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POLICY PROPOSALS TO MINIMISE MEDICINE SUPPLY SHORTAGES IN EUROPE

The Need for Urgent Action

Sustained lack of growth and accompanying austerity measures across much of Europe have eroded national healthcare budgets and exposed structural weaknesses in the pharmaceutical supply chain. Market conditions for pharmaceuticals are increasingly unstable and disruptive as evidenced by an observable adverse trend of drug shortage situations over the past 2-3 years. Deep price cuts in crisis-stricken countries have fuelled arbitrage and threatened supplies. While parallel trade is only one cause of medicine shortages[1], its effects are often acute for patients in those countries worst affected.

Fundamentally, any effective policy response to the problem of patient access will require greater solidarity between Member States, recognising that national policy choices can and do have significant adverse effects in other markets. For example, Denmark references the price of imported parallel traded products in setting the reimbursement price. In Sweden, parallel traded products comprise an estimated 15% of the total pharmaceutical market, driven largely by the fact that pharmacists are under no obligation to pass on any part of the price differential. In Germany, parallel imports must account for at least 5% of quarterly pharmacy sales.[2]

Although superficially attractive, increased levels of parallel trade are unsustainable economically and politically to the extent they result in shortages in lower income markets that are used to service this parallel trade demand.[3]

To understand of the causes of drug shortages and work towards their prevention, there is no need for any new EU legislative intervention. But addressing the problem of shortages meaningfully with the aim of improving patient access to medicines will require the involvement and commitment of all relevant supply chain stakeholders. Corrective measures may take many forms ranging from pharmaceutical companies organising direct supplies in response to an emergency to more structural solutions outlined below.

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1 Evidence available so far does not show any increase of shortages due to manufacturing or quality and compliance issues.

2 The German pharmaceutical market is estimated to have an ex-factory value of approximately €27 billion and the parallel distribution market alone is valued at almost €3 billion (see "The parallel distribution industry: a closer look at savings", EAEPC report of January 2013 at p. 21). This is equivalent to a substantial part of many smaller states' national healthcare budgets.

3 Research shows that the profits enjoyed for parallel traders can be as much as 20 times the net savings to the national healthcare system. See Kanavos and Kowal, Does pharmaceutical parallel trade serve the objectives of cost control?; *Eurohealth Vol 14 No 2, page 25; see also* Kanavos P, Costa-Font J. Pharmaceutical, Parallel Trade in Europe: stakeholder and competition effects. *Economic Policy* 2005;20(44):751–98.

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Better Reporting of Shortages

EFPIA is supportive of existing mechanisms at national and at EU level to require the reporting of anticipated supply interruptions for whatever reason.[4] The pharmaceutical industry is fully aligned with the public policy objective to serve patients with secure supplies of innovative medicines and is committed to working with all stakeholders to ensure that all fulfil their reporting obligations so as to minimize the risk of shortages.

Better Enforcement of Existing Regulatory Obligations

There are a number of straightforward steps that would readily enable authorities to better assure the efficient functioning of the supply chain and anticipate and identify potential supply shortages at an early stage. Better monitoring and rigorous enforcement of existing regulatory obligations on all actors in the supply chain, coupled with further measures to enhance transparency within the supply chain, would considerably improve the status quo. Such improvements can be done at a national level and can be facilitated by the sharing of best practices and closer consultation with stakeholders.

EU law requires verification at each stage of the supply chain to ensure that medicines are received from and supplied to duly authorised players that fulfil their respective regulatory obligations.

Marketing authorisation holders ("MAHs") as well as wholesalers have a fundamental "public service" obligation to ensure "*within the limits of their responsibilities*, *appropriate and continued supplies of medicinal product[s] to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered*."[5]

Wholesalers, brokers and pharmacies are subject to separate licensing regimes. While in principle free to carry out multiple activities, they must have the appropriate licence for each. Distributors are required to have sufficient quality control and emergency plans in place.[6] New requirements have been imposed on those engaged in brokering medicinal products.[7]

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4 In relation to shortages that are due to manufacturing, quality and/or compliance issues, the industry is actively engaged with stakeholders and regulators in communication platforms and works towards the setting up of enhanced notification and visibility systems to make both planned and unforeseen discontinuation of the supply of specific products to specific markets transparent.

5 Directive 2001/83/EC on the Community Code relating to medical products for human use provides that a public service obligation must be warranted on grounds of public health protection, and proportionate in relation to the objective of such protection, [2001] O.J. L.311/67, Article 81, Recital 38.

6 Articles 78-79 and 84 Directive 2001/82/2001 and Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use, [2013] O.J. C.68/1.

7 These amendments were introduced by Directive 2011/62/EU of the European Parliament and of the Council, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] O.J. 174/74.

Strict adherence to these separate regulatory obligations is essential to the integrity and reliability of the overall supply chain. These public service obligations should be interpreted and enforced in a proactive manner which prioritises patient safety. The short term commercial objectives of different actors in the supply chain should not play a role. Pharmacists should not be allowed to engage in wholesale activities without securing the appropriate licence in those countries where wholesale activities are open to them. They must demonstrate that in meeting the mandatory wholesaler obligations, their primary obligation to satisfy local patient demand at the retail level will not in any way be compromised. Non-compliance should result in the application of dissuasive penalties.

Greater Transparency Across the Supply Chain

Greater transparency across the supply chain would make it easier for national authorities to:

- identify enforcement gaps,
- predict when and where shortages are likely to occur,
- focus limited resources on the areas which pose the greatest risk to supply security, and
- devise suitable regulatory responses before patient access is affected.

Many Member States have begun to introduce mechanisms to monitor and track medicine sales. The Czech regime could provide a useful model for other countries since it requires stakeholders to provide accurate data on the volumes sold into and on the national market. This system (see box below for more details) allows the relevant actors to better plan their production cycles and ensure that they are meeting their respective supply obligations based on accurate data. It also provides competent authorities with sufficient information to allow them to swiftly react to anticipated shortages or other supply disruptions without necessarily having to have recourse to export bans. Given its proven effectiveness, this is one solution that could be held out as an example of best practices.

Case Study: Czech Measures to Reduce the Risk of Shortages

Under Czech pharmaceutical regulations, a pharmacy operator can also act as a distributor if it has an applicable wholesale distribution licence. By virtue of amendments to Act No. 378/2007 Coll. (Medicinal Products) relating to the distribution of medicinal products that entered into force on 2 April 2013 pharmacy operators, who also act as distributors, must declare whether they receive stock in their capacity as a pharmacy operator or a distributor. If stock is declared for resale in pharmacies, it cannot subsequently be sold by the pharmacy operator on a wholesale basis.[8]

Czech legislation also imposes a variety of monitoring and notification obligations:

[8] Section 77 (3): "*If the medicinal product is taken by a pharmacy who is also a distributor, the documentation must specify exactly whether the purchaser takes the medicinal products as a pharmacy or as a distributor.*" In Section 77 (9): "*A distributor who is also a pharmacy must not use medicinal products taken by them as a pharmacy for further distribution.*"

- Marketing authorisation holders and/or contract manufacturers must notify the authorities of any concerns about suspected counterfeits produced or imported from third countries

- Distributors/wholesalers must verify that purchased human medicinal products are not counterfeits and report any suspect products immediately

- Marketing authorization holders must provide the authorities with all relevant and available data concerning the volume of medicines sold and prescribed in the territory as well as notify with motivation any planned/foreseen suspension, discontinuation or disruption of supply at least two months in advance.

Increased transparency would also align with the policy objectives of the recently adopted Falsified Medicines Directive,[9] which imposes identification, reporting and quality control obligations on stakeholders to minimise the risk of counterfeit medicines penetrating the supply chain.[10] The Directive also encourages greater transparency and cooperation across borders by obliging national authorities to submit certain information (e.g., compliance records of wholesalers who have passed inspections, and evidence of appropriate authorisations and certificates of good practice) to a centralised, publicly accessible database managed by the European Medicines Agency.

Emergency Intervention as Last Resort to Ensure Security of Supply

Member States are able - as a matter of EU law - to take measures to ensure security of supply where there is a genuine risk of shortages. Such measures include mandatory pre-export notification, consent requirements imposed on wholesalers, and restrictions on pharmacist wholesale activities. In exceptional circumstances, the imposition of limited export bans may be justified in respect of those medicines where there is a demonstrated supply shortage and consequent risk to patient safety.

Such measures are lawful under EU law free movement principles provided they are in response to a genuine public health risk and are proportionate in that they are appropriate to achieve the stated public health objective, and are not more restrictive than is necessary to achieve their legitimate objective. Annex I provides a summary of EU law free movement principles relevant in assessing the compatibility of national law measures intended to reduce supply shortages as well as compliance guidelines to assist in joint advocacy efforts on this topic.

Emergency measures can act as an important safety valve, but they do little to alleviate the underlying problems that give rise to shortages and nor do they address the fundamental malaise of today's inequality of access to innovative medicines. Annex II provides an overview of national law measures designed to reduce the risk of supply shortages.

[9] Directive 2011/62/EU of the European Parliament and of the Council, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] O.J. 174/74 ("Falsified Medicines Directive").

[10] See Article 1(17) Falsified Medicine Directive amending Article 80 of the Directive 2001/83/EC to require wholesalers to (i) keep records of all transactions, (ii) maintain a quality control system, and (iii) inform the relevant authority and the MAH in the event a falsified medicine is discovered.

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Call for Action

National price controls mean there is no single market in pharmaceuticals. Instead of fuelling market distortions leaving patients in lower income, lower price countries, worse off, the objective must be to move away from importing low priced products from other countries to having an affordable price in each market based on objective criteria. In the short term, EFPIA calls for:

1. More consistent and robust enforcement of existing obligations on supply chain operators to improve the integrity of the supply chain.
2. Further measures at Member State level to enhance transparency within the supply chain. Specifically, verification of stakeholders' compliance with their respective regulatory obligations must be based on more accurate supply and demand data to improve the ability of authorities to anticipate and identify potential supply shortages at an early stage before patient access is threatened.
3. EFPIA encourages national authorities, potentially in an EU forum, to consider practical ways of increasing transparency in the supply chain and to foster greater solidarity among Member States to reduce disruptions in the supply chain: countries would be encouraged to abolish the distortive effects of national schemes rewarding parallel trade to the detriment of exporting countries.

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ANNEX I

Summary of EU Law Free Movement Principles Relevant in Assessing the Compatibility of National Law Measures Intended to Reduce Supply Shortages

As a general principle, Member States cannot adopt national measures that impede the free movement of goods across the EU. Exceptionally, national law restrictions are permitted if they are justified on the public policy grounds of ensuring adequate protection of the health and life of humans.[11]

Any public health justifications advanced by a Member State must be (i) genuine (i.e., designed to achieve a real and stated public policy objective, not a disguised restriction on trade or protection of economic interests), and (ii) proportionate (i.e., the measure is appropriate to achieve the stated public health objective and not more restrictive than is necessary to achieve its legitimate objective).

The table below provides an overview of the main types of restrictions and how they would likely be assessed under EU free movement principles:

	National Law Measure	Likely to be Compatible with EU Law
Export Ban	Absolute export ban on all medicines regardless of risk of supply shortage unlimited in time	**NO**
	Export ban for specific medicines where there is a demonstrated risk of shortage and it is subject to regular review by the authorities	**YES**
Obligation to Pre-Notify Intention to Export	No time-limit for authorities' review and wholesalers prohibited from exporting until consent granted	**NO**

[11] The free movement of goods is a fundamental principle of EU law laid down at Articles 34 and 35 TFEU which prohibit quantitative restrictions on imports and exports and all measures having equivalent effect. Article 36 allows for restrictions justified on public policy grounds, including the protection of health and life of humans, animals or plants, and provided they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between EU Member States.

	Authorities obliged to respond within reasonable time (e.g., 30 days) and wholesalers permitted to export if no response received within the time limit	**YES**
	National authorities can object to export of specific medicine reported if there is a genuine risk to security of supply	**YES**
Public Service Obligation	Wholesalers obliged to supply local patients in national territory only	**NO**
	Wholesalers obliged to meet local patient demand but remain free to export excess stock	**YES**
	Obligation on marketing authorisation holders ("MAH") to supply wholesalers in circumstances where the wholesaler claims that the stock is needed to satisfy local patient demand	**UNCLEAR (arguable that MAH cannot be obliged to supply all wholesaler requests provided it can show it supplied sufficient stock to satisfy local patient demand)**
Obligation to Hold Licence	Obligation on operators to have separate licences for specific distribution activities e.g., separate licences for wholesale activities and pharmacy sales	**YES**
	Obligation on pharmacists to declare for which purpose they receive medicines (wholesale or retail)	**YES**
	Obligation on pharmacists to keep separate wholesale and pharmacy stocks and prohibition of diverting pharmacy stock for wholesale distribution	**YES**
	Obligation on wholesalers to receive separate licence to export medicines	**NO**

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COMPLIANCE GUIDELINES ON

COLLECTIVE ADVOCACY EFFORTS

These Guidelines are designed to ensure that when national industry associations and/or individual member companies participate in collective advocacy efforts at EU and/or national level, they avoid engaging in or facilitating any discussion or activity which might violate EU or national competition laws.

Industry associations and/or individual member companies **CAN** lobby national governments to introduce legislative or soft law policy proposals to facilitate better enforcement of regulatory obligations and/or enhance security of supply.

They can:

- participate in discussions with national legislators/regulators designed to improve efficiency of supply chain management;
- support the introduction of national legislative measures designed to reduce the risk to patient safety caused by chronic supply shortages and excessive parallel trade;
- engage with competition authorities to persuade them not to condemn legitimate business practices used by manufacturers/suppliers to efficiently manage their supply chain and reduce the risk of supply shortages/disruptions in national markets;
- support proposals to encourage greater transparency across the supply chain and better collaboration between Member State authorities.

Collective lobbying must **CANNOT** impact commercially sensitive issues related to the parameters of competition between competitors.

National associations and/or individual companies cannot engage in:

- discussions or agreements relating to price;
- discussions relating to current or future supply, distribution, marketing and promotional costs, etc. or quantity information for specific markets;
- discussions relating to specific costs for compliance with existing regulatory obligations in national markets;
- discussions or agreements relating to current or future launch plans for Products and/or future R&D investments for new Product launches in national markets;
- discussions or agreements relating to confidential internal business plans to improve supply chain management and/or reduce risk of supply shortages in national markets;
- threats to take coordinated response against wholesalers/distributors that do not agree with suggested policy amendments and/or are identified as heavy parallel traders to the perceived detriment of supply security.

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ANNEX II

OVERVIEW OF NATIONAL LAW MEASURES DESIGNED TO REDUCE THE RISK OF SUPPLY SHORTAGES

The following is a non-exhaustive overview of legislative measures taken by Member States to safeguard security of supply and patient health needs in 2012-2013. It is an overview based on legal advice obtained by EFPIA during 2013. It does not purport to be definitive.

1. **Bulgaria**

In January 2014, the Bulgarian government published a proposal to amend its "Medicinal Products in Human Medicine Act" ("Human Medicines Act") by introducing a legislative mechanism to limit the export of medicines by wholesalers in circumstances where there is a risk of medicine shortages for compliance with general EU law principles. The draft legislative proposal contained several provisions that would, if implemented, have significant impact on the pharmaceutical supply and distribution chain in Bulgaria. These provisions included:

1. Introduction of an obligation for wholesale distributors to (i) pre-notify the relevant authorities of their intention to export medicines and (ii) to provide data based on prior 6 months on consumption levels of that medicine by the national health insurance fund/health ministry and total volumes supplied by the marketing authorisation holders ("MAH") (Article 217B, Human Medicines Act);

2. Introduction of a right for the relevant authorities to implement an export ban to restrict the ex-territory distribution of medicines (Article 217B(5), Human Medicines Act);

3. New administrative penalties for breach of regulatory obligations (Article 217B(6), Human Medicines Act); and

4. Revised public service obligation to obligate MAHs and wholesalers to ensure adequate and continuous stocks for Bulgarian domestic demand (Articles 68, 207, Human Medicines Act.)

Following the publication of this Legislative Proposal, the parallel traders association in Bulgaria complained to the European Commission arguing that it constituted an infringement of free movement rules. The Commission has warned Bulgaria that it may face infringement proceedings. Consequently, on 30 January 2014, the Bulgarian president vetoed the Legislative Proposal and it will be subject to another vote before Parliament and will need approval by a qualified majority in order to be enacted.

2. Czech Republic

Under Czech pharmaceutical regulations, a pharmacy operator can also act as a distributor if it has an applicable wholesale distribution licence. Recent amendments to Act No. 378/2007 Coll.

(Medicinal Products) relating to the distribution of medicinal products entered into force on 2 April 2013 and require:[12]

- Pharmacy operators, who also act as distributors, to declare whether they receive stock in their capacity as a pharmacy operator or a distributor; and
- If stock is declared for resale in pharmacies, it cannot subsequently be sold by the pharmacy operator on a wholesale basis.[13]

Czech legislation also imposes a variety of monitoring and notification obligations on stakeholders including:

- Obligation on marketing authorisation holders and/or contract manufacturers to notify the authorities about any concerns about suspected counterfeits produced or imported from third countries;
- Obligation on distributor/wholesaler to verify that the obtained human medicinal products are not counterfeits, and if they suspect that they could be counterfeit, to notify the authorities immediately;
- Obligation on the marketing authorization holder to:
    - provide the authorities with all relevant and available data concerning the volume of medicines sold and prescribed in the territory;
    - notify the authorities of any planned/foreseen suspension, discontinuation or disruption of supply at least two months in advance and give reasons for the disruption/discontinuance.

3. France

Recent legislative amendments oblige wholesalers to inform the Agence Nationale de Sécurité du Médicament et des products de santé ("ANSM") of the territory in which they will operate. Within this territory, the wholesaler is subject to a number of public service stocking obligations, including the following:

- The wholesaler must stock at least 90% of medicinal products sold in France;
- The wholesaler must stock the equivalent of two weeks of regular consumption in its territory;
- The wholesaler must be able to supply within 24 hours any order placed before 14:00 on Saturday. [14]

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[12] Act No. 378/2007 Coll. (Medicinal Products) relating to the distribution of medicinal products come into force on 2 April 2013.

[13] Section 77 (3): "*If the medicinal product is taken by a pharmacy who is also a distributor, the documentation must specify exactly whether the purchaser takes the medicinal products as a pharmacy or as a distributor.*" In Section 77 (9): "*A distributor who is also a pharmacy must not use medicinal products taken by them as a pharmacy for further distribution.*"

[14] Art.R-5124-59 FCPH (adopted 28 September 2012).

The French Competition Authority reviewed an earlier version of these amendments (which included a provision restricting the export of any medicine of major therapeutic importance that could not be supplied to French customers with 72 hours) and cautioned that wholesalers must be free to parallel trade any surplus stock over and above the minimum required to meet their local demand obligations.[15]

In December 2011, the government adopted legislation which provides that the prohibition on selling pharmaceutical products at a price higher than the regulated price does not apply to pharmaceutical products not consumed in France and destined for export.[16]

The draft implementing regulation that has not yet been formally adopted would require wholesalers to keep a record and make available to the relevant government authority certain information about the supply source and which retailer (pharmacy or hospital) it sold to.[17]

4. Greece

Since October 2012, the Greek National Organisation for Medicines ("EOF") has imposed temporary export bans on up to 80 individual medicines which are considered to be at risk from supply shortages.[18] The export bans are described as temporary, but no express time-limit is provided for in the Greek pharmaceutical regulations and we understand that all remain in place to date. They are subject to review by the European Commission.[19]

In July 2013, the Greek regulations were amended to increase the sanctions for violation of the export bans and other breaches of stakeholders' regulatory obligations ("July 2013 Amendments"). The main amendments are as follows:

- Article 12A of Greek Legislative Decree 96/1973 requires wholesalers to "*ensure the appropriate and adequate supply of these products to the market so as to meet, at all times, the national needs*." This provision now includes:
    - An obligation on wholesalers to report the volume of medicines subject to an export ban they currently have in stock and to sell these medicines in the Greek market as quickly as possible. Any violation of the underlying export ban will be subject to financial penalty between (€100,000 - €1 million);[20]
    - Imposition of a financial penalty (between €30,000 - €1 million) on wholesalers ***and/or*** marketing authorisation holders ("MAH")[21] if there is a breach of any regulatory obligation leading to a supply shortage;[22]

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15 Opinion n° 12-A-18 of 20 July 2012 ("Avis n° 12-A-18 du 20 juillet 2012 portant sur un projet de décret relatif à l'approvisionnement en médicaments à usage humain.")

16 Article L. 5123-1 FCPH.

17 Opinion n° 12-A-18 of 20 July 2012 ("Avis n° 12-A-18 du 20 juillet 2012 portant sur un projet de décret relatif à l'approvisionnement en médicaments à usage humain"), para. 156.

18 See press reports (here).

19 In response to a question from MEP, Commissioner Tajani noted that the "*Commission is currently assessing the legal issues raised, notably of potential violations of Articles 34-36 TFEU on free movement of goods and of Directive 2001/83/EC*" (Response to MEP question, dated 24 April 2013 (available here).

20 Article 95(4) of July 2013 Amendments.

21 Article 12A only refers to wholesalers' obligations. Article 8(2) of Greek Legislative Decree 96/1973 requires each MAH to "*ensure appropriate and continued supplies of the medicinal products he produces and/or*

- An obligation on wholesalers to: (i) record a medicine's specific barcode on sales vouchers;[23] and (ii) enter the authenticity sticker data into the EOF's online submission database in real time.[24] Violations are subject to a financial penalty of between €5,000 - €100,000 and €100,000 - €1 million respectively.[25]

- Article 27 of Greek Legislative Decree 1316/1983[26] is amended to require MAHs to declare the data of the inventory sheets of the authenticated sticker in the regulator's online database in real time. Violation is subject to a financial penalty of between €30,000 and €300,000.[27]

- The July 2013 Amendments also affect certain obligations on pharmacists (e.g., qualifications, conditions for receiving a prescription and inspections) which we do not consider further in this note.

5. Hungary

On 6 July 2013, the Hungarian government adopted Act CXXVII of 2013, which amended Act XCV of 2005 on pharmaceuticals of human use ("2005 Pharma Act"). The main amendments are:

- Provision for an export ban of a particular medicine if there is a demonstrable risk of supply shortages. The ban will last for as long as there is a threat to security of supply but not longer than 12 months in total (Article 16(8) of the Pharma Act);

- General obligation on MAHs to supply wholesalers in circumstances where the wholesaler claims that the stock is needed to satisfy local patient demand. The wholesaler is not required to provide evidence of local demand but if it receives stock pursuant to this provision, it must keep records of all medicines received for this purpose and can only sell the stock to local healthcare providers and cannot export it (Article 16(5) of the Pharma Act);

- Requires that MAHs supply wholesalers with sufficient volume of certain medicinal products whose active pharmaceutical ingredients are listed in a separate Ministerial decree. The minimum level of stock required for these medicines is also specified by separate ministerial decree (Article 16(5)(a) of the Pharma Act).

- General investigative powers are conferred on the relevant national authority to conduct dawn raids without a warrant and to search premises including private homes/cars when investigating compliance with these regulatory obligations (Article 17/B of the Pharma Act).

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imports in the country." However, Article 8(2) does not appear to be similarly affected by these July 2013 Amendments and it is unclear why MAHs are referred to in the context of Article 12A.

22 Article 95(2) of July 2013 Amendments.

23 Article 95(1) of July 2013 Amendments.

24 Article 95(3) of July 2013 Amendments.

25 Article 19 of Greek Decree 96/1973 is amended to clarify that administrative fines will be imposed by Ministry of Health while revocation of licences will be imposed following a resolution of the EOF Board.

26 Greek Legislative Decree 1316/1983 concerning the establishment, organisation and competence of the National Organisation for Medicines, the National Pharmaceutical Industry, the State Pharmaceutical Warehouse and other provisions.

27 Article 95(6) of July 2013 Amendments.

6. Poland

The Health Ministry introduced legislative proposals in June 2013 designed to improve the efficiency and transparency of the supply chain and help authorities better anticipate, and respond to, potential supply shortages. The main proposals are:

- New definition of the "public service" obligation on marketing authorisation holders and wholesalers to bring it into line with Article 81 of Directive 2001/83. This prioritizes patient needs rather than stakeholders rights and will permit alternative distribution schemes (e.g., direct to pharmacy arrangements), which were previously disputed;
- Improved reporting channels designed to ensure that stakeholders can more easily exchange information with the relevant authorities;
- Creation of a "supply shortages" list which will be regularly monitored and updated;
- Obligation on wholesalers to pre-notify the planned exports of medicines included on the "supply shortages" list;
- Authorities can prevent the export of those medicines if there is a risk of supply shortage and/or threat to patient safety;
- Pharmacies convicted of illegal wholesaling activities no longer subject to criminal penalties but administrative penalties;
- Imposition of additional reporting obligations on wholesalers and pharmacists concerning their finances and business partners including the power to order a tax audit and exchange of information between government bodies.

7. Portugal

On 5 September 2013, the Government published amendments to the Medicines Law in order to reduce the risk of supply shortages. It introduces the following amendments:

- Obligation on wholesalers to ensure they have sufficient quantity and variety of medicines to guarantee adequate and continuous supply in order to secure patients' needs;
- The relevant national authority (INFARMED) has the power to define, *via* regulation, the minimum quantities, or the criteria to determine the minimum quantities of medicines, necessary for MAHs and wholesalers to guarantee continuous supply to satisfy local demand;
- Obligation on wholesalers to pre-notify INFARMED between 5 and 20 days in advance of its intention to export those medicines which have been included on a specific public list of "at risk" medicines. INFARMED can prohibit the export in circumstances where it is necessary for protection of public health or to guarantee patient access to medicines and in accordance proportionality and appropriateness principles. The decision must be taken within three days of notification.

In November 2013, two new pieces of legislation were published introducing additional obligations in respect of a specific list of 47 medicinal products (Seretaide and Avamys included):

- Obligation on MAHs to provide INFARMED with data on volumes sold to wholesalers and/or pharmacies on a monthly basis;

- Obligation on wholesalers to provide INFARMED with data on volumes sold to pharmacies on a monthly basis;
- Obligation on pharmacies to provide INFARMED with data on volumes dispensed on a monthly basis;
- Obligation on all stakeholders to provide advance notification to INFARMED on intention to export medicines. In line with the October amendments, INFARMED can prohibit such export in certain circumstances.

8. Romania

In April 2013, the Romanian government introduced an export ban in respect of 22 dedicatory INNs which is due to expire on 31 December 2013 unless extended.

On 13th of April 2013, the Romanian government introduced mandatory monthly reporting obligation on MAHs and wholesalers in respect of medicine volumes introduced onto the Romanian market and sold by wholesalers/importers.

On 5 November, the Romanian government published revised proposals to amend Law 95/2006 on Healthcare Reform. The current proposals include:

- Obligation on pharmacies to provide INFARMED with data on volumes dispensed on a monthly basis;
- Obligation on all stakeholders to provide advance notification to INFARMED on intention to export medicines. In line with the October amendments, INFARMED can prohibit such export in certain circumstances.
- New administrative penalties for breach of regulatory obligations;
- Obligation on MAHs to notify the Drug Agency at least 6 months in advance in the event of a temporary or permanent cessation or disruption in supply of a medicine;
- Obligation on MAHs/other stakeholders to notify the relevant authorities of a medicine's sales volume and prescription volume in Romania.
- Obligation on all supply chain stakeholders to declare to relevant authority all sponsorship activities and any other expenses incurred in relation to healthcare professionals and/or medical association; and
- A national company - Unifarm - can purchase public medicines without being subject to public tender rules.

9. Slovakia

Under Slovak law, medicinal products can be exported by (a) manufacturing license holders, and (b) wholesale distribution license holders. Recent amendments to Act No. 362/2011 Coll. (Medicinal Products and Medical Devices) concerning the export of medicinal products came into force on 2 January 2013 and provide:

- Wholesale distribution licensees[28] must inform the State Institute for Drug Control ("SIDC") of their intention to export medicines 30 days prior to date of intended export;[29]
- Export can only occur if the SIDC does not object within 30 days of notification (silence is considered as acquiescence), and export must take place within 3 months of the date of notification;[30]
- The SIDC can only object to exports on the grounds that they will jeopardise security of supply of that human drug and the provision of healthcare in Slovakia.[31]

10. Spain

On 11 October 2013, the government published Spanish Royal Decree 782/2013 on the distribution of medicinal products for human use ("Royal Decree 782/2013").[32] It authorizes the relevant authority to take necessary remedial action, including the imposition of an export ban, where there is a risk of supply shortages in respect of medicines for which there is no available therapeutic substitute registered in Spain.

[28] Medicinal products can also be exported by drug manufacturing license holders. They are not subject to the notification requirements.
[29] The notification must include certain data including the drug serial code; the package size and number of packages, the batch number and destination country and planned export date.
[30] The SIDC can request additional information from the distributor but the 30 days time period does not lapse (see Article 19a(4)).
[31] See Article 19(a), Act No. 362/2011 Coll. (Medicinal Products and Medical Devices).
[32] It develops existing regulations on the supply of medicinal products foreseen in (i) Article 68 of Spanish Law 29/2006, Guarantees and Rational Use of Medicinal products and Medical Devices (July 2006) and in (ii) Royal Decree 2259/1994 on wholesalers and wholesale distribution of medicinal products (November 1994.)