public service obligation" means the obligation of wholesale distributors to guarantee at all times an assortment of medicinal products capable of meeting the requirements of a geographically determined territory and to ensure the delivery of the requested orders within a very short period of time throughout that territory;"
Right to be supplied	**Loi du 25 Mars 1964 sur les médicaments, Article 12 quinquies §1** « Les titulaires de l' AMM d'un médicament et, une fois que ce médicament est mis sur le marché, les distributeurs en gros de ce médicament, assurent de façon effective, dans la limite de leur responsabilité respective, un approvisionnement approprié et continu de ce médicament pour les personnes habilitées à délivrer ou à fournir des médicaments, de manière à couvrir les besoins des patients ou des animaux. » **Arrêté royal relatif aux médicaments à usage humain et vétérinaire (14.12.2006), Article 79** « Le titulaire de l'autorisation de fabrication est tenu au moins : 3) lorsqu'il est fait appel aux dispositions de l'article 95, § 1er, alinéa 1er, de s'engager à livrer les médicaments qui sont mis sur le marché aux titulaires d'une autorisation de distribution en gros chargées d'obligations de service public tels que visés à l'article 100 du Chapitre II, Titre VII de la présente Partie, ci-après dénommés grossistes-répartiteurs, de manière à ce que ceux-ci	**Law of 25 March 1964 on medicines, Article 12 quinquies §1** "The holders of the marketing authorisation for a medicinal product and, once this medicinal product is placed on the market, the wholesale distributors of this medicinal product, effectively ensure, within the limits of their respective responsibilities, an appropriate and continuous supply of this medicinal product for the persons entitled to deliver or supply medicinal products, so as to cover the needs of patients or animals." **Royal Decree on medicinal products for human and veterinary use (14.12. 2006), Article 79:** "The holder of the manufacturing authorisation is required at least : 3) when the provisions of Article 95, § 1, paragraph 1 are invoked, to undertake to deliver the medicinal products that are placed on the market to holders of a wholesale distribution authorisation with public service obligations as referred to in Article 100 of Chapter II, Title VII of this Part, hereinafter referred to as wholesaler-distributors, in such a way that the latter

	puissent satisfaire aux obligations visées à l'article 12quinquies de la loi sur les médicaments et à l'article 101 du Chapitre II, Titre VII de la présente Partie. Cette obligation ne vaut pas lorsque les médicaments sont fabriqués en vertu d'un contrat de sous-traitance; »	can fulfil the obligations referred to in Article 12quinquies of the Law on Medicinal Products and in Article 101 of Chapter II, Title VII of this Part. This obligation shall not apply where medicinal products are manufactured under a subcontracting agreement;"
Separate licensing system for full-line wholesalers	**Loi du 25 Mars 1964 sur les médicaments, Article 1(20)** « " grossiste - répartiteur " :le distributeur en gros chargé d'obligations de service public en ce qui concerne les médicaments à usage humain et/ou à usage vétérinaire »	**Law of 25 March 1964 on medicinal products, Article 1(20)** ""wholesaler - distributor": the wholesale distributor entrusted with public service obligations in respect of medicinal products for human and/or veterinary use."

Bulgaria (BG)

	Original version	EN translation
PSO	**Закон за лекарствените продукти в хуманната медицина Обн., ДВ, бр. 31 от 13.04.2007, Чл. 207.** « (1) Притежателят на разрешение за търговия на едро, който извършва дейността си на територията на Република България, е длъжен да: […] 6в. (нова – ДВ, бр. 18 от 2014 г.) осигурява снабдяването на достатъчни количества лекарствени продукти за задоволяване на здравните потребности на населението на Република България; »	**Law on Medicinal Products in Human Medicine, SG No. 31 of 13.04.2007, Art. 207.** "Art. 207. (1) The holder of a wholesale distribution authorisation who carries out his activity on the territory of the Republic of Bulgaria shall: […] 6c. (new - SG 18/2014) ensure the supply of sufficient quantities of medicinal products to meet the health needs of the population of the Republic of Bulgaria"
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Croatia (HR)

	Original version	EN translation
PSO	**Zakon o lijekovima, pročišćeni tekst zakona, NN 76/13, 90/14, 100/18 na snazi od 22.11.2018 članak 3** « 85. Obveza javne usluge je obzeva veleprodaja i nositelja odobrenja az stavljanje lijeka u promet vezano za osiguranje pavrodobne, trajne i primjerene opskrbe likejovima na određenom geografskom produčju. » « Članak 118 […] (2) Veleprodaje su obevze osigurati opskrbu likejovima u najkraćem mogućem roku »	**Medicines Act, consolidated text of the law, NN 76/13 , 90/14 , 100/18 effective from 11/22/2018, Article 3** "85. The public service obligation is the obligation of wholesalers and marketing authorisation holders to ensure the timely, permanent and adequate supply of medicinal products in a specific geographic area." "Article 118 […] (2) Wholesalers are obliged to ensure the supply of medicines as soon as possible"
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Cyprus (CY)

	Original version	EN translation
PSO	**Ο Περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμος του 2001 (70(I)/2001)** « ΜΕΡΟΣ I, 2 (Ερμηνεία) […] "υποχρέωση δημόσιας υπηρεσίας" σημαίνει την υποχρέωση που επιβάλλεται στους ενδιαφερόμενους χονδρέμπορους να διαθέτουν μονίμως ένα διαφοροποιημένο σύνολο φαρμακευτικών προϊόντων κατάλληλων για την κάλυψη των απαιτήσεων ενός γεωγραφικά καθορισμένου εδάφους και για την εξασφάλιση της παράδοσης των απαιτούμενων προμηθειών σε πολύ σύντομα χρονικά διαστήματα σε όλη την έκταση του εν λόγω εδάφους· » « Υποχρεώσεις κατόχου άδειας χονδρικής πώλησης 84.—(1) Ο κάτοχος της άδειας χονδρικής πώλησης έχει τουλάχιστο τις εξής υποχρεώσεις: […] (5)Ο κάτοχος άδειας κυκλοφορίας φαρμακευτικού προϊόντος, καθώς και οι κάτοχοι άδειας χονδρικής πώλησης που διανέμουν το εν λόγω φαρμακευτικό προϊόν, το οποίο όντως κυκλοφορεί στην αγορά, εξασφαλίζουν, εντός των ορίων των αρμοδιοτήτων τους, τον κατάλληλο και συνεχή εφοδιασμό της αγοράς των φαρμακείων και των προσώπων που έχουν άδεια να διαθέτουν φαρμακευτικά προϊόντα, με το φαρμακευτικό προϊόν αυτό ώστε να καλύπτονται οι ανάγκες των ασθενών στη Δημοκρατία. »	**The Drugs for Human Use (Quality Control, Supply and Prices) Law of 2001 (70 (I) / 2001)** "Part I, §2 (Interpretation) […] "public service obligation" means the obligation imposed on the wholesalers concerned to have permanently a diversified set of medicinal products suitable to meet the requirements of a geographically defined territory and to ensure the delivery of the required supplies in a very short time in that territory;" "Obligations of a wholesale license holder 84 (1) The holder of the wholesale license has at least the following obligations: […] (5) The marketing authorization holder of a medicinal product, as well as the holders of the wholesale authorization distributing the said medicinal product, which is actually placed on the market, shall ensure, within the limits of their responsibilities, the appropriate and continuous supply of the pharmacy market. and persons licensed to dispose of medicinal products, with this medicinal product in order to meet the needs of patients in the Republic."
Right to be supplied	*See Public Service Obligation*	*See Public Service Obligation*
Separate licensing system for full-line wholesalers	*None*	*None*

Czechia (CZ)

	Original version	EN translation
PSO	**Act on Medicinal Products and on Amendments to Certain Related Acts (Act on Medicinal Products) Act No. 378/2007 Coll. (31.12.2007), § 77:** « § 77 Práva a povinnosti distributora (1) Distributor je povinen […] h) zajistit dodávky humánních léčivých přípravků provozovatelům oprávněným vydávat léčivé přípravky v množství a časových intervalech odpovídajících potřebě pacientů v České republice. Distributor, který požádal o dodání léčivých přípravků a zároveň učinil vůči držiteli rozhodnutí o registraci písemné prohlášení dle § 33 odst. 3 písm. g) bodu 4, je povinen dodávat takto získané léčivé přípravky pouze provozovatelům oprávněným vydávat léčivé přípravky, a to do 2 pracovních dnů od obdržení požadavku na dodání léčivých přípravků. Distributor nesmí léčivé přípravky získané dle § 33 odst. 3 písm. g) bodu 4 distribuovat do zahraničí. V případě, že provozovatel lékárny má vůči distributorovi alespoň jeden peněžitý dluh po dobu delší než 30 dnů po lhůtě splatnosti, je podmínkou dodání, že cena léčivého přípravku bude zaplacena nejpozději v okamžiku převzetí provozovatelem lékárny. Distributor nemá povinnost dle tohoto odstavce, pokud je přerušeno či ukončeno uvádění daného léčiva na trh v České republice, »	**Act on Medicinal Products and on Amendments to Certain Related Acts (Act on Medicinal Products) Act No. 378/2007 Coll. (31.12.2007), Article 77:** "§ 77 Distributor rights and obligations (1) The distributor is obliged […] h) to ensure the supply of medicinal products for human use to operators authorized to dispense medicinal products in quantities and time intervals corresponding to the needs of patients in the Czech Republic. A distributor who has requested the supply of medicinal products and at the same time has made a written declaration against the marketing authorization holder pursuant to Section 33 para. g) point 4, is obliged to deliver the medicinal products thus obtained only to operators authorized to dispense medicinal products, within 2 working days of receiving the request for the supply of medicinal products. The distributor may not obtain medicinal products obtained in accordance with § 33 par. g) point 4 to be distributed abroad. In the event that the pharmacy operator has at least one monetary debt to the distributor for a period longer than 30 days after the due date, the condition of delivery, that the price of the medicinal product will be paid at the latest at the time of taking over by the pharmacy operator. The Distributor is not obliged under this paragraph if the marketing of the given medicinal product in the Czech Republic is interrupted or terminated"

Right to be supplied	**Zákon o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech) Zákon č. 378/2007 Sb. (31.12.2007), §33** : « § 33 Práva a povinnosti držitele rozhodnutí o registraci […] (3) Držitel rozhodnutí o registraci je dále povinen […] 3. zajistit po uvedení léčivého přípravku do oběhu léčivý přípravek pro potřeby pacientů v České republice jeho dodávkami v odpovídajícím množství a časových intervalech; prováděcí právní předpis stanoví způsob zajištění potřeb pacientů ve vztahu k množství a časovým intervalům dodávek léčivých přípravků, 4. zásobit každého distributora, který vůči držiteli rozhodnutí o registraci učiní písemné prohlášení, že léčivé přípravky požaduje pro péči o pacienty v České republice dle § 77 odst. 1 písm. h), léčivými přípravky v množství a časových intervalech tak, aby tento distributor disponoval léčivými přípravky v množství odpovídajícímu alespoň průměrné poptávce provozovatelů oprávněných k výdeji léčivých přípravků u tohoto distributora po dobu 2 týdnů. Držitel rozhodnutí o registraci nemá povinnost stanovenou v tomto bodě, pokud : a) distributor má vůči držiteli rozhodnutí o registraci alespoň jeden peněžitý dluh po dobu delší než 30 dnů po lhůtě splatnosti, b) distributorovi byla v posledních 2 letech před podáním objednávky udělena Státním ústavem pro kontrolu léčiv pokuta za dodání hrazeného léčivého přípravku do jiného členského státu nebo třetí země v rozporu s § 77 odst. 1 písm. h), která již nabyla právní moci, c) je přerušeno či ukončeno uvádění daného léčiva na trh v České republice. »	**Act on Medicinal Products and on Amendments to Certain Related Acts (Act on Medicinal Products) Act No. 378/2007 Coll. (31.12.2007), Article 33**: "§ 33 Rights and obligations of the marketing authorization holder […] (3) The holder of the registration decision is further obliged : […] 3. to provide the medicinal product for the needs of patients in the Czech Republic after its introduction into circulation by its deliveries in appropriate quantities and time intervals; the implementing legislation shall stipulate the method of ensuring the needs of patients in relation to the quantity and time intervals of the supply of medicinal products, 4. to supply any distributor who makes a written declaration to the marketing authorization holder that he requires medicinal products for the care of patients in the Czech Republic pursuant to § 77 para. h), medicinal products in quantities and time intervals so that this distributor has at his disposal medicinal products in quantities corresponding to at least the average demand of the operators authorized to dispense medicinal products at this distributor for a period of 2 weeks. The marketing authorization holder shall not have the obligation set out in this point if : a) the distributor has at least one monetary debt to the marketing authorization holder for a period longer than 30 days after the due date, b) in the last 2 years before placing the order, the distributor was fined by the State Institute for Drug Control for delivery of the reimbursed medicinal product to another Member State or a third country in violation of § 77 para. h) which has already entered into force,

		c) the marketing of the given medicinal product in the Czech Republic is interrupted or terminated.”
Separate licensing system for full-line wholesalers	*None*	*None*

Denmark (DK)

	Original version	EN translation
PSO	**Bekendtgørelse af lov om lægemidler, LBK nr 99 af 16/01/2018, Kap 9** « § 75. Den, der bringer et lægemiddel til mennesker på markedet, og engrosforhandlere af et sådant lægemiddel, skal efter regler fastsat af Sundhedsstyrelsen sikre passende og fortsat levering af det pågældende lægemiddel, såfremt der er tale om: 1) Et lægemiddel, der er omfattet af apoteksforbehold, jf. § 60, stk. 1. 2) Et serum, en vaccine, et immunologisk testpræparat eller et lægemiddel fremstillet af plasma. 3) Et radioaktivt lægemiddel. 4) Et lægemiddel, herunder bestemte pakningsstørrelser, lægemiddelformer og styrker af lægemidlet, som efter Sundhedsstyrelsens nærmere bestemmelse kan forhandles til brugerne uden for apotekerne, jf. § 60, stk. 2. »	**Ordinance of the Law on Medicinal Products, LBK nr 99 af 16/01/2018, Chapter 9** " § 75. Any person who places a medicinal product for human use on the market and wholesale distributors of such a medicinal product shall, in accordance with rules laid down by the National Board of Health, ensure the adequate and continuous supply of the medicinal product in question, if any: 1) A medicinal product subject to pharmacy reservation, cf. section 60(1). 2) A serum, a vaccine, an immunological test preparation or a medicinal product derived from plasma. 3) A radioactive medicinal product. (4) A medicinal product, including certain pack sizes, pharmaceutical forms and strengths of the medicinal product, which may be sold to users outside pharmacies, as determined by the National Board of Health, pursuant to section 60(2)."
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Estonia (EE)

	Original version	EN translation
PSO	**Ravimiseadus1, Vastu võetud 16.12.2004 RT I 2005, 2, 4** « § 44. Ravimite tootmise ja ravimite hulgimüügi tegevusloa omaja kohustused (1) Ravimite tootmise ja ravimite hulgimüügi tegevusloa omaja on kohustatud: 5) tagama püsiva ja piisava ravimite valiku ning kiire kohaletoimetamise Eesti piires; »	**Medicines Act1, Adopted 16.12.2004, RT I 2005, 2, 4** "§ 44. Obligations of the holder of a manufacturing and wholesale distribution authorisation for medicinal products (1) The holder of a licence for the manufacture of medicinal products and the wholesale distribution of medicinal products shall: 5) ensure a stable and sufficient selection of medicinal products and prompt delivery within Estonia;"
Right to be supplied	**Ravimiseadus1, Vastu võetud 16.12.2004 RT I 2005, 2, 4** « § 64. Müügiloa hoidja (3) Ravimi turustamine peab vastama ravivajadusele. Müügiloa hoidja teatab Ravimiametile kirjalikult müügiloaga ravimi tegeliku turustamise algusest Eestis ning vähemalt kaks kuud varem, välja arvatud erandlike asjaolude esinemisel, ravimi Eestis turustamise katkestamisest või lõpetamisest ja selle põhjusest. Eelkõige teavitab müügiloa hoidja Ravimiametit käesoleva seaduse § 76 lõike 6 punktides 1 ja 3 nimetatud asjaolude esinemisest. »	**Medicines Act1, Adopted 16.12.2004, RT I 2005, 2, 4** "§ 64. Marketing authorisation holder (3) The distribution of a medicinal product must correspond to the need for treatment. A marketing authorisation holder must give written notice to the State Agency of Medicines of the commencement of the actual distribution of an authorised medicinal product in Estonia and, at least two months in advance, unless there are exceptional circumstances, give notice of interrupting or terminating the distribution of the medicinal product in Estonia and the reasons thereof. Above all, the marketing authorisation holder must inform the State Agency of Medicines about the existence of the circumstances specified in clauses 1 and 3 of subsection 6 of § 76 of this Act."
Separate licensing system for full-line wholesalers	*None*	*None*

France (FR)

	Original version	EN translation
PSO	**Code de la santé publique, Article L5124-17-2 (28.01.2016) (Modifié par LOI n°2016-41 du 26 janvier 2016 - art. 151)** « Les grossistes-répartiteurs sont tenus de respecter sur leur territoire de répartition les obligations de service public déterminées par décret en Conseil d'Etat. Ils assurent l'approvisionnement continu du marché national de manière à couvrir les besoins des patients sur leur territoire de répartition. Ils participent à la prévention et à la gestion des ruptures de médicaments, au titre des obligations de service public mentionnées au premier alinéa. » **Code de la santé publique, Article R5124-59 (28.09.2012) (Modifié par Décret n°2012-1096 du 28 septembre 2012 - art. 5)** « L'entreprise exerçant l'activité de grossiste-répartiteur déclare au directeur général de l'Agence nationale de sécurité du médicament et des produits de santé le territoire sur lequel chacun de ses établissements exerce son activité de répartition. La déclaration du territoire de répartition envisagée est jointe au dossier accompagnant la demande d'autorisation d'ouverture mentionnée à l'article L. 5124-3. Le territoire déclaré est compatible avec les obligations prévues aux 1° et 2° ci-dessous. La demande de modification mentionnée au 9° de l'article R. 5124-10 du territoire de répartition déclaré est accompagnée de tout élément d'information justifiant du respect des obligations prévues aux 1° et 2° ci-dessous pour l'ensemble du territoire de répartition. Le directeur général de l'agence peut demander tout élément justifiant du respect de ces obligations. Il peut refuser,	**Public Health Code, Article L5124-17-2 (28.01.2016) (Amended by LOI n°2016-41 of 26 January 2016 - art. 151)** "Wholesaler-distributors are required to comply with the public service obligations determined by decree in the Council of State in their distribution territory. They shall ensure the continuous supply of the national market in order to cover the needs of patients in their distribution territory. They participate in the prevention and management of drug shortages, as part of the public service obligations mentioned in the first paragraph." **Public Health Code, Article R5124-59 (28.09.2012) (Amended by Decree n°2012-1096 of 28 September 2012 - art. 5)** "The company carrying out the activity of wholesaler-distributor declares to the Director General of the National Agency for the Safety of Medicines and Health Products the territory in which each of its establishments carries out its distribution activity. The declaration of the planned distribution territory shall be attached to the file accompanying the application for authorisation to open a business as referred to in Article L. 5124-3. The declared territory is compatible with the obligations set out in 1° and 2° below. The request for modification of the declared distribution territory mentioned in 9° of Article R. 5124-10 shall be accompanied by any information justifying compliance with the

	par décision motivée et dans le délai prévu à l'article R. 5124-10, tout ou partie de la modification demandée du territoire de répartition déclaré. Une commune dans laquelle l'établissement dessert habituellement au moins une officine de pharmacie ou une pharmacie à usage intérieur fait partie de ce territoire. L'entreprise dispose, en vue de sa distribution, d'une manière effective et suffisante pour couvrir les besoins du territoire de répartition déclaré, d'un assortiment de médicaments comportant au moins les neuf dixièmes des présentations de spécialités pharmaceutiques effectivement commercialisées en France telles que définies au 1° ci-dessous. Les médicaments achetés par le grossiste-répartiteur ou cédés au grossiste-répartiteur sont distribués de manière à couvrir les besoins des patients en France, sur le territoire de répartition déclaré. Sur son territoire de répartition, l'établissement est tenu aux obligations de service public suivantes : 1° Il est en mesure, en dehors du samedi après 14 heures, du dimanche et des jours fériés : a) De satisfaire à tout moment la consommation de sa clientèle habituelle durant au moins deux semaines ; b) De livrer dans les vingt-quatre heures toute commande passée avant le samedi 14 heures, de toute présentation des spécialités effectivement commercialisées, à l'exception des médicaments réservés à l'usage hospitalier, des plantes médicinales et des médicaments homéopathiques ; néanmoins, pour les spécialités pharmaceutiques appartenant à des groupes génériques, il doit être en mesure de livrer la spécialité de référence et au moins une spécialité générique et, dans le cas d'un groupe générique sans spécialité de référence, au moins deux spécialités ; c) De livrer tout médicament et, lorsqu'il en assure la distribution dans les conditions prévues à l'article R. 5124-8, tout autre produit, objet ou article mentionné à l'article L. 4211-1 et tout produit officinal divisé	obligations set out in 1° and 2° below for the entire distribution territory. The Director General of the Agency may request any evidence of compliance with these obligations. He may refuse, by reasoned decision and within the time limit laid down in Article R. 5124-10, all or part of the requested change to the declared distribution territory. A municipality in which the establishment usually serves at least one pharmacy or a pharmacy for internal use is part of this territory. The undertaking shall have available for distribution, in an effective and sufficient manner to cover the needs of the declared distribution territory, an assortment of medicinal products comprising at least nine tenths of the presentations of proprietary medicinal products actually marketed in France as defined in 1° below. The medicinal products purchased by the wholesaler-distributor or transferred to the wholesaler-distributor are distributed in such a way as to cover the needs of patients in France, in the declared distribution territory. In its distribution territory, the establishment is bound by the following public service obligations: 1° It shall be able, outside Saturdays after 2 p.m., Sundays and public holidays : a) To satisfy at all times the consumption of its regular customers for at least two weeks; b) To deliver within twenty-four hours any order placed before Saturday 2 p.m., of any presentation of the specialities actually marketed, with the exception of medicines reserved for hospital use, medicinal plants and homeopathic medicines;

	mentionné au 4° de l'article L. 5121-1 exploité en France à toute officine qui le lui demande ; 2° Le samedi, à partir de 14 heures, ainsi que le dimanche et les jours fériés, il est tenu de participer à un système d'astreinte inter-entreprises, permettant la livraison de médicaments dans les délais et au maximum dans les huit heures, afin de répondre : a) A la demande du préfet après avis du directeur général de l'agence régionale de santé, aux situations présentant un caractère d'urgence sanitaire, notamment dans le cadre de l'application de l'article L. 3131-1 ; b) A la demande du pharmacien d'officine assurant le service de garde prévu à l'article L. 5125-22, pour répondre aux besoins urgents en médicaments soumis à prescription au titre d'une des catégories prévues à l'article R. 5121-36 et en vaccins, dans les conditions définies par une charte conclue entre les organisations représentatives des grossistes-répartiteurs et des pharmaciens d'officine ; à défaut d'accord entre elles ou si l'organisation retenue ne permet pas de satisfaire les besoins urgents en médicaments, un arrêté du ministre de la santé définit ces conditions. Le tableau des astreintes est transmis semestriellement pour le semestre suivant par les organisations représentatives à l'agence régionale de santé territorialement compétente et à l'Agence nationale de sécurité du médicament et des produits de santé. Ces dispositions ne font pas obstacle à ce qu'un établissement livre exceptionnellement en cas d'urgence une officine de pharmacie ou une pharmacie à usage intérieur d'un établissement de santé située hors de son territoire de répartition. A titre exceptionnel et en l'absence d'autre source d'approvisionnement, le directeur général de l'Agence nationale de sécurité du médicament et des produits de santé peut, de sa propre initiative, ou à la demande du préfet après avis du directeur général de l'agence régionale de santé, imposer à un établissement de livrer une officine de pharmacie ou une pharmacie à usage	nevertheless, for pharmaceutical specialities belonging to generic groups, he must be able to deliver the reference speciality and at least one generic speciality and, in the case of a generic group without a reference speciality, at least two specialities; c) To deliver any medicinal product and, when it ensures the distribution thereof under the conditions provided for in Article R. 5124-8, any other product, object or article mentioned in Article L. 4211-1 and any divided officinal product mentioned in 4° of Article L. 5121-1 operated in France to any pharmacy that requests it; 2° On Saturdays, from 2 p.m. onwards, as well as on Sundays and public holidays, it is obliged to participate in an inter-company standby system, allowing the delivery of medicines within the time limit and at most within eight hours, in order to respond : a) At the request of the prefect, after consultation with the director general of the regional health agency, to situations of a health emergency nature, in particular within the framework of the application of article L. 3131-1 ; b) At the request of the dispensing pharmacist providing the on-call service provided for in Article L. 5125-22, to meet urgent needs for medicinal products subject to prescription in one of the categories provided for in Article R. 5121-36 and for vaccines, under the conditions defined by a charter concluded between the organisations representing wholesaler-distributors and dispensing pharmacists; in the absence of an agreement between them or if the organisation chosen does not make it possible to meet urgent needs for medicinal products, an order by the Minister for Health defines these conditions.

	intérieur d'un établissement de santé située hors de son territoire de répartition. »	The on-call schedule is sent every six months for the following six months by the representative organisations to the regional health agency with territorial jurisdiction and to the Agence nationale de sécurité du médicament et des produits de santé. These provisions do not prevent an establishment from exceptionally supplying, in an emergency, a pharmacy or a pharmacy for internal use in a health care establishment located outside its distribution territory. Exceptionally and in the absence of any other source of supply, the Director General of the National Agency for the Safety of Medicines and Health Products may, on his own initiative, or at the request of the prefect after obtaining the opinion of the Director General of the regional health agency, require an establishment to deliver a pharmacy or an in-house pharmacy of a health care establishment located outside its allocation territory."
Right to be supplied	**Code de la santé publique Article R5124-48-1 (01.09.2021) (Modifié par Décret n°2021-349 du 30 mars 2021 - art. 1)** « Les titulaires d'autorisation de mise sur le marché et les entreprises pharmaceutiques et organismes exploitant ou distribuant en France un médicament assurent, dans la limite de leur responsabilité respective, un approvisionnement approprié et continu des pharmacies et des personnes autorisées à délivrer des médicaments, de manière à couvrir les besoins des patients en France. Les titulaires d'autorisation de mise sur le marché et les entreprises pharmaceutiques exploitant des médicaments assurent un approvisionnement approprié et continu de tous les établissements autorisés au titre d'une activité de grossiste-répartiteur mentionnée au 5° de l'article R. 5124-2 afin de permettre à ces derniers de remplir les	**Public Health Code Article R5124-48-1 (01.09.2021) (Amended by Decree n°2021-349 of 30 March 2021 - art. 1)** " Marketing authorisation holders and pharmaceutical companies and organisations exploiting or distributing a medicinal product in France shall ensure, within the limits of their respective responsibilities, an appropriate and continuous supply to pharmacies and persons authorised to supply medicinal products, in order to cover the needs of patients in France. Marketing authorisation holders and pharmaceutical companies exploiting medicinal products shall ensure an appropriate and

	obligations prévues à l'article R. 5124-59 et de manière à couvrir les besoins des patients en France. En outre, les titulaires d'autorisation de mise sur le marché et les entreprises pharmaceutiques exploitant des médicaments peuvent faire appel aux entreprises se livrant à l'activité de dépositaire mentionnées au 4° de l'article R. 5124-2 pour prévenir et gérer toute situation de rupture. »	continuous supply to all establishments authorised to carry out the activity of wholesaler-distributor referred to in 5° of Article R. 5124-2 in order to enable the latter to fulfil the obligations set out in Article R. 5124-59 and to cover the needs of patients in France. In addition, marketing authorisation holders and pharmaceutical companies exploiting medicinal products may call upon the companies engaged in the activity of pre-wholesalers mentioned in 4° of Article R. 5124-2 to prevent and manage any situation of disruption."
Separate licensing system for full-line wholesalers	*None*	*None*

Finland (FI)

	Original version	EN translation
PSO	**Lääkelaki 395/1987, (4.11.2005/853) 37§** « 37 § Lääketukkukaupan on pyrittävä varmistumaan siitä, että sillä on tarvetta vastaava määrä lääkkeitä myytävänä. Lääketukkukaupan tulee viipymättä ilmoittaa lääkkeitä tilanneelle apteekille, sairaala-apteekille, lääkekeskukselle tai eläinlääkärille tilatun lääkkeen jakelukatkoksesta. Lääketukkukaupan tulee sisällyttää ilmoitukseen tiedot lääkkeen saatavuushäiriöstä sekä arvio toimituskatkoksen kestosta. »	**Medicines Act 395/1987, consolidated version of 2005 Section 37** "Section 37 Pharmaceutical wholesalers must endeavour to ensure that they have the right amount of medicines to sell to meet demand. The wholesaler must immediately inform the pharmacy, hospital pharmacy, pharmaceutical centre or veterinary surgeon ordering the medicines of any interruption in the supply of the medicine ordered."
Right to be supplied	**Lääkelaki 395/1987, (4.11.2005/853) 26§** « 26 § (4.11.2005/853) Myyntiluvan haltijan ja 22 §:ssä tarkoitetun rekisteröinnin haltijan on huolehdittava siitä, että myyntiluvan saanutta lääkevalmistetta sekä rekisteröityä perinteistä kasvirohdosvalmistetta on jatkuvasti lääkkeiden tukkukauppojen ja apteekkien saatavissa potilaiden ja muiden käyttäjien tarvetta vastaavasti. »	**Medicines Act 395/1987, consolidated version of 2005 Section 26** "Section 26 (853/2005) Holders of marketing authorisations and holders of registrations referred to in section 22 must ensure that medicinal products that have been granted a marketing authorisation and registered traditional herbal medicinal products are constantly available to medicinal product wholesalers and pharmacies to meet the needs of patients and other users."
Separate licensing system for full-line wholesalers	*None*	*None*

Germany (DE)

	Original version	EN translation
PSO	**Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 §52b** "(1) Pharmazeutische Unternehmer und Betreiber von Arzneimittelgroßhandlungen, die im Geltungsbereich dieses Gesetzes ein tatsächlich in Verkehr gebrachtes Arzneimittel vertreiben, das durch die zuständige Bundesoberbehörde zugelassen worden ist oder für das durch die Europäische Gemeinschaft oder durch die Europäische Union eine Genehmigung für das Inverkehrbringen gemäß Artikel 3 Absatz 1 oder 2 der Verordnung (EG) Nr. 726/2004 erteilt worden ist, stellen eine angemessene und kontinuierliche Bereitstellung des Arzneimittels sicher, damit der Bedarf von Patienten im Geltungsbereich dieses Gesetzes gedeckt ist. […] (3) Vollversorgende Arzneimittelgroßhandlungen müssen im Rahmen ihrer Verantwortlichkeit eine bedarfsgerechte und kontinuierliche Belieferung der mit ihnen in Geschäftsbeziehung stehenden Apotheken gewährleisten. Satz 1 gilt entsprechend für andere Arzneimittelgroßhandlungen im Umfang der von ihnen jeweils vorgehaltenen Arzneimittel."	**Medicinal Products Act in the version published on 12 December 2005, last amended on 27 September 2021, Article 52b:** "(1) Pharmaceutical entrepreneurs and operators of wholesale businesses for medicinal products who, within the purview of this Act, distribute a medicinal product that has actually been placed on the market, which has been authorised for marketing by the competent higher federal authority or for which a marketing authorisation pursuant to Article 3 (1) or (2) of Regulation (EC) No. 726/2004 has been granted by the European Community or the European Union, ensure an adequate and continuous supply of the medicinal product so that the demand from patients within the purview of this Act is met. […] '(3) Full-range wholesalers of medicinal products must, within the framework of their responsibility, guarantee a demand-oriented and continuous supply to the pharmacies with which they do business. Sentence 1 applies accordingly to other medicinal product wholesale businesses for the totality of the medicinal products they hold in stock in each case."
	Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 §52b "(2) […] "Vollversorgende Arzneimittelgroßhandlungen sind Großhandlungen, die ein vollständiges, herstellerneutral gestaltetes Sortiment an apothekenpflichtigen Arzneimitteln unterhalten, das nach Breite und Tiefe so beschaffen ist, dass damit der Bedarf von Patienten von den mit der Großhandlung in	**Medicinal Products Act in the version published on 12 December 2005, last amended on 27 September 2021, Article 52b:** "(2) '[…] Full-range wholesalers of medicinal products are wholesale businesses that maintain a complete, manufacturer-independent assortment of pharmacy-only medicinal products which, in terms of depth and scope, is constituted in such a way that the demand from

	Geschäftsbeziehung stehenden Apotheken werktäglich innerhalb angemessener Zeit gedeckt werden kann; die vorzuhaltenden Arzneimittel müssen dabei mindestens dem durchschnittlichen Bedarf für zwei Wochen entsprechen. Satz 1 gilt nicht für Arzneimittel, die dem Vertriebsweg des § 47 Absatz 1 Nummer 2 bis 10 oder des § 47a oder des § 47b unterliegen oder die aus anderen rechtlichen oder tatsächlichen Gründen nicht über den Großhandel ausgeliefert werden können."	patients from the pharmacies with which the wholesaler does business can be met within an appropriate space of time on weekdays; the medicinal products to be kept in stock must correspond, in such a case, to at least the average demand for a period of two weeks. Sentence 1 does not apply to medicinal products that are subject to the distribution channels specified in section 47 (1) sentence 1 nos. 2 to 10 or section 47a or section 47b or which, for other legal or practical reasons, cannot be supplied through the wholesale business."
Right to be supplied	**Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 §52b** "(2) Pharmazeutische Unternehmer müssen im Rahmen ihrer Verantwortlichkeit eine bedarfsgerechte und kontinuierliche Belieferung vollversorgender Arzneimittelgroßhandlungen gewährleisten.[…]"	**Medicinal Products Act in the version published on 12 December 2005, Article 52b:** "(2) Pharmaceutical entrepreneurs must guarantee, within the framework of their responsibility, a demand-oriented and continuous supply to the full-range wholesalers of medicinal products.[…]"
Different licensing system	**Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 §52b** "(2) […] "Vollversorgende Arzneimittelgroßhandlungen sind Großhandlungen, die ein vollständiges, herstellerneutral gestaltetes Sortiment an apothekenpflichtigen Arzneimitteln unterhalten, das nach Breite und Tiefe so beschaffen ist, dass damit der Bedarf von Patienten von den mit der Großhandlung in Geschäftsbeziehung stehenden Apotheken werktäglich innerhalb angemessener Zeit gedeckt werden kann; die vorzuhaltenden Arzneimittel müssen dabei mindestens dem durchschnittlichen Bedarf für zwei Wochen entsprechen. Satz 1 gilt nicht für Arzneimittel, die dem Vertriebsweg des § 47 Absatz 1 Nummer 2 bis 10 oder des § 47a oder des § 47b unterliegen oder die aus anderen rechtlichen oder tatsächlichen Gründen nicht über den Großhandel ausgeliefert werden können."	**Medicinal Products Act in the version published on 12 December 2005, Article 52b:** "(2) '[…] Full-range wholesalers of medicinal products are wholesale businesses that maintain a complete, manufacturer-independent assortment of pharmacy-only medicinal products which, in terms of depth and scope, is constituted in such a way that the demand from patients from the pharmacies with which the wholesaler does business can be met within an appropriate space of time on weekdays; the medicinal products to be kept in stock must correspond, in such a case, to at least the average demand for a period of two weeks. Sentence 1 does not apply to medicinal products that are subject to the distribution channels specified in section 47 (1) sentence 1 nos. 2 to 10 or section 47a or section 47b or which, for other legal or practical reasons, cannot be supplied through the wholesale business."

Greece (EL)

	Original version	EN translation
PSO	**Εναρμόνιση της ελληνικής νομοθεσίας προς την αντί– στοιχη νομοθεσία της Ε.Ε. στον τομέα της παραγω– γής και της κυκλοφορίας φαρμάκων που προορίζο– νται για ανθρώπινη χρήση, σε συμμόρφωση με την υπ' αριθμ. 2001/83/ΕΚ Οδηγία «περί κοινοτικού κώδι– κα για τα φάρμακα που προορίζονται για ανθρώπινη χρήση» (L 311/28.11.2001), όπως ισχύει και όπως τρο– ποποιήθηκε με την Οδηγία 2011/62/ΕΕ, όσον αφορά την πρόληψη της εισόδου ψευδεπίγραφων φαρμά– κων στη νόμιμη αλυσίδα εφοδιασμού (L 174/1.7.2011)** « Άρθρο 107 Όσον αφορά την προμήθεια φαρμάκων σε φαρμακεία και πρόσωπα που έχουν άδεια ή είναι εξουσιοδοτημένα να διαθέτουν φάρμακα στο κοινό, επιβάλλονται στον κάτοχο της άδειας χονδρικής πώλησης η οποία έχει χο– ρηγηθεί από άλλο κράτος μέλος, οι ίδιες υποχρεώσεις και δη οι υποχρεώσεις δημόσιας υπηρεσίας που επι– βάλλονται και στα πρόσωπα στα οποία έχει χορηγηθεί στην Ελλάδα η άδεια χονδρικής πώλησης φαρμάκων. Ο κάτοχος της άδειας κυκλοφορίας φαρμάκου, καθώς και οι κάτοχοι άδειας χονδρικής πώλησης, εξασφαλίζουν και των προσώπων που έχουν άδεια να διαθέτουν φάρ– μακα, ώστε να καλύπτονται οι ανάγκες των ασθενών που βρίσκονται στην Ελλάδα. »	**Harmonisation of Greek legislation with the counterpart legislation of the EU in the field of the production and marketing of medicinal products for human use, in compliance with Directive No. Directive 2001/83/EC on the Community code relating to medicinal products for human use (L 311/28.11.2001), as in force and as amended by Directive 2011/62/EU, as regards the prevention of the entry of falsified medicinal products into the legal supply chain (L 174/1.7.2011), Article 107** "Article 107. With regard to the supply of medicinal products to pharmacies and persons authorised or authorised to supply medicinal products to the public, the holder of a wholesale distribution authorisation granted by another Member State shall be subject to the same obligations, namely public service obligations, as those imposed on persons who have been granted a wholesale distribution authorisation in Greece. The holder of the marketing authorisation for a medicinal product and the holders of a wholesale marketing authorisation shall ensure that the persons authorised are also able to make medicinal products available in order to meet the needs of patients in Greece."
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Hungary (HU)

	Original version	EN translation
PSO	**2005. évi XCV. Törvény az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról, §16** « 3) A gyógyszer-nagykereskedelmi engedély jogosultja köteles azon gyógyszereket beszerezni és forgalmazni, amelyek forgalmazására nagykereskedelmi tevékenységi engedélyt kapott. (3a) A gyógyszer-nagykereskedelmi engedély jogosultja a (3) bekezdés szerinti forgalmazási tevékenysége körében köteles a megrendelések szokásos üzletmenet szerinti arányos kielégítése mellett a betegellátási szükségletet is figyelembe venni. »	**Act XCV of 2005.** **on medicinal products for human use and amending other acts regulating the pharmaceutical market, §16** "(3) The holder of a wholesale pharmaceutical licence shall be obliged to procure and distribute the medicinal products for which it has been granted a wholesale activity licence. (3a) A holder of a wholesale distribution licence shall, in its distribution activities under paragraph (3), take into account patient care needs in addition to the proportionate fulfilment of orders in the ordinary course of business."
Right to be supplied	**2005. évi XCV. Törvény az emberi alkalmazásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról, §16** « 16. § […] (2a) A közfinanszírozásban részesülő gyógyszerrel való folyamatos ellátásról a forgalomba hozatali engedély jogosultja - amennyiben a forgalomba hozatali engedély jogosult belföldön forgalmazási tevékenységet nem végez - a forgalmazó (a továbbiakban: szerződött forgalmazó) köteles gondoskodni. […] (5) A forgalomba hozatali engedély jogosultja az általa forgalmazott gyógyszerek nagykereskedelmi forgalmazási lehetőségét a Magyarországon gyógyszer-nagykereskedelmi tevékenységi engedéllyel rendelkező gyógyszer-nagykereskedőnek biztosítja,	**Act XCV of 2005.** **on medicinal products for human use and amending other acts regulating the pharmaceutical market, §16** "16. § […] (2a) The marketing authorisation holder shall ensure the continued supply of publicly funded medicinal products by the distributor (hereinafter referred to as "the authorised distributor"), where the marketing authorisation holder does not carry out distribution activities in the country. […] (5) The marketing authorisation holder shall provide the wholesale distribution facility for the medicinal products it markets to a wholesale distributor of medicinal products holding a wholesale

	amennyiben a nagykereskedő olyan nyilatkozat tesz, hogy a beszerezni kívánt gyógyszer magyarországi betegellátási szükséglet kielégítéséhez kell. Az e bekezdés alapján beszerzett gyógyszer kizárólag magyarországi egészségügyi szolgáltatónak adható tovább és nagykereskedelmi tevékenység keretében az országból nem vihető ki. »	distribution authorisation in Hungary, provided that the wholesale distributor makes a declaration that the medicinal product to be supplied is necessary to meet the patient care needs of Hungary. Medicinal products procured under this paragraph may be supplied only to a health care provider in Hungary and may not be exported from Hungary in the course of wholesale activities"
Separate licensing system for full-line wholesalers	*None*	*None*

Italy (IT)

	Original version	EN translation
PSO	**Decreto legislativo 24 aprile 2006, n. 219, Art. 105** « Article 105 Dotazioni minime e fornitura dei medicinali 1. Fatta eccezione per chi importa medicinali e per chi distribuisce esclusivamente materie prime farmacologicamente attive o gas medicinali o medicinali disciplinati dagli articoli 92 e 94 ((ovvero dall'articolo 96)) , o medicinali di cui detiene l'AIC o la concessione di vendita, il titolare dell'autorizzazione alla distribuzione all'ingrosso e' tenuto a detenere almeno: a) i medicinali di cui alla tabella 2 allegata alla farmacopea ufficiale della Repubblica italiana; b) il novanta per cento dei medicinali in possesso di un'AIC, inclusi i medicinali omeopatici autorizzati ai sensi dell'articolo 18; tale percentuale deve essere rispettata anche nell'ambito dei soli medicinali generici. L'obbligo di chi commercia all'ingrosso farmaci di detenere almeno il 90 per cento delle specialita' in commercio non si applica ai medicinali non ammessi a rimborso da parte del servizio sanitario nazionale, fatta salva la possibilita' del rivenditore al dettaglio di rifornirsi presso altro grossista. 2. Il titolare di un'AIC di un medicinale e i distributori di tale medicinale immesso effettivamente sul mercato assicurano, nei limiti delle loro responsabilita', forniture appropriate e continue di tale medicinale alle farmacie e alle persone autorizzate a consegnare medicinali in modo da soddisfare le esigenze dei pazienti.	**Legislative Decree No 219 of 24 April 2006, Art. 105** "Article 105 Minimum stocks and supply of medicinal products 1. With the exception of persons importing medicinal products and persons dispensing exclusively pharmacologically active starting materials or medicinal gases or medicinal products covered by Articles 92 and 94 ((or Article 96)) or medicinal products for which he holds a marketing authorisation or a licence, the holder of the wholesale distribution authorisation shall be required to hold at least: (a) the medicinal products referred to in Table 2 annexed to the Official Pharmacopoeia of the Italian Republic; (b) 90 % of the medicinal products with a marketing authorisation, including homeopathic medicinal products authorised under Article 18; this percentage must also be complied with in the case of generic medicinal products only. The obligation of the wholesaler to hold at least 90% of the specialities on the market does not apply to medicinal products that are not eligible for reimbursement by the national health service, without prejudice to the possibility for the retailer to obtain supplies from another wholesaler. 2. The holder of a marketing authorisation for a medicinal product and the distributors of that medicinal product actually placed on the market shall, within the limits of their responsibilities, ensure appropriate and continuous supplies of that medicinal product to pharmacies and persons authorised to supply medicinal

	3. La fornitura alle farmacie, anche o pedaliere, o agli altri soggetti autorizzati a fornire medicinali al pubblico ((, ivi compresi i punti vendita di medicinali previsti dall'articolo 5 del decretolegge 4 luglio 2006, n. 223, convertito, con modificazioni, dalla legge 4 agosto 2006, n. 248,)) dei medicinali di cui il distributore e' provvisto deve avvenire con la massima sollecitudine e, comunque, entro le dodici ore lavorative successive alla richiesta, nell'ambito territoriale indicato nella dichiarazione di cui all'articolo 103, comma 2, lettera d). 4. Il titolare dell'AIC e' obbligato a fornire entro le quarantotto ore, su richiesta delle farmacie, anche ospedaliere, ((o dei punti vendita di medicinali previsti dall'articolo 5 del decretolegge 4 luglio 2006, n. 223, convertito, con modificazioni, dalla legge 4 agosto 2006, n. 248,)) un medicinale che non e' reperibile nella rete di distribuzione regionale. »	products in order to meet the needs of patients. 3. The supply to pharmacies, including hospital pharmacies, or to other persons authorised to supply medicinal products to the public ((, including the points of sale of medicinal products provided for in Article 5 of Decree-Law No 223 of 4 July 2006, converted, with amendments, by Law No 248 of 4 August 2006,)) of the medicinal products supplied by the distributor shall take place as soon as possible and, in any event, within twelve working hours following the request, within the territorial area indicated in the declaration referred to in Article 103(2)(d). 4. The holder of the marketing authorisation is obliged to supply within 48 hours, at the request of pharmacies, including hospital pharmacies, ((or of the points of sale of medicinal products envisaged by article 5 of decree-law no. 223 of 4 July 2006, converted, with amendments, by law no. 248 of 4 August 2006)), a medicinal product which is not available in the regional distribution network.”
Right to be supplied	**Decreto legislativo 24 aprile 2006, n. 219, Art. 105** « […] 2. Il titolare di un'AIC di un medicinale e i distributori di tale medicinale immesso effettivamente sul mercato assicurano, nei limiti delle loro responsabilita', forniture appropriate e continue di tale medicinale alle farmacie e alle persone autorizzate a consegnare medicinali in modo da soddisfare le esigenze dei pazienti. […] 4. Il titolare dell'AIC e' obbligato a fornire entro le quarantotto ore, su richiesta delle farmacie, anche ospedaliere, ((o dei punti vendita di medicinali previsti dall'articolo 5 del decretolegge 4 luglio 2006, n. 223, convertito, con modificazioni, dalla legge 4 agosto 2006, n. 248,)) un medicinale che	**Legislative Decree No 219 of 24 April 2006, Art. 105** “[…] 2. The holder of a marketing authorisation for a medicinal product and the distributors of that medicinal product actually placed on the market shall, within the limits of their responsibilities, ensure appropriate and continuous supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products in order to meet the needs of patients. […] 4. The holder of the marketing authorisation is obliged to supply within 48 hours, at the request of pharmacies, including hospital pharmacies, ((or of the points of sale of medicinal products envisaged by article 5 of decree-law no.

	non e' reperibile nella rete di distribuzione regionale. »	223 of 4 July 2006, converted, with amendments, by law no. 248 of 4 August 2006)), a medicinal product which is not available in the regional distribution network."
Separate licensing system for full-line wholesalers	*None*	*None*

Ireland (IE)

	Original version	EN translation
PSO		**S.I. No. 538/2007 - Medicinal Products (Control of Wholesale Distribution) Regulations 2007** "11. The [Distribution] authorisation holder shall, in respect of a medicinal product that has actually been placed on the market in the State and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product to the persons referred to in paragraph 4(d) and (e), so that the needs of patients in the State in respect of such medicinal product are covered."
Right to be supplied		*None*
Separate licensing system for full-line wholesalers		*None*

Latvia (LV)

	Original version	EN translation
PSO	**Farmācijas likums 1997** *None*	**Pharmacy law of 1997, consolidated version** *None*
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Lithuania (LT)

	Original version	EN translation
PSO	**Lietuvos Respublikos farmacijos įstatymas, 2006-06-22, X-709** « 33 straipsnis. Didmeninio platinimo licencijos turėtojo pagrindinės pareigos Didmeninio platinimo licencijos turėtojas privalo: [...] 8) bendradarbiaudamas su vaistinių preparatų rinkodaros teisių turėtojais, užtikrinti tinkamą ir reikiamo dažnumo vaistinių preparatų tiekimą vaistinėms ir asmens sveikatos priežiūros įstaigoms; »	**Law on Pharmacy, 22 June 2006 No. X-709** "Article 33. Main Duties of the Wholesale Distribution License Holder The wholesale distribution license holder must: [...] 8) cooperate with marketing authorization holders to ensure the availability and frequent supply of medicinal products to pharmacies and personal health care establishments;"
Right to be supplied	*See Public Service Obligation*	*See Public Service Obligation*
Separate licensing system for full-line wholesalers	*None*	*None*

Luxembourg (LU)

	Original version	EN translation
PSO	**Loi du 6 janvier 1995 relative à la distribution en gros des médicaments (version consolidée, loi du 21 juillet 2012) Article 5bis** « 1.Le grossiste-répartiteur visé à l'alinéa 3 du paragraphe 1. de l'article 3 est chargé d'une obligation de service public.En vertu de cette obligation il est tenu: 1) de posséder de façon permanente un stock de médicaments lui permettant d'approvisionner journellement les pharmacies du pays. Ce stock doit correspondre, d'une part, aux deux tiers au moins du nombre des médicaments à usage humain bénéficiant d'une autorisation de mise sur le marché au Luxembourg et qui sont effectivement mis sur ce marché et, d'autre part, à la valeur moyenne des chiffres d'affaires mensuels de l'année précédente par médicament. Il doit inclure d'office les médicaments essentiels ou vitaux désignés par le ministre ayant la Santé dans ses attributions; 2) d'assurer à la requête du ministre de la Santé le stockage des médicaments acquis par l'Etat pour répondre à des situations d'exception. Les frais y afférents sont pris en charge par le budget de l'Etat sur base d'une convention à conclure entre le ministre de la Santé et le grossiste-répartiteur; 3) de participer à un tour de garde établi d'un commun accord entre tous les grossistes-répartiteurs, ou établi d'office par le ministre de la Santé, à défaut d'accord, et garantissant un approvisionnement approprié de la population; 4) de prendre toutes les dispositions utiles pour assurer la livraison d'urgence de médicaments dans les meilleurs délais, et dans les vingt-quatre heures de leur commande au plus tard.	**Law of 6 January 1995 on the wholesale distribution of medicinal products (consolidated version, law of 21 July 2012) Article 5bis** "1.The wholesaler-distributor referred to in paragraph 1. of Article 3, subparagraph 3 is entrusted with a public service obligation. By virtue of this obligation he is required: (1) to hold a permanent stock of medicines enabling him to supply the country's pharmacies on a daily basis. This stock must correspond, on the one hand, to at least two thirds of the number of medicinal products for human use which have been granted a marketing authorisation in Luxembourg and which are actually placed on the market and, on the other hand, to the average value of the monthly turnover of the previous year per medicinal product. It must automatically include essential or vital medicinal products designated by the Minister for Health; 2) to ensure, at the request of the Minister of Health, the storage of medicines acquired by the State to respond to exceptional situations. The related costs shall be borne by the State budget on the basis of an agreement to be concluded between the Minister of Health and the wholesaler-distributor; 3) to participate in a duty rota established by mutual agreement between all wholesaler-distributors, or established automatically by the Minister of Health, in the absence of agreement, and guaranteeing an appropriate supply to the population 4) to take all necessary steps to ensure the emergency delivery of medicines as

	2. Les détenteurs d'une autorisation de distribuer en gros délivrée au Luxembourg autres que les grossistes-répartiteurs, ainsi que les personnes pouvant se prévaloir d'une autorisation équivalente délivrée dans un autre Etat membre conformément à l'alinéa 4 du paragraphe 1. de l'article 3, sont tenus d'assurer un approvisionnement continu des médicaments effectivement mis par eux sur le marché au Luxembourg pour les pharmacies du pays, de manière à couvrir les besoins de la population. »	soon as possible, and within twenty-four hours of their order at the latest. 2. Holders of a wholesale distribution authorisation issued in Luxembourg, other than wholesaler-distributors, as well as persons entitled to an equivalent authorisation issued in another Member State in accordance with Article 3(1)(4), shall be obliged to ensure a continuous supply of medicinal products actually placed on the market in Luxembourg by them for the country's pharmacies, so as to cover the needs of the population.”
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Malta (MT)

	Original version	EN translation
PSO		**Subsidiary legislation 458.37, wholesale distribution and brokering of medicinal products and active substances regulations 24th December, 2012, Paragraph 9(3)** "9. (3) Every wholesale dealer shall, within the limits of his responsibilities, ensure that an appropriate and continuous supply of medicinal products is furnished to pharmacies and persons authorized to supply medicinal products in order to satisfy the needs of patients."
Right to be supplied		*None*
Separate licensing system for full-line wholesalers		*None*

Netherlands (NL)

	Original version	EN translation
PSO	**Geneesmiddelenwet, Wet van 8 februari 2007 tot vaststelling van een nieuwe Geneesmiddelenwet, Artikel 36§2:** "De groothandelaar draagt er voorts voor zorg dat hij over een zodanig assortiment en een zodanige voorraad van geneesmiddelen beschikt dat hij snel kan voldoen aan de vraag naar geneesmiddelen van degenen die bevoegd zijn geneesmiddelen ter hand te stellen."	**Medicines Act of Act of 8 February 2007, Article 36 §2 :** "The wholesaler also ensures that he has such a range and stock of medicines that he can quickly meet the demand for medicines from those who are authorized to supply medicines."
Right to be supplied	**Geneesmiddelenwet, Wet van 8 februari 2007 tot vaststelling van een nieuwe Geneesmiddelenwet, Artikel 49§9:** "De houder van een handelsvergunning draagt ervoor zorg dat het geneesmiddel waarop de handelsvergunning betrekking heeft, in voldoende mate voorradig is voor groothandelaren of apothekers teneinde in de behoeften van patiënten te kunnen voorzien."	**Medicines Act of Act of 8 February 2007, Article 49§9:** "The holder of a marketing authorization ensures that the medicinal product to which the marketing authorization relates is sufficiently available for wholesalers or pharmacists in order to be able to meet the needs of patients."
Separate licensing system for full-line wholesalers	*None*	*None*

Poland (PL)

	Original version	EN translation
PSO	**Ustawa z dnia 6 września 2001 r. Prawo farmaceutyczne Art. 85a**	**Act of 6 September 2001. Pharmaceutical Law, Article 85a**
	"85a.	"85a.
	1. Hurtownie farmaceutyczne są obowiązane do zbywania produktów leczniczych, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych, określonych w wykazie, o którym mowa w ust. 3, wyłącznie do innych hurtowni farmaceutycznych, aptek, punktów aptecznych oraz zakładów leczniczych podmiotów leczniczych, działających na terytorium Rzeczypospolitej Polskiej.	(1) Pharmaceutical wholesalers shall be obliged to sell medicinal products, foodstuffs for special nutritional purposes and medical devices, specified in the list referred to in paragraph 3, only to other pharmaceutical wholesalers, pharmacies, pharmacy points and medical establishments of medical entities operating in the territory of the Republic of Poland.
	2. Wytwórcy, autoryzowani przedstawiciele, dystrybutorzy i importerzy wyrobów medycznych oraz producenci i importerzy środków spożywczych specjalnego przeznaczenia żywieniowego są obowiązani do zbywania wyrobów lub środków określonych w wykazie, o którym mowa w ust. 3, wyłącznie do hurtowni farmaceutycznych działających na terytorium Rzeczypospolitej Polskiej.	(2) Manufacturers, authorized representatives, distributors and importers of medical devices and manufacturers and importers of foodstuffs for particular nutritional uses shall be obliged to sell the products or means specified in the list referred to in paragraph (3) exclusively to pharmaceutical wholesalers operating on the territory of the Republic of Poland.
	3. Minister właściwy do spraw zdrowia ogłasza, w drodze obwieszczenia, wykaz produktów leczniczych, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych, które mogą być zbywane zgodnie z ust. 1 lub 2.	(3) The Minister competent for health shall announce, by means of a notice, a list of medicinal products, foodstuffs for special nutritional purposes and medical devices which may be disposed of in accordance with paragraph (1) or (2).
	4. Przepisów ust. 1–3 nie stosuje się do tworzenia albo odtwarzania rezerw strategicznych.	(4) The provisions of sections 1-3 shall not apply to the creation or restoration of strategic reserves.
	5. Minister właściwy do spraw zdrowia może wyrazić zgodę na zbywanie przez podmioty wymienione w ust. 1 i 2 produktów leczniczych, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych, określonych w wykazie, o którym mowa w ust. 3, na rzecz innego podmiotu niż hurtownia	(5) The minister responsible for health matters may consent to the disposal of medicinal products, foodstuffs for special nutritional purposes and medical devices, as defined in the list referred to in paragraph (3), by the entities listed in paragraphs (1) and (2)

	farmaceutyczna, apteka, punkt apteczny lub zakład leczniczy podmiotu leczniczego.”	to an entity other than a pharmaceutical wholesaler, a pharmacy, a point of pharmacy or a medicinal establishment of a medicinal entity.”
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Portugal (PT)

	Original version	EN translation
PSO	**Decreto-Lei n.º 176/2006, de 30 de agosto Estatuto do Medicamento, versão consolidada com alterações à data de 22/08/2019**	**Decree-Law No. 176/2006, of 30 August 2006 Medicinal Products Statute, consolidated version with changes as of 22/08/2019, Article 6**
	« Art. 6 1 A garantia de acesso aos medicamentos constitui um dever de serviço público essencial, que incide sobre todo o território nacional, não podendo ser limitado pelos titulares de autorização de introdução no mercado, ou de registo, de um medicamento, pelos distribuidores por grosso ou pelas farmácias e demais entidades e pessoas habilitadas a dispensar medicamentos ao público. 2 Os fabricantes, titulares de autorização de introdução no mercado, importadores, distribuidores por grosso, farmácias de oficina, serviços farmacêuticos hospitalares e locais autorizados a vender medicamentos não sujeitos a receita médica estão obrigados a fornecer, a dispensar ou a vender os medicamentos que lhes sejam solicitados, nas condições previstas no presente decreto-lei e na demais legislação aplicável. 3 Os responsáveis pelo fabrico, titulares de autorização de introdução no mercado, distribuição, venda e dispensa de medicamentos têm de respeitar o princípio da continuidade do serviço à comunidade, designadamente diligenciando, junto de qualquer interveniente do circuito do medicamento, no sentido de garantir a satisfação da prescrição ou pedido de fornecimento apresentado. »	"Art. 6 1 The guarantee of access to medicines constitutes an essential public service duty that applies to the entire national territory and may not be limited by the holders of marketing or registration authorisation for a medicine, by wholesale distributors or by pharmacies and other entities and persons authorised to dispense medicines to the public. 2 Manufacturers, holders of marketing authorisation, importers, wholesale distributors, pharmacies, hospital pharmacies and places authorised to sell medicines not subject to medical prescription shall be obliged to supply, dispense or sell the medicines that are requested to them under the conditions laid down in this Decree-Law and in other applicable legislation. 3 Those responsible for the manufacture, holders of marketing authorisations, distribution, sale and dispensing of medicines shall respect the principle of continuity of service to the community, namely by endeavouring with any intervening party in the circuit of medicines in order to guarantee the satisfaction of the prescription or request for supply presented."
	« Artigo 94.º-A 1 - O distribuidor por grosso de medicamentos no mercado nacional está sujeito ao	« Article 94-A 1 - The wholesale distributor of medicines on the national market is

	cumprimento das obrigações previstas na presente secção e às obrigações previstas no artigo 6.º 2 - A atividade de distribuição no mercado nacional é exercida por entidades independentes dos titulares de autorização de introdução no mercado, que detêm um conjunto abrangente de medicamentos, constituído de tal forma que garante um sistema de fornecimento contínuo e permanente de medicamentos às farmácias, serviços farmacêuticos hospitalares e locais autorizados a vender medicamentos não sujeitos a receita médica. 3 - Para efeitos do disposto no número anterior, o distribuidor por grosso no mercado nacional deve criar e conservar um stock mínimo e garantir o abastecimento do mercado tão breve quanto possível, nos termos, forma e prazo fixados em regulamento do INFARMED, I. P. » Artigo 100.º 1 - O titular de autorização de exercício da atividade de distribuição por grosso de medicamentos deve respeitar as seguintes disposições: [...] c) Dispor permanentemente de medicamentos em quantidade e variedade suficientes para garantir o fornecimento adequado e contínuo das farmácias, serviços farmacêuticos hospitalares e demais entidades legalmente autorizadas para a aquisição, venda e dispensa de medicamentos em território nacional, de forma a garantir, de forma prioritária, a satisfação das necessidades dos doentes; [...] 2 - Para assegurar o cumprimento do disposto na alínea c) do número anterior, o órgão máximo do INFARMED, I.P., pode definir, por regulamento: a) As quantidades mínimas ou os critérios de determinação das quantidades mínimas de medicamentos que devem ser mantidas permanentemente pelos distribuidores que operam no território nacional, para garantia	subject to compliance with the obligations set out in this section and the obligations set out in article 6. 2 - The distribution activity in the national market is carried out by entities independent of the holders of marketing authorization, which hold a comprehensive set of medicines, constituted in such a way as to guarantee a system of continuous and permanent supply of medicines to pharmacies, services hospital pharmacists and places authorized to sell over-the-counter medicines. 3 - For the purposes of the provisions of the previous number, the wholesale distributor in the national market must create and maintain a minimum stock and guarantee the market supply as soon as possible, under the terms, form and deadline established in the regulation of INFARMED, I. P. » Article 100 1 - The holder of authorization to exercise the activity of wholesale distribution of medicines must comply with the following provisions: [...] c) Permanently own medicines in sufficient quantity and variety to guarantee the adequate and continuous supply of pharmacies, hospital pharmaceutical services and other entities legally authorized for the acquisition, sale and dispensing of medicines in the national territory, in order to guarantee, as a priority, the satisfaction of patients' needs; [...] 2 - In order to ensure compliance with the provisions of subparagraph c) of the previous number, the highest body of INFARMED, I.P., may define, by regulation: a) The minimum quantities or criteria for determining the minimum quantities of medicines that must be kept permanently by distributors

	de continuidade do fornecimento e do acesso aos medicamentos por parte dos doentes.	operating in the national territory, to guarantee continuity of supply and access to medicines by patients.
Right to be supplied	*See Public Service Obligation*	*See Public Service Obligation*
Separate licensing system for full-line wholesalers	*None*	*None*

Romania (RO)

	Original version	EN translation
PSO	**Lege nr. 95 din 14 aprilie 2006, Articolul 792** « Art. 804 (1) În ceea ce priveşte furnizarea de medicamente către farmacişti şi persoanele autorizate să elibereze medicamente către populaţie, ANMDMR nu trebuie să aplice unui deţinător de autorizaţie de distribuţie angro acordată de alt stat membru al UE nicio obligaţie, în special obligaţii de serviciu public, mai restrictivă decât cele aplicate persoanelor autorizate să efectueze activităţi echivalente în România. (2) Deţinătorul unei autorizaţii de punere pe piaţă/Reprezentantul deţinătorului autorizaţiei de punere pe piaţă pentru un medicament şi distribuitorii angro ai acelui medicament pus efectiv pe piaţă în România au obligaţia de a asigura, în limitele responsabilităţilor lor, stocuri adecvate şi continue din acel medicament către unităţi farmaceutice şi persoanele juridice care au dreptul să furnizeze medicamente către public, astfel încât nevoile pacienţilor din România să fie acoperite, în condiţiile prevăzute prin ordin al ministrului sănătăţii; Ministerul Sănătăţii stabileşte, prin ordin al ministrului sănătăţii, în sarcina unităţilor de distribuţie angro a medicamentelor, importatorilor, fabricanţilor autorizaţi şi a farmaciilor cu circuit închis şi deschis obligaţii de raportare a stocurilor şi a operaţiunilor comerciale de medicamente, inclusiv distribuţia în afara teritoriului României, efectuate cu medicamentele de uz uman din portofoliul/stocul propriu având preţul aprobat în conformitate cu prevederile prezentului titlu.	**Law no.95 of 14 April 2006, Art. 792** "Art. 804 (1) As regards the supply of medicinal products to pharmacists and persons authorised to dispense medicinal products to the public, ANMDMR shall not apply to a holder of a wholesale distribution authorisation granted by another EU Member State any obligation, in particular public service obligations, more restrictive than those applied to persons authorised to carry out equivalent activities in Romania. (2) The marketing authorisation holder/representative of the marketing authorisation holder for a medicinal product and the wholesale distributors of that medicinal product actually placed on the market in Romania are obliged to ensure, within the limits of their responsibilities, adequate and continuous stocks of that medicinal product to pharmaceutical establishments and legal persons entitled to supply medicinal products to the public, so that the needs of patients in Romania are covered, under the conditions laid down by order of the Minister of Health; The Ministry of Health shall establish, by order of the Minister of Health, obligations for wholesale distribution units of medicines, importers, authorized manufacturers and closed and open circuit pharmacies to report stocks and commercial operations of medicines, including distribution outside the territory of Romania, carried out with medicines for human use from their own portfolio/stock having the price approved in accordance with the provisions of this Title.

	(3) Măsurile pentru implementarea prevederilor prezentului articol trebuie să fie justificate prin protecția sănătății publice și să fie proporționale cu obiectivele acestei protecții, conform regulilor Tratatului Uniunii Europene, în special cele privind libera circulație a mărfurilor și concurenta. »	3. Measures for the implementation of this Article shall be justified by the protection of public health and be proportionate to the objectives of such protection, in accordance with the rules of the Treaty on European Union, in particular those on the free movement of goods and competition."
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Slovakia (SK)

	Original version	**EN translation**
PSO	**Zákon o liekoch a zdravotníckych pomôckach a o zmene a doplnení niektorých zákonov (Zákon č. 362/2011 Z. z.), §18** « (1) Držiteľ povolenia na veľkodistribúciu liekov je povinný […] (f) zabezpečiť pre územie, na ktorom má povolenú veľkodistribúciu humánnych liekov, dodanie liekov, ktoré sú uvedené v zozname kategorizovaných liekov,22) najneskôr do 24 hodín od prijatia objednávky od držiteľa povolenia na poskytovanie lekárenskej starostlivosti; na požiadanie ministerstva zdravotníctva zabezpečiť aj iné lieky v ním určenej lehote, »	**Act on Medicinal Products and Medical Devices and on Amendments to Certain Acts (Act no. 362/2011 Coll.), §18** "(1) The holder of an authorization for the wholesale distribution of medicinal products is obliged […] (f) to ensure, for the territory in which the wholesale distribution of medicinal products for human use is authorised, the supply of medicinal products included in the list of categorised medicinal products,22) not later than 24 hours from the receipt of the order from the holder of the authorisation for the provision of pharmaceutical care; at the request of the Ministry of Health, to ensure the supply of other medicinal products within the time limit specified by the Ministry of Health"
Right to be supplied	*None*	*None*
Separate licensing	*None*	*None*

system for full-line wholesalers		

Slovenia (SI)

	Original version	EN translation
PSO	**Zakon o zdravilih (Uradni list RS, št. 17/14 in 66/19), 6. Člen**	**Medicinal Products Act (Official Gazette of the Republic of Slovenia, Nos. 17/14 and 66/19), Article 6**
	« 54. Obveznost opravljanja storitev v javnem interesu je obveznost veletrgovcev, da zagotavljajo stalen in ustrezen nabor zdravil, s katerim zadoščajo zahtevam v Republiki Sloveniji na njenem celotnem ozemlju in v ustrezno kratkem času, ki ga na podlagi dokazljive zdravstvene potrebe oziroma zdravstvene dokumentacije določi izvajalec zdravstvene dejavnosti, in dostavljajo zahtevane dobave v Republiki Sloveniji. »	"54. The obligation to provide services in the public interest is the obligation of wholesalers to provide a constant and appropriate range of medicines that meet the requirements of the Republic of Slovenia throughout its territory and in a suitably short time determined by the healthcare provider. activities, and deliver the required deliveries in the Republic of Slovenia."
	Zakon o zdravilih (Uradni list RS, št. 17/14 in 66/19), 108. Člen	**Medicinal Products Act (Official Gazette of the Republic of Slovenia, Nos. 17/14 and 66/19), Article 108**
	« 108. Člen (obveznost opravljanja storitev v javnem interesu)	"Article 108 (obligation to provide services in the public interest)
	(1) Veletrgovec z zdravili, ki ima dovoljenje za poln obseg opravljanja dejavnosti prometa z zdravili na debelo, zagotavlja stalen in ustrezen nabor zdravil, ki so lahko v prometu v skladu z obveznostjo opravljanja storitev v javnem interesu, v ustrezno kratkem času, najpozneje v 24 urah med tednom oziroma najpozneje v 72 urah med vikendom in prazniki od prejetega naročila za zdravila iz prvega in drugega odstavka ter tretje alineje tretjega odstavka 20. člena tega zakona. Če izvajalec zdravstvene ali veterinarske dejavnosti ali lekarna potrebuje dostavo zdravil v krajših rokih od navedenih, to navede v naročilu veletrgovcu z zdravili na podlagi dokazljive zdravstvene potrebe ali zdravstvene dokumentacije. »	(1) A wholesaler of medicinal products authorized for the full scope of the activity of wholesale trade in medicinal products shall provide a permanent and appropriate set of medicinal products that may be placed on the market in accordance with the obligation to provide services in the public interest. 24 hours during the week or no later than 72 hours during weekends and holidays from the received order for medicinal products referred to in the first and second paragraphs and the third indent of the third paragraph of Article 20 of this Act. If a health or veterinary practitioner or pharmacy needs to deliver medicines within a shorter period than specified,

		it shall state this in the order to the wholesaler of medicines on the basis of a demonstrable medical need or medical documentation.
	(2) Veletrgovec z zdravili, ki ima dovoljenje za produktno omejeno opravljanje dejavnosti prometa z zdravili na debelo, zagotavlja stalen in ustrezen nabor zdravil iz dovoljenja JAZMP za opravljanje te dejavnosti, s katerim zadošča zahtevam nemotene preskrbe s temi zdravili v skladu z obveznostjo opravljanja storitev v javnem interesu v 24 urah med tednom oziroma najpozneje v 72 urah med vikendom in prazniki od prejetega naročila za zdravila iz prvega in drugega odstavka ter tretje alineje tretjega odstavka 20. člena tega zakona. Če izvajalec zdravstvene ali veterinarske dejavnosti ali lekarna potrebuje dostavo zdravil prej kot v navedenih rokih, to navede v naročilu veletrgovcu z zdravili na podlagi dokazljive zdravstvene potrebe ali zdravstvene dokumentacije. »	(2) A wholesaler of medicinal products authorized for the restricted pursuit of the activity of wholesale trade in medicinal products shall provide a permanent and appropriate set of medicinal products from the JAZMP authorization for the performance of this activity, which satisfies the requirements of uninterrupted supply of these medicinal products. in the public interest within 24 hours during the week or no later than 72 hours during weekends and holidays from the received order for medicinal products referred to in the first and second paragraphs and the third indent of the third paragraph of Article 20 of this Act. If the health or veterinary operator or pharmacy needs the delivery of medicines earlier than the specified deadlines, this shall be stated in the order to the wholesaler of medicines on the basis of a demonstrable medical need or medical documentation.”
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*

Spain (ES)

	Original version	EN translation
PSO	**Real Decreto 782/2013, de 11 de octubre, sobre distribución de medicamentos de uso humano, Article 3** Art. 3 Garantia de abastecimiento […] 2. Los almacenes mayoristas y los laboratorios titulares de autorización de comercialización de medicamentos deberán garantizar, dentro de los límites de su responsabilidad, y en los plazos de entrega acordados, un abastecimiento adecuado y continuado de los medicamentos a las oficinas y servicios de farmacia legalmente autorizados en el territorio nacional, de modo que estén cubiertas las necesidades de los pacientes. »	**Royal Decree 782/2013, of 11 October, on distribution of medicines for human use, Article 3** "Article 3. Supply guarantee […] 2. The wholesale warehouses and laboratories holding marketing authorization for medicines must guarantee, within the limits of their responsibility, and within the agreed delivery times, an adequate and continuous supply of medicines to legally authorized pharmacy offices and services. authorized in the national territory, so that the needs of patients are covered."
Right to be supplied	**Real Decreto 782/2013, de 11 de octubre, sobre distribución de medicamentos de uso humano, Article 2** « Art. 2 Principios Generales […] 2. Los laboratorios farmacéuticos que distribuyan directamente sus medicamentos y los almacenes mayoristas, tendrán que garantizar, dentro de los límites de sus responsabilidades, un abastecimiento adecuado y continuado de medicamentos para responder a las necesidades de las oficinas de farmacia y servicios farmacéuticos del territorio nacional. Para ello, deberán disponer de unas existencias mínimas de medicamentos, conforme establece el artículo 70.1 de la Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios que permitan garantizar la continuidad de la distribución. »	**Royal Decree 782/2013, of 11 October, on distribution of medicines for human use, Article 2** "Article 2. General principles […] 2. Pharmaceutical laboratories that directly distribute their medicinal products and wholesale warehouses shall have to guarantee, within the limits of their responsibilities, an adequate and continuous supply of medicinal products to meet the needs of pharmacies and pharmaceutical services in the national territory. To this end, they shall hold a minimum stock of medicinal products, in accordance with article 70.1 of Law 29/2006, of 26 July, on guarantees and rational use of medicinal products and medical devices, in order to guarantee the continuity of distribution."
Separate licensing system for full-line wholesalers	*None*	*None*

Sweden (SE)

	Original version	EN translation
PSO	**Lag (2009:366) om handel med läkemedel, kap2 §6** « 6 § Den som har tillstånd enligt 1 § att bedriva detaljhandel med läkemedel till konsument ska 3. tillhandahålla samtliga förordnade läkemedel, och samtliga förordnade varor som omfattas av lagen (2002:160) om läkemedelsförmåner m.m. så snart det kan ske. » **Lag (2009:366) om handel med läkemedel, 2 kap 3a§** « Öppenvårdsapotekens grunduppdrag 3 a § I öppenvårdsapotekens grunduppdrag ingår att verka för en god och säker läkemedelsanvändning genom att 1. säkerställa att konsumenten så snart det kan ske får tillgång till förordnade läkemedel och varor. »	**Law (2009: 366) on trade in medicines, Chapter 2, section 6** "Section 6 A person who has a permit in accordance with section 1 to conduct retail trade in medicinal products to consumers shall 3. provide all prescribed medicines, and all ordered goods covered by the Act (2002: 160) on pharmaceutical benefits, etc. as soon as possible" **Law (2009: 366) on trade in medicines, Chapter 2, section 3** "The outpatient pharmacy's basic assignment Section 3(a) The outpatient pharmacy's basic assignment includes working for a good and safe use of medicines by: 1. Ensuring that the consumer has access to prescribed medicines and goods as soon as possible;"
Right to be supplied	*None*	*None*
Separate licensing system for full-line wholesalers	*None*	*None*