



# The fighting in Spain against counterfitting: the Directive and the Delegated Act

**Belén Escribano**

Head of the Pharmaceutical Inspection  
and Enforcement Department



# Overview

- Background
- Directive implementation in Spain
- The Delegated Act
- Final thoughts



# Are falsified medicinal products a real risk?

- No falsified medicinal products have been found in the legal supply chain in Spain
- But in the illegal supply chain the answer is **yes!**





# Reasons for action

## Active substances (AS) & excipients

- Risks to public health posed by falsified (adulterated) and low quality AS
- Most AS manufactured in third countries: impossible to inspect all sites
- Absence of harmonized control and supervision on manufacturers, importers and distributors of AS across EU
- Lack of provisions concerning quality of excipients

## Medicinal Products (MP) distribution

- Increase of cases of falsified MP in the legal supply chain: very difficult to identify
- Global increase of illegal MP trade
- Lack of control of some actors involved in the supply chain

## Distance sales of MP

- Internet is the main way in the EU to access falsified MPs



# AEMPS has been proactive against the risks of falsified medicinal products

– 2 National Strategies have been implemented involving all stakeholders:

- 2008 -2011
- 2012-2015



Includes actions for all stakeholders!





## AEMPS activities not limited to the implementation of FMD provisions...

L 174/74

EN

Official Journal of the European Union

1.7.2011

### DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114, and point (c) of Article 168(4), thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of

medicinal products from other illegal medicinal products, as well as from products infringing intellectual property rights. Furthermore, medicinal products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms 'active substance' and 'excipient' should also be defined.

(6) Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with Directive 2001/83/EC. However, today's distribution network for medicinal products is increasingly complex and involves many players who are not necessarily wholesale distributors as referred to in that Directive. In order to ensure the reliability of the supply chain, legislation in relation to medicinal products

**But also:**

- **Active cooperation with EC in delegated and implementing acts & EMA tasks**
- **Promotion of the coordination and harmonization of EEMM: HMA Task Force**



## FMD transposition: new legal framework in Spain

- Update of our Law on guarantees and rational use of medicinal products and medical devices
- New Royal Decree on medicinal products for human use distribution
- Update of the Royal Decree that regulates the manufacture of medicinal products and active substances
- New Royal Decree on Internet sales of non-prescription medicinal products





# Public Registry of manufacturers, importers and distributors of active substances (since July 2014)

[www.aemps.gob.es](http://www.aemps.gob.es)

AEMPS - Registro Unificado de Empresas de Sustancias Activas<br><i>Register of Manufacturers, I - Windows Internet Explorer

https://labofar.aemps.es/labofar/registro/ruesa/consulta.do

Favoritos Servicios Intranet de la AE... Sitios sugeridos Galería de Web Slice

AEMPS - Registro Unificado de Empre...

GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

### Registro Unificado de Empresas de Sustancias Activas

Register of Manufacturers, Importers and Distributors of Active Substances

Búsqueda de empresas y/o sustancias / Search of companies and/or active substances

Nombre de la empresa / Name of the company

Nombre de la sustancia activa / Name of active substance

Buscar / Search

158 filas, mostrando desde 1 a 50.

<</> 1. 2. 3. 4 [2/22]

Empresa / Company	Dirección / Address	Localidad / Location
ABELLO LINDÉ, S.A.	C/ Bailén, 105	Barcelona
ACEITES ESPECIALES DEL MEDITERRANEO S.A.	LOS PARALES S/N, SECTOR 1, VALLE DE ESCOMBRERAS	CARTAGENA
ACOFARMA DISTRIBUCION S.A.	c/ Llobregat 20, Pol. Santa Margarita	TERRASSA
Air Líquide Ibérica de Gases	PASEO DE LA CASTELLANA 35	MADRID
ALCOA FARMAS, S.A.	Avenida de Madrid, 82	Alcalá de Henares
ALCALIBER, S.A.	PLAZA DE COLÓN, 2 - TORRE 1, PLANTA 13	MADRID
ALFARIN QUIMICA, S.A.	CALLE IBIZA 35 - 5ª C	MADRID
ALGRY QUIMICA, S.L.	POL. IND. NUEVO PUERTO	PALOS DE LA FRONTERA
ALMIRALL, S.A.	Ronda General Mitre, 151	Barcelona
ANDERSEN, S.A.	Avda. de la Uana, nº 123, Pol. Ind. La Uana	Rubi
ANDRES DINTAUBA, S.A.	C/ Prudenci Bertrana, 5, Pol. Ind. Agro-Reus	Reus
ANTIBIOTICOS S.A.	Avenida de Antibióticos, 59-61	León
AUSOCHEM, S.L.	C/ ARIBAU, 123, 2ª 3ª	BARCELONA
AZELIS ESPAÑA S.A.	World Trade Center Alameda Park, Playa de la Pau, s/n, Edificio 8, 1ª Planta	Cornellá de Llobregat
BALEAR DE MEDICAMENTOS, S.A.	C/ Río Amo 10-12 Ca'n Negre 139 (Polígono Ca'n Buf)	Santa Eulàlia del Riu
BAMA GEVE, S.L.U.	Avda. Diagonal, 490 - 4º, 2ª	Barcelona
BAYER HISPANIA, S.L.	Avda. Baix Llobregat, 3 y 5	Sant Joan Despi
BCN PEPTIDES, S.A.	Polígono Industrial Els Vinyets-Els Fogars Sector II	Sant Quintí de Mediona
BIOIBERICA, S.A.	Ctra. Nacional II, Km 680,6	Palafolls
BIONORICA EXTRACTS, S.L.	AVDA. ES RAIGUER, S/N	CONSELL
BIOQUIM, S.A.	C/Alemanyà nº 1, Pol. Ind. Pla de Llerona	Les Franqueses
BIOSEARCH, S.A.	Camino de Puchil, 66	Granada
BOEHRINGER INGELHEIM ESPAÑA, S.A.	C/ Prat de la Ribá, 56	Sant Cugat del Vallés
BOAL QUIMICA, S.A.	C/ NICARAGUA, 79	BARCELONA
BRENTAG QUIMICA S.A.U.	CALLE TORRE DE LOS HERBEROS 10, POLIGONO INDUSTRIAL LA ISLA	DOS HERMANAS
Carall S.L.U.	Marie Curie, 6	Martorell
CENTRO COOPERATIVO FARMACÉUTICO, S.C.L. (CECOFAR)	Polígono Industrial El Pino, C/ Pino Central Nº 38	Sevilla
CHENO IBERICA, S.A.	Gran Vía Carlos III, 96, 7ª	Barcelona
CHEMISWISS IBERICA S.L.	C/ ROSSELLÓ 188 4º b	Barcelona
COFARES DEL NOROESTE Y DEL CANTABRICO S.A.	Parque Empresarial Piedadela C-6, Parcela1-108	Betanzos
COFARES SURESTE S.A.	Santa Engracia, 31	Madrid
COFARES SUROESTE S.A.	C/ Joaquín Sánchez Valverde 14	Badajoz
COMERCIAL ANÓNIMA VICENTE FERRER, S.A.U. (C.A. VICENTE FERRER)	C/Cabanyes num. 51-57 del Polígono Industrial Can Salvatella	BARBERÀ DEL VALLÈS
COMPANIA FARMACÉUTICA MADRILEÑA, S.A.	C/Batalla de Brunete, 15	PUBLABRADA
COOPERATIVA D'APOTECARIS S.C.L.	AVDA. 16 DE JULIO, 23	PALMA DE MALLORCA

Listo pero con errores en la página.

Intranet local | Modo protegido: desactivado

ES 11:29 25/09/2014

Information  
of 183  
companies





## Increased information about distribution and brokering of medicinal products in our website

The screenshot shows the website of the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) in a Windows Internet Explorer browser. The address bar shows the URL: [http://www.aemps.gob.es/industria/distribucion\\_medicamentos/home.htm](http://www.aemps.gob.es/industria/distribucion_medicamentos/home.htm). The website header includes the AEMPS logo and navigation links. The main content area is titled 'Industria' and features a sidebar with various links. The main text area is titled 'Distribución de medicamentos y Catálogo de entidades de distribución' and includes a paragraph about the distribution chain and a list of links to various documents and catalogs. The bottom of the browser window shows the taskbar with various application icons and the system clock.

Agencia Española de Medicamentos y Productos Sanitarios - Industria - Distribución de medicamen - Windows Internet Explorer

[http://www.aemps.gob.es/industria/distribucion\\_medicamentos/home.htm](http://www.aemps.gob.es/industria/distribucion_medicamentos/home.htm)

Favoritos | Servicios Intranet de la AE... | Sitios sugeridos | Galería de Web Slice

Agencia Española de Medicamentos y...

Bienvenidos | Benvinguts | Ongi etorri | Benvidos | Benvinguts | Welcome

Buscar

Síguenos: Imprimir Mapa web Contactar Enlaces

La AEMPS | Medicamentos de uso humano | Medicamentos veterinarios | Productos sanitarios | Cosméticos e higiene | **Industria**

Portada de industria

Registro de medicamentos

Registro de Laboratorios Farmacéuticos

Etiquetado y prospectos

CIMA: Centro de Información Online de Medicamentos de la AEMPS

Notas informativas

Principios activos

Inspección de normas de correcta fabricación

Inspección de buenas prácticas de laboratorio

Inspección de buena práctica clínica

Inspección de buenas prácticas de farmacovigilancia

**Distribución de medicamentos y Catálogo de entidades de distribución**

Inicio > Industria

**Distribución de medicamentos y Catálogo de entidades de distribución**

Última actualización: 15/10/2014

La cadena de distribución de medicamentos, desde su fabricación o importación hasta su dispensación tiene una importancia crítica en el mantenimiento de las garantías de la calidad del medicamento. Por ello, todos los eslabones de la cadena de distribución deben cumplir con la normativa y documentos de referencia aplicables con el fin de que los medicamentos se conserven, transporten y suministren en las condiciones adecuadas.

- [Legislación sobre laboratorios farmacéuticos y entidades de distribución](#)
- [Nuevas buenas prácticas de distribución de la UE](#)
- [Formatos de autorización y certificación de entidades de distribución](#)
- [Catálogo de entidades de distribución](#)
- [Entidades de intermediación de medicamentos de uso humano \(Bróker\)](#)
- [Comprobación de la legalidad de proveedores y clientes](#)
- [Instrucciones para la comunicación de sospechas de uso indebido de medicamentos o su desvío al tráfico ilícito](#)

Catálogo de entidades de distribución

Registro de entidades de intermediación de medicamentos de uso humano (Bróker)

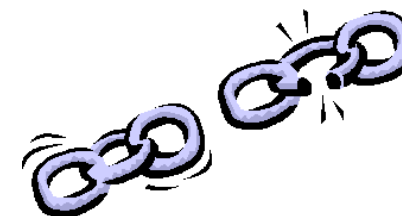
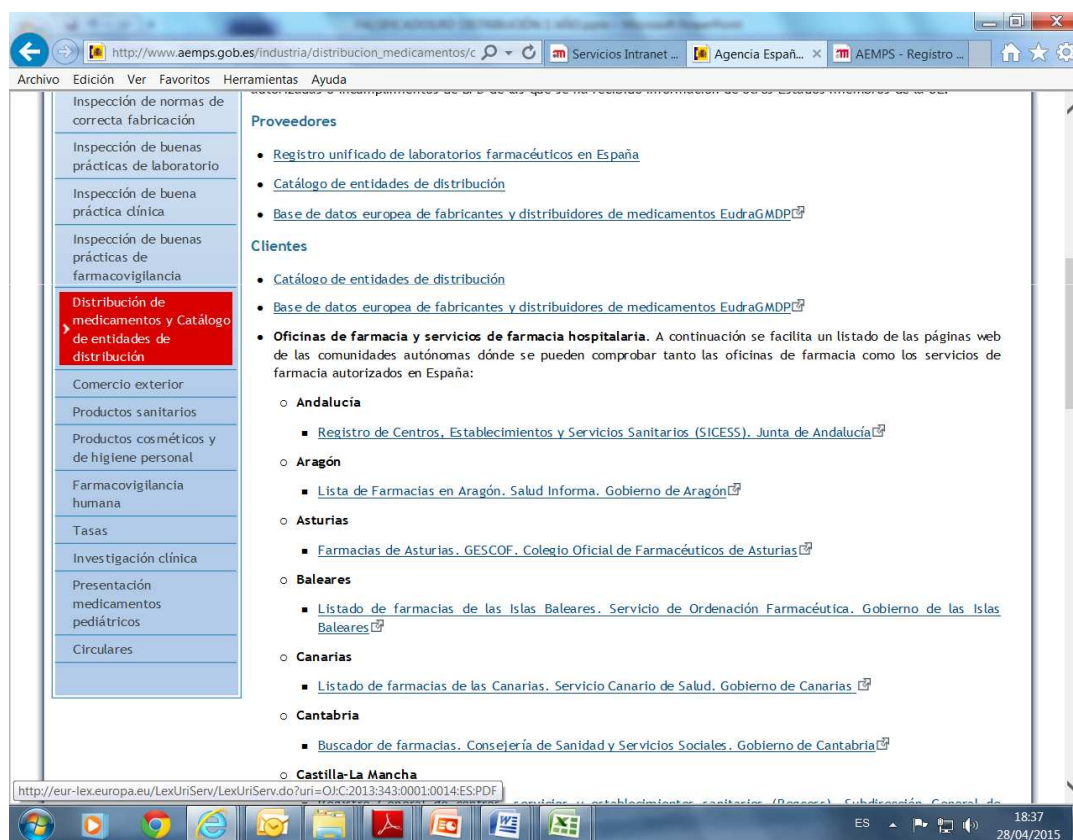
Intranet local | Modo protegido: desactivado

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# Support for the verification of suppliers and customers

## GDP requirement essential for the safety of the supply chain!



Links to facilitate the verification of all stakeholders involved in the supply chain of medicinal products are provided in our website **www.aemps.gob.es**



## Public Registry of brokers

Agencia Española de Medicamentos y Productos Sanitarios - Industria - Distribución de medicamen - Windows Internet Explorer

http://www.aemps.gob.es/industria/distribucion\_medicamentos/entidades-intermediacion-MUH-brokers/re

Bienvenidos | Benvinguts | Ongi etorri | Benvidos | Welcome | Benvinguts

Buscar  Aceptar

Síguenos: Imprimir Mapa web Contactar Enlaces

La AEMPS Medicamentos de uso humano Medicamentos veterinarios Productos sanitarios Cosméticos e higiene **Industria**

Inicio » Industria » Distribución de medicamentos y Catálogo de entidades de distribución

» Registro entidades de intermediación de medicamentos de uso humano (Bróker)

Última actualización: 10/09/2014

REGISTRO ENTIDADES DE INTERMEDIACIÓN DE MEDICAMENTOS DE USO HUMANO (BRÓKER)	
Número de registro	BR-001-ES
Razón social	ORIANI PHARMA IBERIA S.L.U.
Persona de contacto	PhilippeOllivier
Dirección	C/Buenaventura Muñoz 35, ático 1ª, 8018, Barcelona
Número de registro	BR-002-ES
Razón social	MEDIFARM CONSULTING IBERICA, S.L.
Persona de contacto	Olivier Tarelli
Dirección	C/ Sagrada Familia nº.10, 8810, Sant Pere de Ribes, Barcelona
Número de registro	BR-003-ES
Razón social	JOSÉ ESTÉVEZ ALLEN C.B.
Persona de contacto	José Estevez Nieto
Dirección	Primer de Mayo, 22 Bajo, 37004, Salamanca
Número de registro	BR-004-ES
Razón social	YESFAL SERVICES, S.L.
Persona de contacto	José María Rovira Anglada
Dirección	Avda. Jordá, 26, 08035, Barcelona

Listo Intranet local | Modo protegido: desactivado 100% 16:24 25/09/2014

16 companies  
registered



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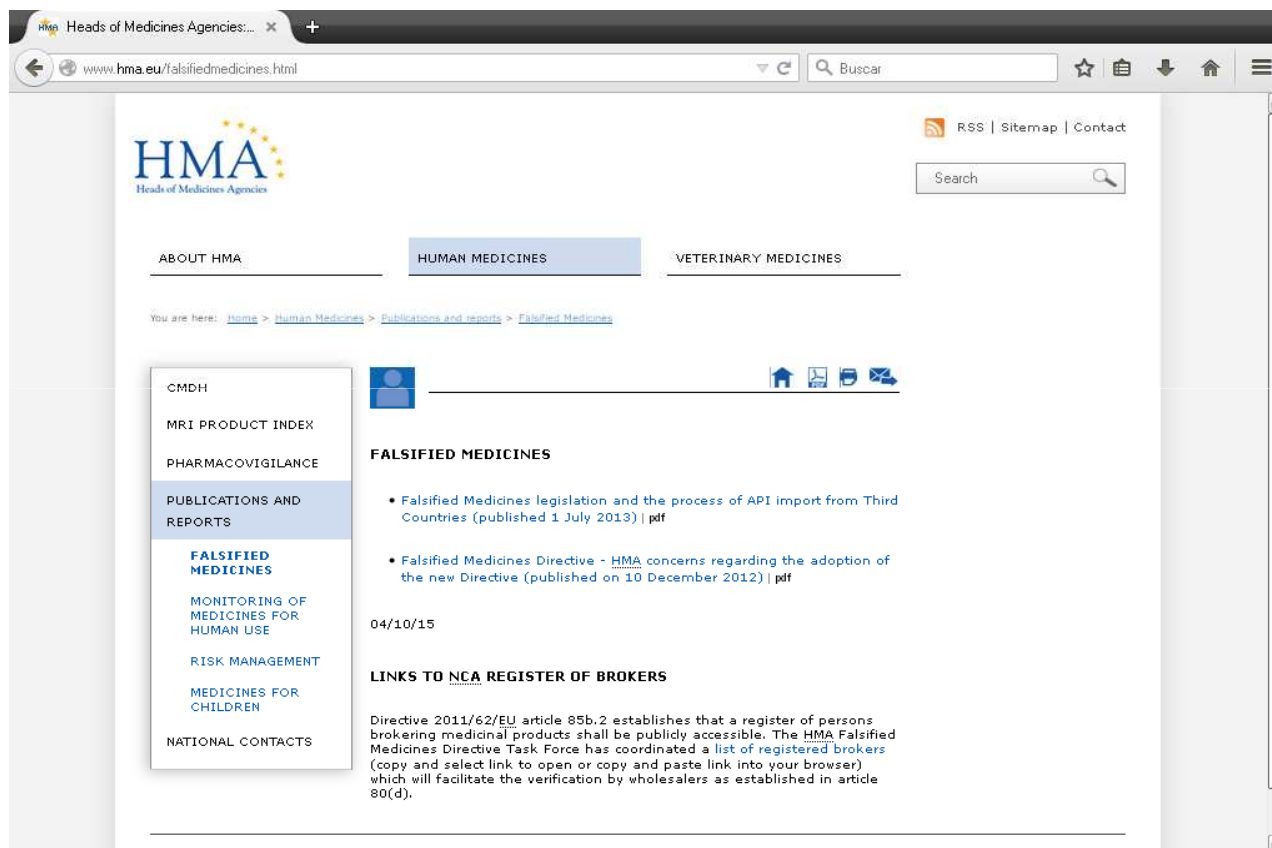


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medicamentos y  
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## Links to 23 national registries of brokers included at HMA website



Activity promoted by TF HMA FMD

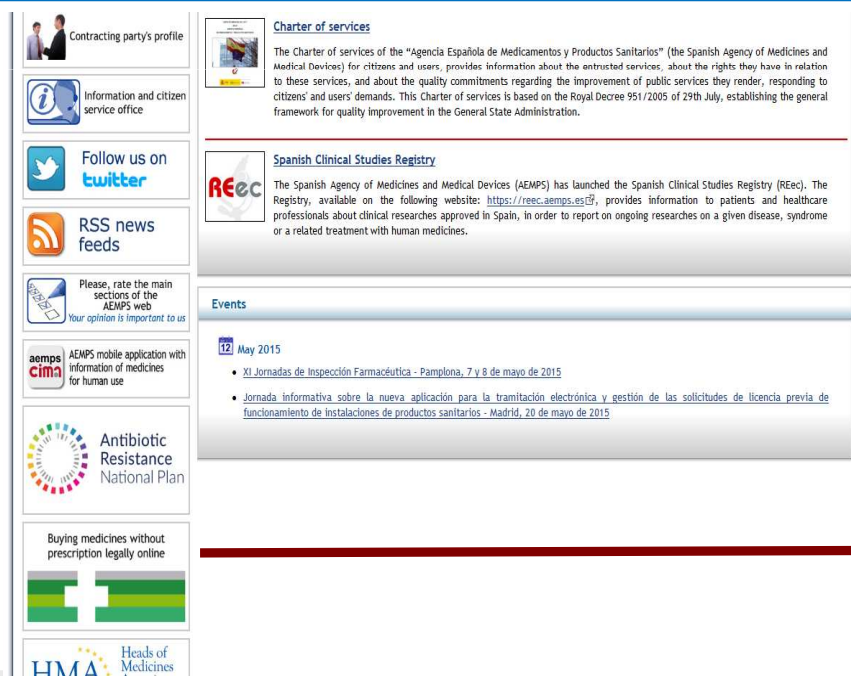




## Distant sales: DISTAFARMA

The portal website, active since 1<sup>st</sup> July 2015, has been developed by AEMPS and is used by the 17 autonomous regions

<http://www.aemps.gob.es/en/home.htm>



The screenshot shows the AEMPS website home page. On the left is a sidebar with links: 'Contracting party's profile', 'Information and citizen service office', 'Follow us on twitter', 'RSS news feeds', 'Please, rate the main sections of the AEMPS web', 'AEMPS mobile application with information of medicines for human use', 'Antibiotic Resistance National Plan', and 'Buying medicines without prescription legally online'. The main content area includes 'Charter of services', 'Spanish Clinical Studies Registry' (with a REEC logo), and an 'Events' section for May 2015 listing two events. At the bottom left of the main area is a link to 'Buying medicines without prescription legally online' with a green cross icon. A red arrow points from this link to a separate box on the right.

Buying medicines without  
prescription legally online

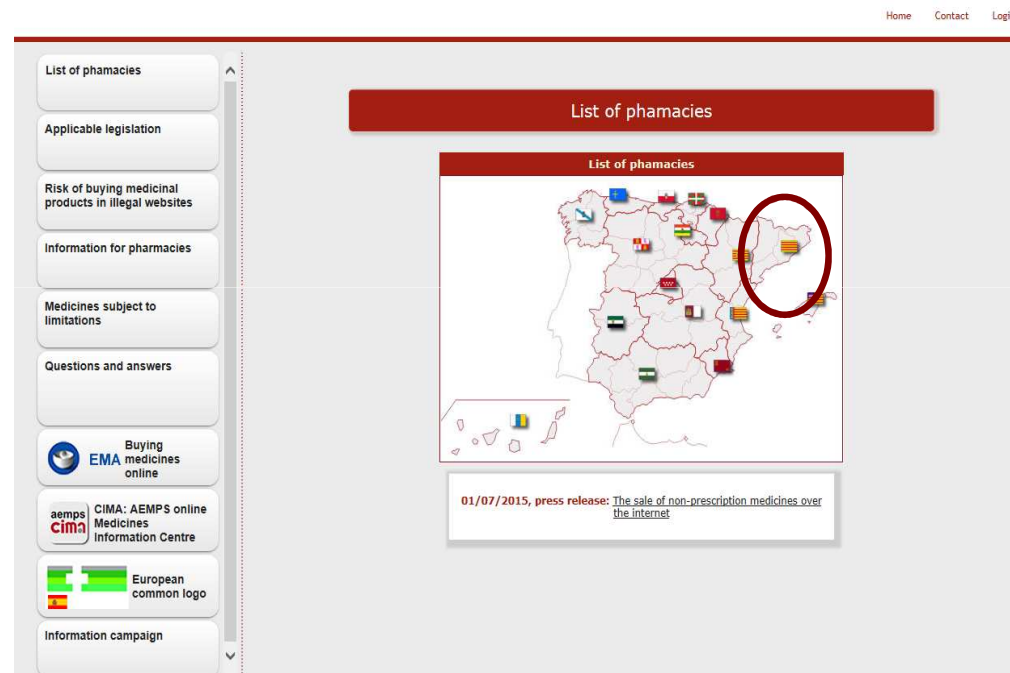






# DISTAFARMA:content

- Clicking on each region it is possible to access to the list of authorized pharmacies
- In the left side there is information related to:
  - Relevant national legislation
  - Purpose of the EU logo
  - Information on the risks of purchasing medicines illegally from the Internet
  - A link to the website established by the European Medicines Agency (EMA)





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# DISTAFARMA: Regional Authority site

Generalitat de Catalunya  
Departament de Salut

Venta a distancia al público a través de sitios web de medicamentos de uso humano no sujetos a prescripción médica

Inici Accés usuaris registrats

LLISTAT ACTUALITZAT D'OFICINES DE FARMÀCIA

Provincia: Seleccione una opción Actualitzar filtre  
Localitat: Netejar filtre

Cognoms, Nom	Domicili	Localitat Província	Enllaç Web Telèfon
D'OCÓN NAVEZA, JOAQUIN	Carrer Santa Fe, 5	RIELLS I VIABREA GERONA	<a href="http://www.farmaciaonline.com">http://www.farmaciaonline.com</a> 938 472 204
ARNIGES GÓMEZ, M <sup>a</sup> VICTORIA	Avinguda Mediterrània, 3	MALGRAT DE MAR BARCELONA	<a href="http://www.farmaciaarniges.com">http://www.farmaciaarniges.com</a> 937 654 479
POICH SABATER, JOSEP MARIA	Carrer del Mar, 25	SANT PERE PESCADOR GERONA	<a href="http://www.farmaciacostabrava.com">http://www.farmaciacostabrava.com</a> 972 520 015
Ruiz Fernandez, Pedro	Carrer de la Ciutat d'Elx, 11	BARCELONA BARCELONA	<a href="http://www.farmaciasaorera.com">http://www.farmaciasaorera.com</a> 933 497 840
Gelabert Camprubi, Ramon	Carrer Rubió i Ors, 128	CORNELLÀ DE LLOBREGAT BARCELONA	<a href="http://farmafamily.es">http://farmafamily.es</a> 933 772 482
Morales Guarch, Maria Dolors	Carrer Rambla, 165	SABADELL BARCELONA	<a href="http://www.farmaciamorales.cat">http://www.farmaciamorales.cat</a> 937 250 518
BARRANCO NICOLAS, ESTHER	Carretera de Cardener, 55	CALLÚS BARCELONA	<a href="https://www.farmanostra.cat">https://www.farmanostra.cat</a> 938 360 077
GALCERA PIÑOL, MONICA	Passeig Marítim, 249	CASTELLDEFELS BARCELONA	<a href="http://www.farmaplava.com">http://www.farmaplava.com</a> 936 657 409

OFICINAS DE FARMACIA  
Gestió de comunicacions

- Comunicación previa
- Estado comunicación
- Información general

EMA Venta a distancia

agencia española de medicamentos y productos sanitarios Venta a distancia

Logotipo común europeo

Legislación aplicable

Riesgos de la compra de medicamentos en sitios web ilegales

Medicamentos con limitaciones

Catalunya  
Barcelona  
(BARCELONA)

Telèfon  
93598344

Correu Electrònic  
mrbana@agencat.cat

ES 14:34  
21/10/2015

## LISTED PHARMACIES

Name of the owner of the pharmacy  
Physical address  
Link to the website  
Telephone number

PROCEDURE OF  
NOTIFICATION BY THE  
PHARMACY







## DISTAFARMA: Current situation (20/10/2015)

**106** pharmacies have been  
**listed** so far out of a total of  
more than 21.000  
pharmacies in Spain

**New notifications: 29**

**Pending of validation: 32**





# Safety Features

- **With the purpose of verify:**
  - Authenticity & identify individual packs
  - Whether the outer packaging has been tampered with



UNIQUE IDENTIFIER (UI)



ANTITAMPERING DEVICE (ATD)

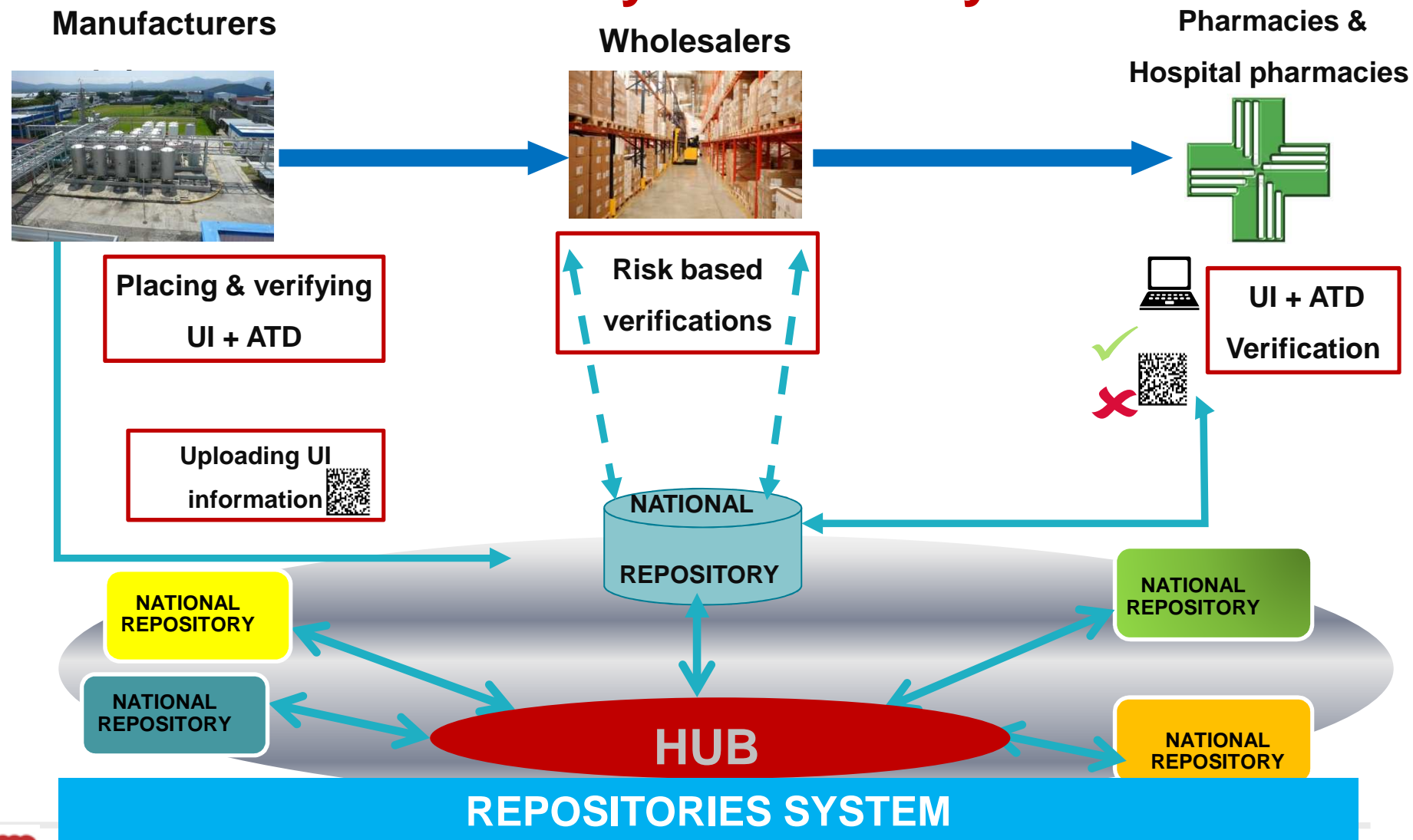
- **To be borne by:**
  - Medicinal products subject to **prescription** unless **low** falsification risk

**Not for medicinal products without prescription unless at risk of falsification**

- **Commission delegated act expected for the first term of 2016**



# Future Safety Features System





# Some challenges for the future system

- 28 +3 countries: a huge pharmaceutical market with hundreds of thousands of medicinal products
- Adequate connection, interoperability and permanent synchronisation of all repositories of the repository system
- System accessible by hundreds of thousands users
- Quick answer needed for the verifications
- Proportionate effort for all stakeholders



## Final thoughts

*The new requirements should effectively decrease the risks of falsified medicinal products and:*

- Increase the **quality** of medicinal products (active substances & excipients)
- **Reinforce** the supply chain against penetration of falsified medicinal products/active substances
- Provide **protection** for our citizens when buying medicinal products in Internet
- Allow **detection** of falsified medicinal products before they reach the patients



**ENSURE THE AVAILABILITY OF SAFE PRODUCTS!**



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**Thank you!**

