



Preventing shortages due to parallel trade in Spain : a proportionate approach

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Some initial thoughts

- Shortages are an **important public health issue** because of its impact on patients
- **Main reasons in Spain** for shortages of medicinal products (authorised and marketed):
 - Manufacturing problems
 - Distribution issues: **parallel trade** or export to 3rd countries
 - Commercial reasons
- **National Competent Authorities** must try to ensure adequate supply of medicinal products



**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

(OJ L 311, 28.11.2001, p. 67)

Article 81

With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.



**EU legal frame:
ensuring supply**



Our previous scenario

- National **legal frame** included MAHs/ distributors obligations
 - To keep the **market supplied** (Law 29 /2006)
 - To **notify any export** of medicinal products for human use to AEMPS (Law 29 /2006)
- An **IT system** was developed by AEMPS to cross export notifications vs current shortages (2008)
- Comprehensive **information on shortages** was **published** in our website (2009)
- **Shortages due to parallel trade** accounted a high percentage of total shortages



TFUE: Free movement of goods in the EU but restrictions are possible when justified

CHAPTER 3

PROHIBITION OF QUANTITATIVE RESTRICTIONS BETWEEN MEMBER STATES

Article 34

(ex Article 28 TEC)

Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 35

(ex Article 29 TEC)

Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.

Article 36

(ex Article 30 TEC)

The provisions of Articles 34 and 35 shall not preclude prohibitions or **restrictions** on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; **the protection of health and life of humans,** animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

CONSOLIDATED VERSION

OF

THE TREATY ON THE FUNCTIONING OF THE

EUROPEAN UNION

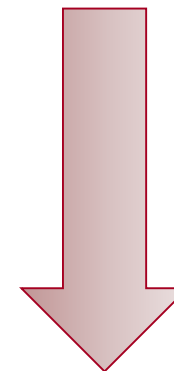
Introduction of restrictions for parallel trade in the Spanish legal frame

2010:

“The shipment of medicinal products of human use authorized in Spain to **other Members States** shall require a **previous notification** to the Spanish Agency of Medicines and Medical Devices, in agreement with the **instructions** that will be issued with this regard” (Article 54.5 of RD 824/2010) <http://www.boe.es/buscar/doc.php?id=BOE-A-2010-10827>

Pilot Project 1354/10/ENTR

Detailed information about
the future system and the reasons
for including every medicinal product were sent to EC



2012:

The notification system started in **July 2012** (Instruction 2/2012)

Notifications before sending medicinal products to other Members States (Instruction 2/2012)

Who must send them ?

- **Wholesale distributors** (MAHs and manufacturers only if required by AEMPS)

When?

- At least **3 days** before the shipment departure

How?

- Through **an electronic system**

Which medicinal products?

- Only those whose lack may cause a **healthcare problem** (included in a list published at AEMPS website)

<https://labofar.aemps.es/labofar/registro/medicamentosEEE/consulta.do?metodo=detalleBusqueda>



Our current list (1)

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD		agencia española de medicamentos y productos sanitarios		Medicamentos sujetos a notificación previa	
38 filas, mostrando desde 1 a 20. [<</<] 1, 2 [>/>>]					
Número de Registro	Medicamento	Código Nacional	Presentación		
61250	HAVRIX 1440, SUSPENSION INYECTABLE EN JERINGA PRECARGADA	676858	HAVRIX 1440, SUSPENSION INYECTABLE EN JERINGA PRECARGADA, 1 jeringa precargada de 1 ml		
33209	LEUKERAN 2 mg	917583	LEUKERAN 2 mg , 100 comprimidos		
33209	LEUKERAN 2 mg	779470	LEUKERAN 2 mg, 50 comprimidos		
33209	LEUKERAN 2 mg	917583	LEUKERAN 2 mg , 100 comprimidos		
33209	LEUKERAN 2 mg	779470	LEUKERAN 2 mg, 50 comprimidos		
57726	LIXACOL 400 mg COMPRIMIDOS	979054	LIXACOL 400 mg 100 comprimidos		
52146	MADOPAR 250 mg COMPRIMIDOS	669770	MADOPAR 250 mg comprimidos , 100 comprimidos		
41137	MELFALAN ASPEN 2 mg	941476	MELFALAN ASPEN 2 mg, 50 comprimidos		
80570	MERCAPTOPYRINA SILVER 50 MG COMPRIMIDOS	709752	MERCAPTOPYRINA SILVER 50 MG COMPRIMIDOS , 24 comprimidos		
97051004	MIRAPEXIN 0,18 mg comprimidos	659920	MIRAPEXIN 0,18 mg comprimidos, 100 comprimidos		
97051003	MIRAPEXIN 0,18 mg comprimidos	659912	MIRAPEXIN 0,18 mg comprimidos, 30 comprimidos		
97051014	MIRAPEXIN 0,26 mg comprimidos de liberación prolongada	664188	MIRAPEXIN 0,26 mg comprimidos de liberación prolongada, 30 comprimidos		
97051006	MIRAPEXIN 0,7 mg comprimidos	659946	MIRAPEXIN 0,7 mg comprimidos, 100 comprimidos		
97051005	MIRAPEXIN 0,7 mg comprimidos	659938	MIRAPEXIN 0,7 mg comprimidos, 30 comprimidos		
97051020	MIRAPEXIN 1,05 mg comprimidos de liberación prolongada	664189	MIRAPEXIN 1,05 mg comprimidos de liberación prolongada, 30 comprimidos		
97051023	MIRAPEXIN 2,1 mg comprimidos de liberación prolongada	664190	MIRAPEXIN 2,1 mg comprimidos de liberación prolongada, 30 comprimidos		
52602	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE	789347	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE , 1 ampolla de 1 ml		
52602	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE	789354	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE , 5 ampollas de 1 ml		
52602	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE	789347	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE , 1 ampolla de 1 ml		
52602	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE	789354	MODECATE 25 mg/ml SOLUCIÓN INYECTABLE , 5 ampollas de 1 ml		

[Histórico de listados de medicamentos sujetos a notificación previa de acuerdo a Circular 2/2012](#)

[Circular 2/2012: Notificación previa de envíos de medicamentos a otros Estados miembros](#)

<https://labofar.aemps.es/labofar/registro/medicamentosEEE/consulta.do?metodo=detalleBusqueda>



38 filas, mostrando desde 21 a 38.

[<</>] 1, 2 [>/>>]

Número de Registro	Medicamento	Código Nacional	Presentación
18498	MYSOLINE	656560	MYSOLINE, 100 comprimidos
46454	NUVACTHEN DEPOT 1 mg /1 ml	797191	NUVACTHEN DEPOT 1 mg /1 ml , 3 ampollas
63189	PROGRAF 0,5 mg CAPSULAS DURAS	888065	PROGRAF 0,5 mg 30 cápsulas duras
61006	PROGRAF 1 mg CAPSULAS DURAS	680645	PROGRAF 1 mg 30 cápsulas duras
61006	PROGRAF 1 mg CAPSULAS DURAS	885780	PROGRAF 1 mg 60 cápsulas duras
61006	PROGRAF 1 mg CAPSULAS DURAS	680645	PROGRAF 1 mg 30 cápsulas duras
61006	PROGRAF 1 mg CAPSULAS DURAS	885780	PROGRAF 1 mg 60 cápsulas duras
61005	PROGRAF 5 mg CAPSULAS DURAS	680660	PROGRAF 5 mg 30 cápsulas duras
55866	SINEMET PLUS 25/100 mg COMPRIMIDOS	700579	SINEMET PLUS 100 comprimidos
51794	SINEMET 25/250 mg COMPRIMIDOS	654763	SINEMET 25/250 mg COMPRIMIDOS, 120 comprimidos
51794	SINEMET 25/250 mg COMPRIMIDOS	654762	SINEMET 25/250 mg COMPRIMIDOS, 60 comprimidos
51794	SINEMET 25/250 mg COMPRIMIDOS	654763	SINEMET 25/250 mg COMPRIMIDOS, 120 comprimidos
51794	SINEMET 25/250 mg COMPRIMIDOS	654762	SINEMET 25/250 mg COMPRIMIDOS, 60 comprimidos
58859	TERBASMIN TURBUHALER 500 microgramos/inhalacion POLVO PARA INHALACION	692382	TERBASMIN TURBUHALER 500 microgramos/inhalacion POLVO PARA INHALACION , 1 inhalador de 100 dosis
08470005	VIMPAT 100 mg COMPRIMIDOS	661369	VIMPAT 100 mg COMPRIMIDOS, 56 comprimidos
08470008	VIMPAT 150 mg COMPRIMIDOS	661370	VIMPAT 150 mg COMPRIMIDOS, 56 comprimidos
08470011	VIMPAT 200 mg COMPRIMIDOS	661372	VIMPAT 200 mg COMPRIMIDOS, 56 comprimidos
08470001	VIMPAT 50 mg COMPRIMIDOS	661368	VIMPAT 50 mg COMPRIMIDOS, 14 comprimidos

[Histórico de listados de medicamentos sujetos a notificación previa de acuerdo a Circular 2/2012](#)

[Circular 2/2012: Notificación previa de envíos de medicamentos a otros Estados miembros](#)

Agencia Española de Medicamentos y Productos Sanitarios

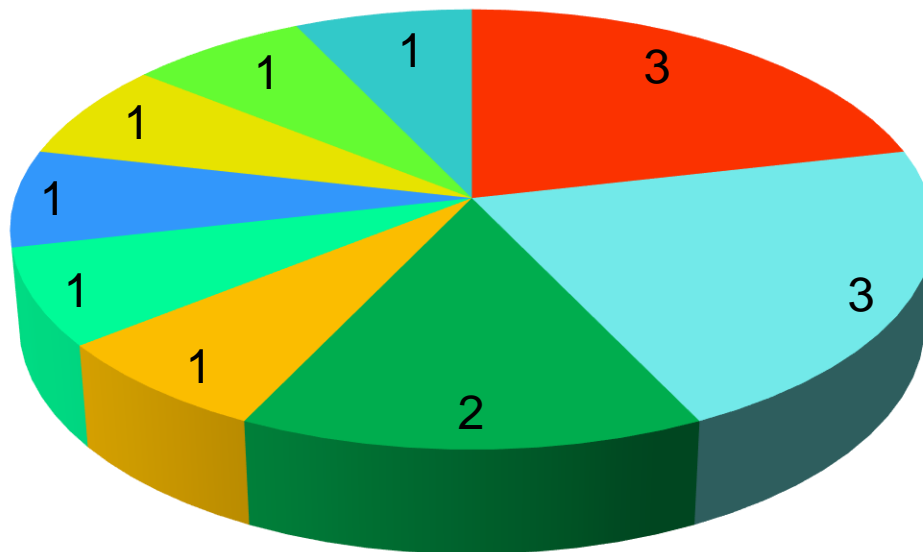
C/ Campezo, 1 (Edificio 8) - 28022 MADRID | e-Mail: consultas.labofar@aemps.es

- **14 medicinal products (38 pharmaceutical presentations)***
- The list is updated according to healthcare needs (it has been already updated **in 8 ocasiones**)



* The current number of authorised medicinal products is **13.804** and **30.306** presentations

Therapeutic groups of the medicinal products included



- Antineoplasics:3
- Antiparkinsonians :3
- Antiepileptic :2
- Vaccines:1
- Intestinal anti-inflammatory :1
- Antipsychotics :1
- Hormone:1
- Immunosuppressive:1
- Adrenergic Inhalators:1

AEMPS actions

- Every 6 months MAHs of the products in the list are requested to send **information about supply and demand:**
 - Expected quantities to be placed on the market during the next 6 months
 - Average-sales of the last 12 months
- An individual assessment is performed after **every notification** and a decision is taken **quickly (max. 3 days)**
- When the shipment may result in a shortage AEMPS notifies the **wholesaler and customs inspectors that it can't proceed**

Decisions on notifications received 2012-2017

545 notifications received

4 in 2012 → 4 not allowed

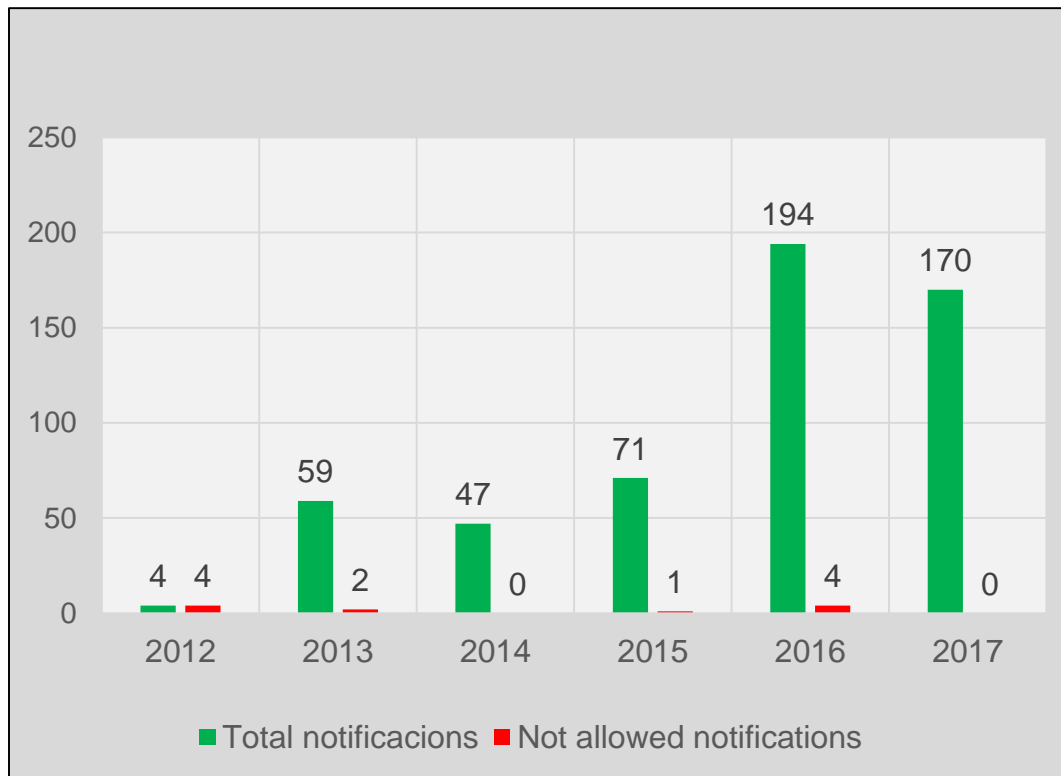
59 in 2013 → 2 not allowed

47 in 2014 → All allowed

71 in 2015 → 1 was not allowed

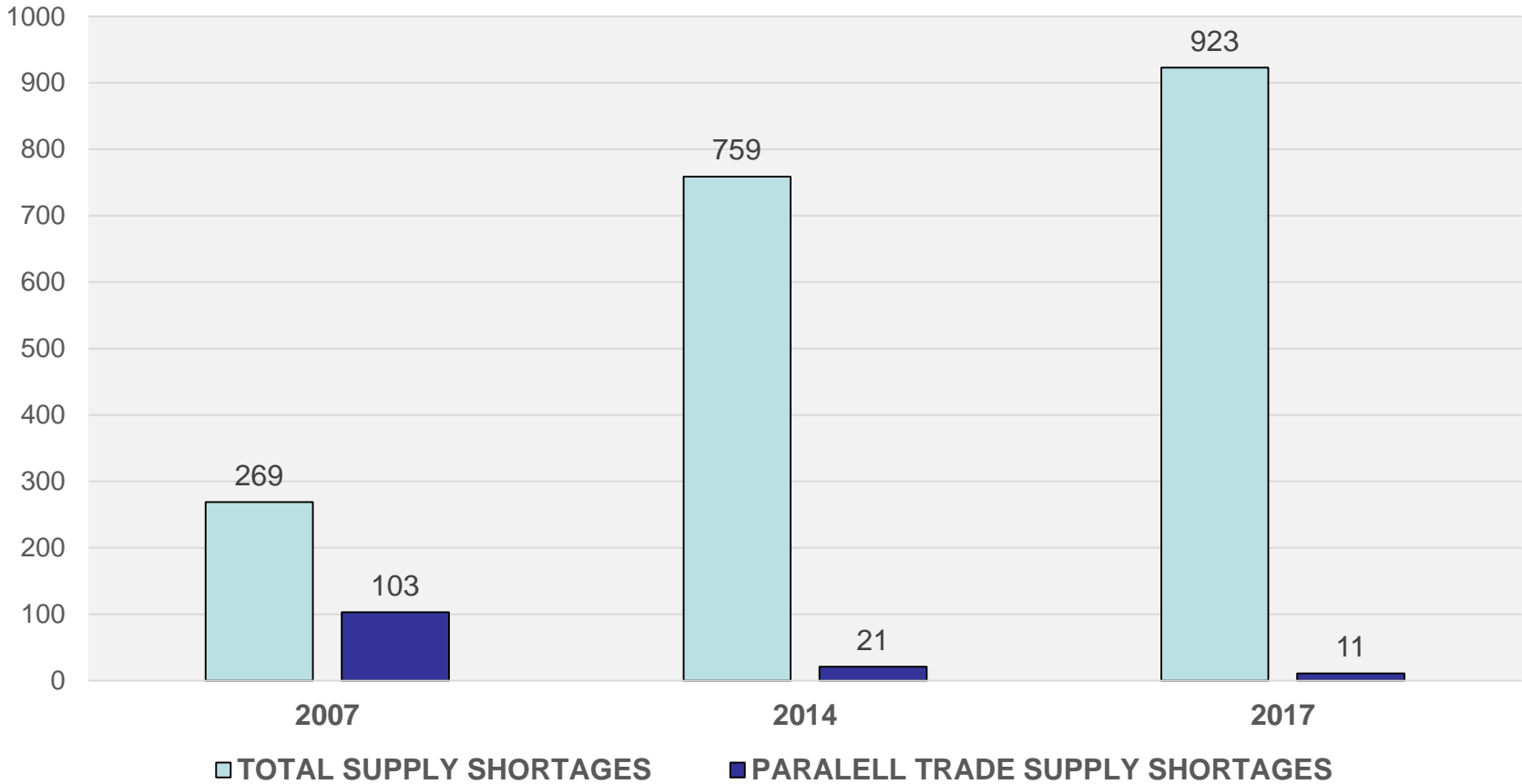
194 in 2016 → 4 were not allowed

170 in 2017 → All allowed



Only 11 shipments were not allowed (2%)

The number of shortages due to parallel trade has decreased in Spain





Final thoughts

- The system is being effective and still allows parallel trade of the products included in the list when sufficient quantities to meet patients needs remain on the market
- In Spain shortages due to parallel trade have decreased but not only due to this notification system
- The measures have proven to be proportionate and reinforce patient protection



Благодаря!