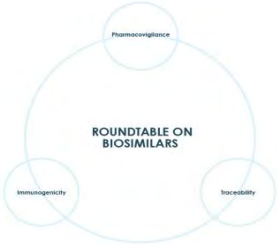


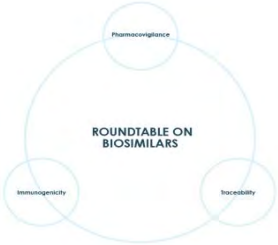
Olga Delgado Sanchez, PharmD

- Head of Pharmacy Department, Coordinator of Pharmacy, Health Products and Medicines Policy, University Hospital Son Espases, Palma de Mallorca, Spain

GaBI Scientific Meetings

ROUNDTABLE ON BIOSIMILARS
Pharmacovigilance, Traceability, Immunogenicity

15 November 2016, Real Academia Nacional de Farmacia, Madrid, Spain



Pharmacist perspective Biosimilars: something more than clinical evidence

Olga Delgado Sanchez, PharmD, Spain

15 November 2016

GaBi
GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

Universidad de Alcalá

PPCI
Pro Pharma Communications International

Generics and Biosimilars Initiative (GaBI)

Building trust in cost-effective treatments

ROUNDTABLE ON BIOSIMILARS

Pharmacovigilance, Traceability, Immunogenicity

Organized in collaboration with Universidad de Alcalà

Pharmacist Perspective

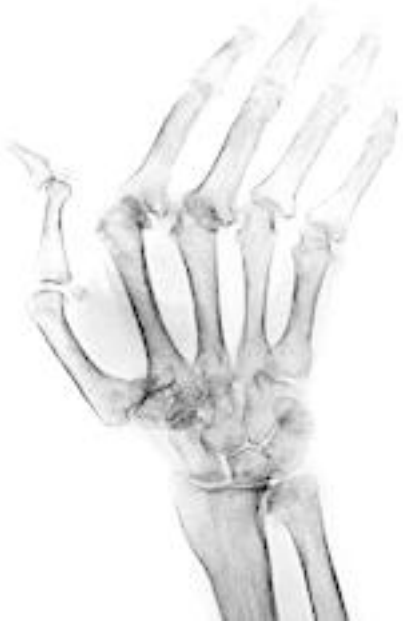
Olga Delgado
Spanish Society of Hospital Pharmacy

Meeting Date: 15 November 2016, Tuesday

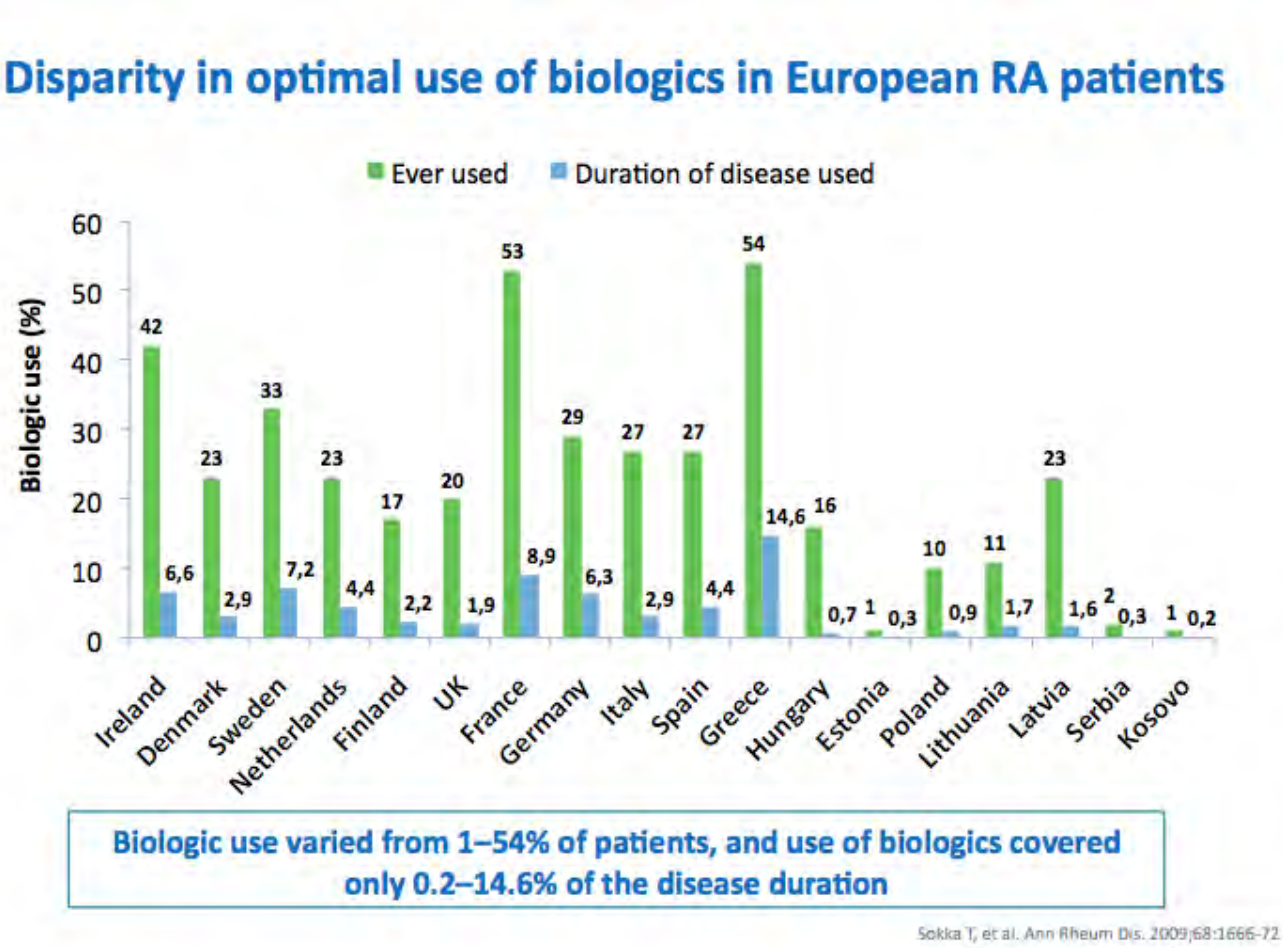
Meeting Location: Room Aula Santos Ruiz, G/F, Real Academia Nacional de Farmacia, Madrid, Spain

reflexiones sobre lo que sabemos a estas horas

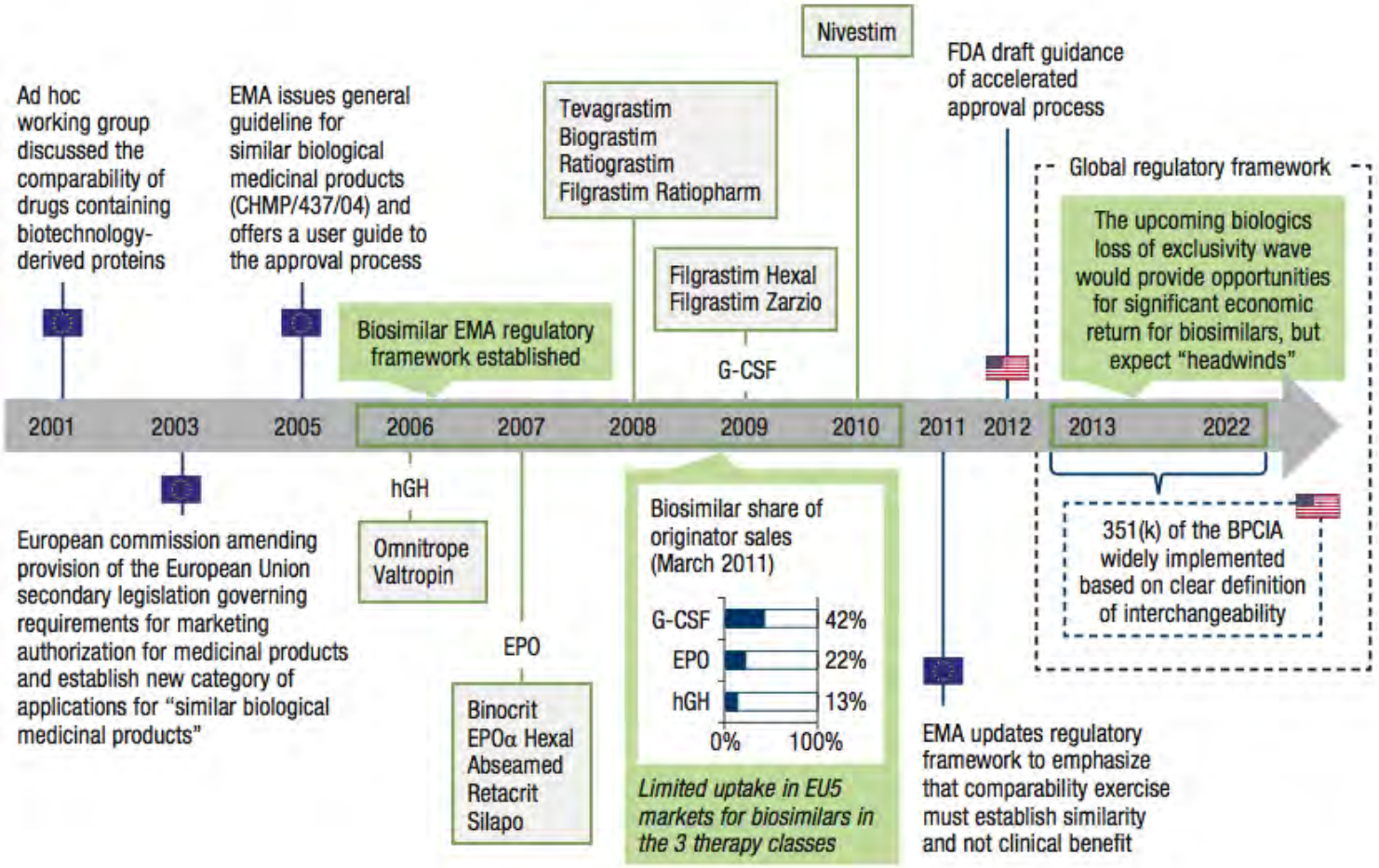
1 Biológicos



1 Biológicos con limitación uso

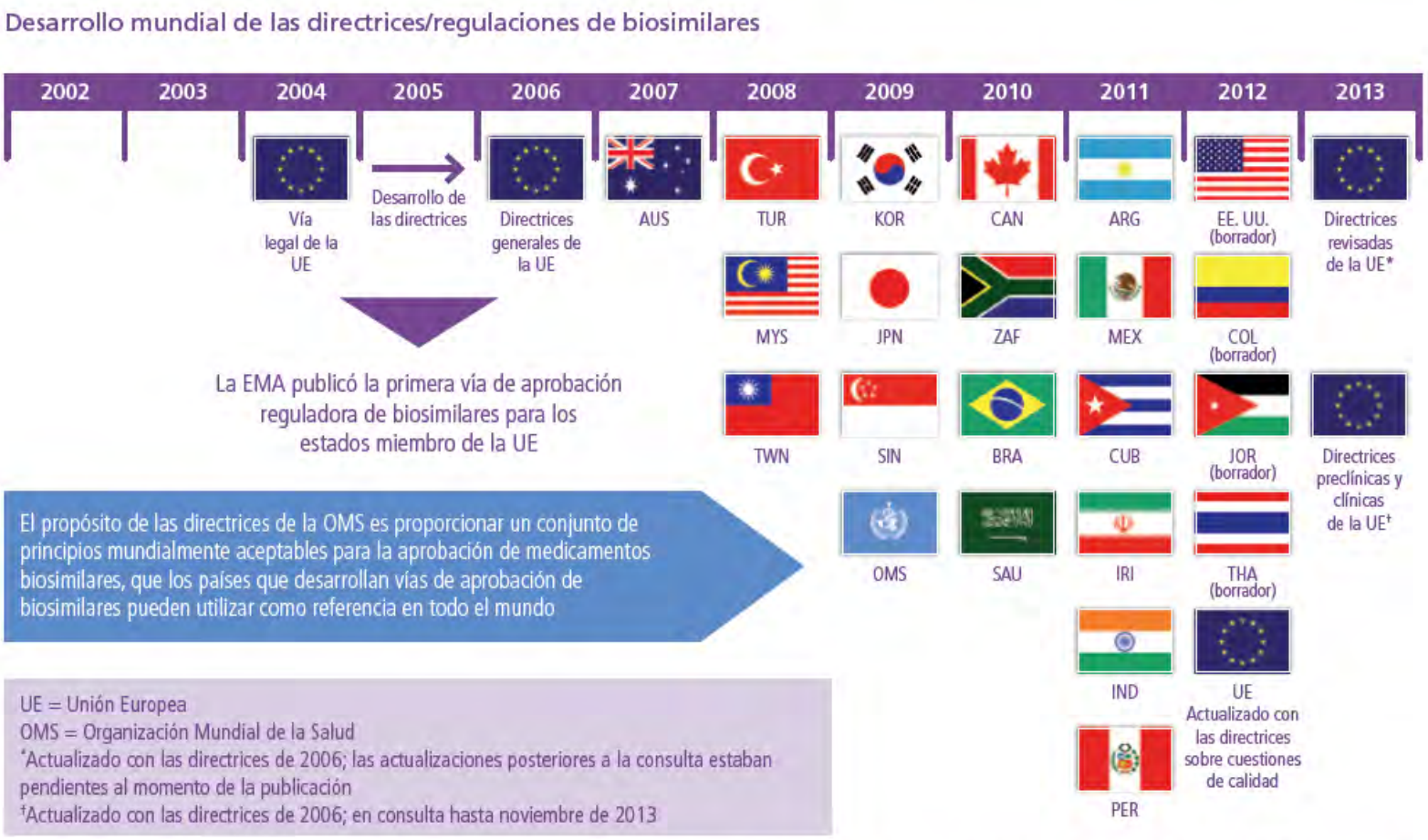


2 madurez regulatoria



Demonstrating Value for Biosimilars: A Conceptual Framework Sotiris Rompas, PhD; Thomas Goss, PharmD; Sally Amanuel, BSc, MA, MBA; Victoria Coutinho, BSc, PhD; Zhihong Lai, PhD; Paola Antonini, MD, PhD; Michael F. Murphy, MD, PhD Am Health Drug Benefits. 2015;8(3):129-139

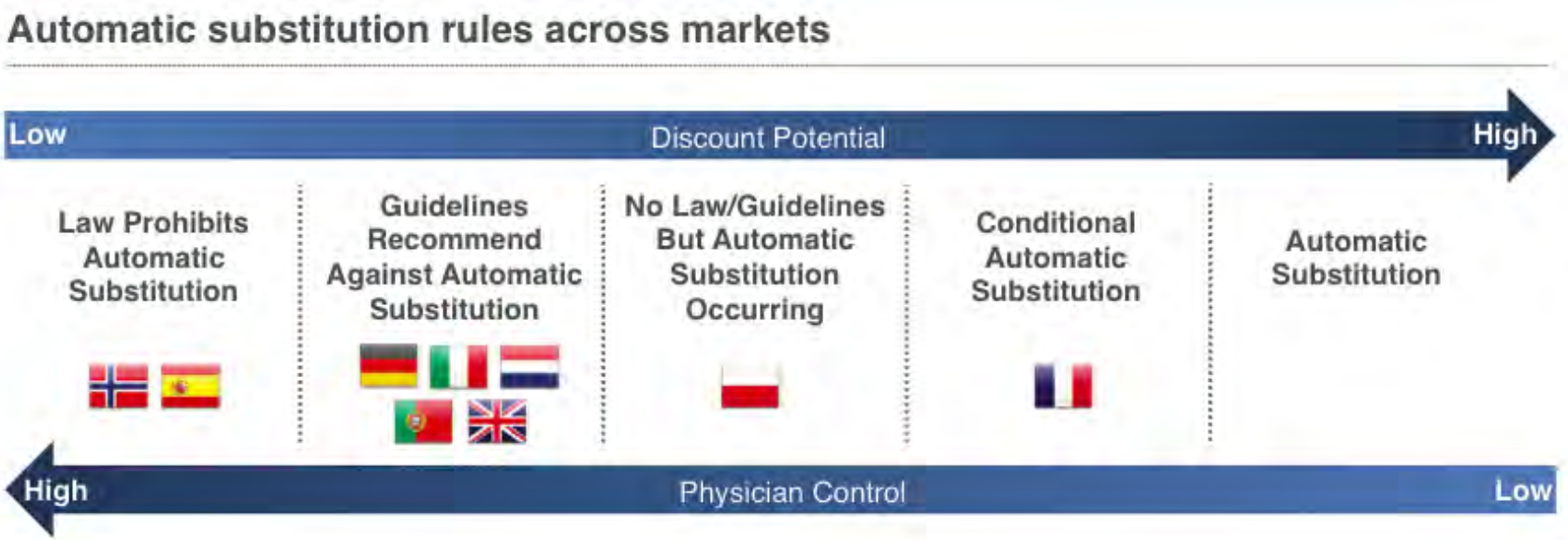
2 madurez regulatoria



[Adaptado de los plazos provistos por Amgen. Fuente de datos: información disponible públicamente por las autoridades nacionales sanitarias y las directrices reguladoras de la OMS]

https://www.iapo.org.uk/sites/default/files/files/IAPO_Biosimilars_Factsheet_3_ES.pdf

Sustitución e Intercambio



Impacr-of Market-Access-Factors-Across-Europe.

Interchangeability

FDA will have the authority to determine whether the biosimilar product is interchangeable with the reference product based upon data submitted in the application. To be deemed interchangeable, a biosimilar's "risk of safety and diminished efficacy" will need to be ascertained by "alternating or switching" between the two products in multiple administrations. In the end, the risk of using the biosimilar cannot be higher than that of the reference product if interchangeability is to be allowed. The risk evaluation and mitigation regulations as outlined in the *Federal Food, Drug, and Cosmetic Act* also apply to biosimilars.

- FDA contempla la designación de intercambiable entre biosimilares
- El farmacéutico puede cambiarlos sin prescripción médica específica
- Mayor introducción mercado, mejor acceso y ahorro económico

Listado de Medicamentos No Sustituibles: Biológicos

2.054 filas, mostranto desde 701 a 725.

[<</<] 25, 26, 27, 28, **29**, 30, 31, 32 [>/>>]

Código Nacional	Número de Registro	Medicamento	Nombre del Formato	COD_PA	Principios Activos	Código ATC	Nombre ATC	Tipo
608687	56029	HEPARINA SODICA CHIESI 5000 UI/ml	HEPARINA SODICA CHIESI 5000 UI/ml, 100 viales de 5 ml	1706SO	HEPARINA SODICA	B01AB01	Heparina	Biológicos
641639	58693	HEPARINA SODICA ROVI 25.000 UI SOLUCION INYECTABLE VIAL	HEPARINA SODICA ROVI 25.000 UI SOLUCION INYECTABLE VIAL , 100 viales de 5 ml	1706SO	HEPARINA SODICA	B01AB01	Heparina	Biológicos
994822	58693	HEPARINA SODICA ROVI 25.000 UI SOLUCION INYECTABLE VIAL	HEPARINA SODICA ROVI 25.000 UI SOLUCION INYECTABLE VIAL , 1 vial de 5 ml	1706SO	HEPARINA SODICA	B01AB01	Heparina	Biológicos
994806	58691	HEPARINA SODICA ROVI 5.000 UI SOLUCION INYECTABLE VIAL	HEPARINA SODICA ROVI 5.000 UI SOLUCION INYECTABLE VIAL , 1 vial de 5 ml	1706SO	HEPARINA SODICA	B01AB01	Heparina	Biológicos
641647	58691	HEPARINA SODICA ROVI 5.000 UI SOLUCION INYECTABLE VIAL	HEPARINA SODICA ROVI 5.000 UI SOLUCION INYECTABLE VIAL , 100 viales de 5 ml	1706SO	HEPARINA SODICA	B01AB01	Heparina	Biológicos
664609	70955	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION, 1 vial de 10 ml	3848HW	INMUNOGLOBULINA HUMANA ANTIHEPATITIS B	J06BB04	Inmunoglobulina antihepatitis B	Biológicos
682628	70955	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION, 1 vial de 100 ml	3848HW	INMUNOGLOBULINA HUMANA ANTIHEPATITIS B	J06BB04	Inmunoglobulina antihepatitis B	Biológicos
664608	70955	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION, 1 vial de 2 ml	3848HW	INMUNOGLOBULINA HUMANA ANTIHEPATITIS B	J06BB04	Inmunoglobulina antihepatitis B	Biológicos
664610	70955	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION	HEPATECT 50 UI/ml SOLUCION PARA PERFUSION, 1 vial de 40 ml	3848HW	INMUNOGLOBULINA HUMANA ANTIHEPATITIS B	J06BB04	Inmunoglobulina antihepatitis B	Biológicos
903674	00145001	HERCEPTIN 150 mg POLVO PARA CONCENTRADO PARA SOLUCION PARA PERFUSION	HERCEPTIN 150 mg POLVO PARA CONCENTRADO PARA SOLUCION PARA PERFUSION, 1 vial	1168A	TRASTUZUMAB	L01XC03	Trastuzumab	Biológicos
699409	100145002	Herceptin 600 mg/5ml solucion inyectable	Herceptin 600 mg/5ml solucion inyectable 1 vial de 5 ml	1168A	TRASTUZUMAB	L01XC03	Trastuzumab	Biológicos

3 solidez clínica y económica

J Crohns Colitis. 2016 Sep 22. pii: jjw166. [Epub ahead of print]

Switching from Remicade® to Remsima® is safe and feasible: a prospective, open-label study.

Buer LC[1], Moum BA[2], Cvancarova M[3], Warren DJ[4], Medhus AW[5], Høivik ML[5].

⊕ Author information

Abstract

BACKGROUND AND AIMS: A biosimilar version of infliximab (CT-P13/Remsima®) recently entered the European market. The clinical data on its use in inflammatory bowel disease are sparse, especially on switching from the originator Remicade®. In this study, we aimed to prospectively investigate the feasibility, safety and immunogenicity of switching from Remicade® to Remsima® in a real-life IBD population.

METHODS: All adult patients who were treated with Remicade® in the Department of Gastroenterology at Oslo University Hospital were switched to Remsima®. The follow-up lasted for 6 months. In addition, a retrospective registration was performed with a start time of 6 months before switching drugs. The primary endpoints were i) the proportion of patients remaining on medication 6 months after switching and ii) adverse events during the 6 months after switching. The secondary endpoints included i) disease activity scores (Harvey-Bradshaw Index and Partial Mayo Score), C-reactive protein, haemoglobin, faecal calprotectin, Infliximab dose and interval, p-infliximab and ii) the development of antidrug antibodies.

RESULTS: In total, 143 IBD patients were switched, 99 with Crohn's disease and 44 with ulcerative colitis. The large majority (97%) remained on the medication throughout follow-up. A low number of adverse events were observed. No change in disease activity, C-reactive protein, haemoglobin, faecal calprotectin, Infliximab dose and interval or p-Infliximab was detected. Three patients developed new detectable antidrug antibodies.

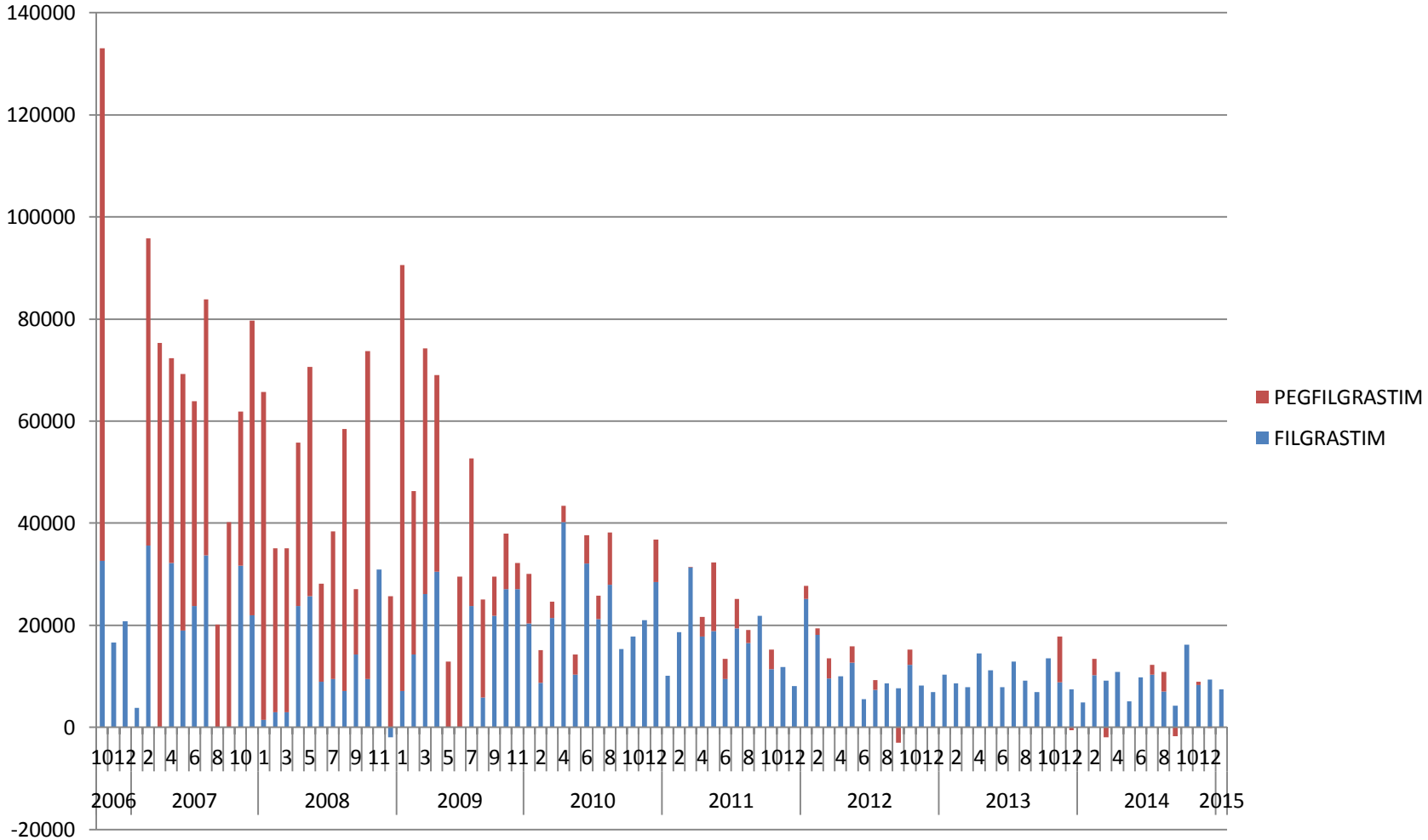
CONCLUSIONS: Our study demonstrated that switching from Remicade® to Remsima® was feasible and with few adverse events, including very limited antidrug antibody formation and loss of response.

Biosimilares disminuyen precio todo el grupo

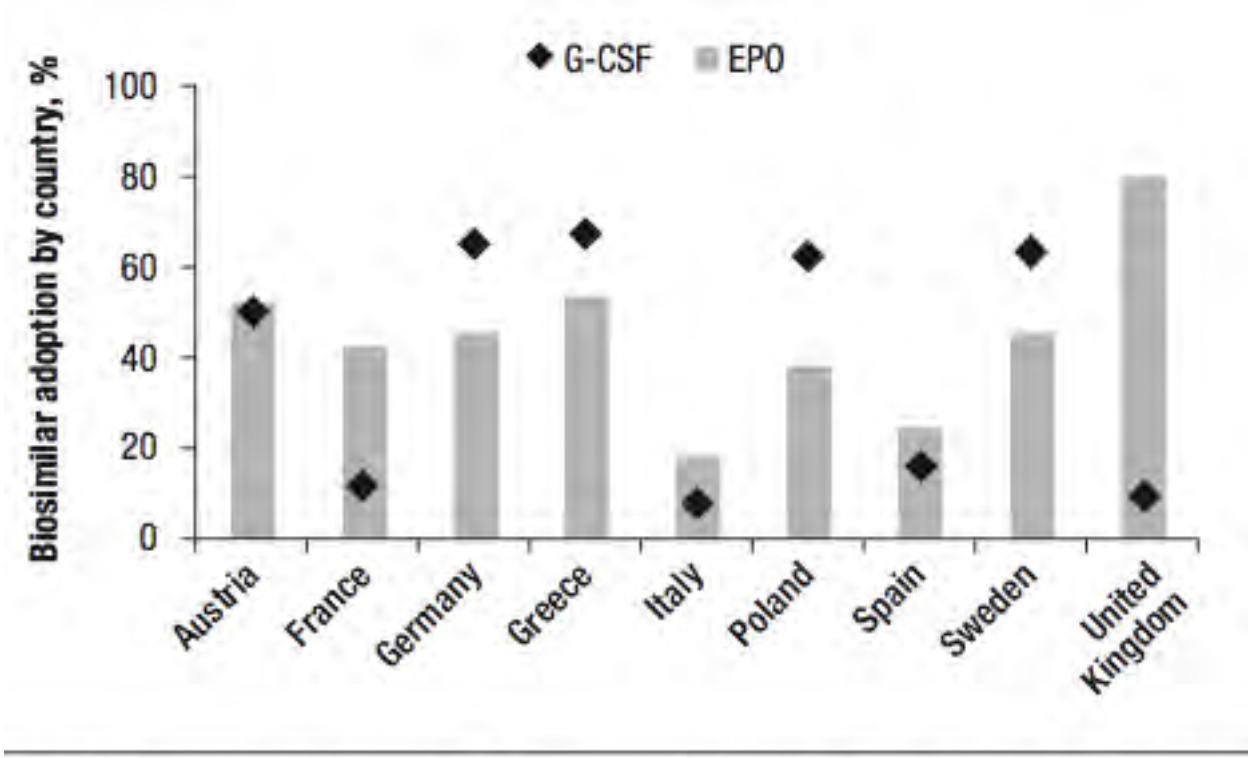
	Price per TD 2015/ Year before Biosimilar entrance		
	Biosimilar and Reference product	Accessible market	Total market
EPO	-33%	-34%	-26%
G-CSF	-32%	-32%	-23%
GH	-19%	-13%	-13%
Anti-TNF	-8%	-8%	-4%

IMS Impact of Biosimilar Competition 2016.

Evolución del gasto en factores estimulantes de colonias de granulocitos HUSE



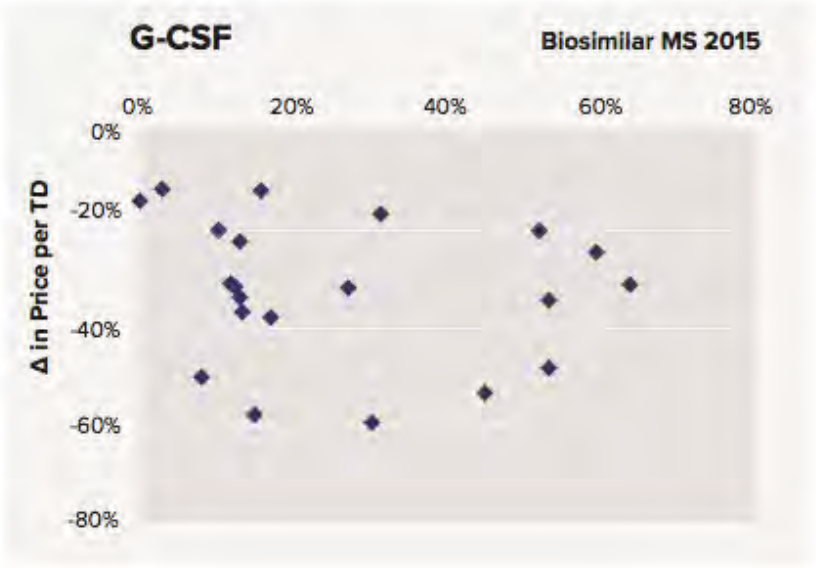
Penetración histórica EU

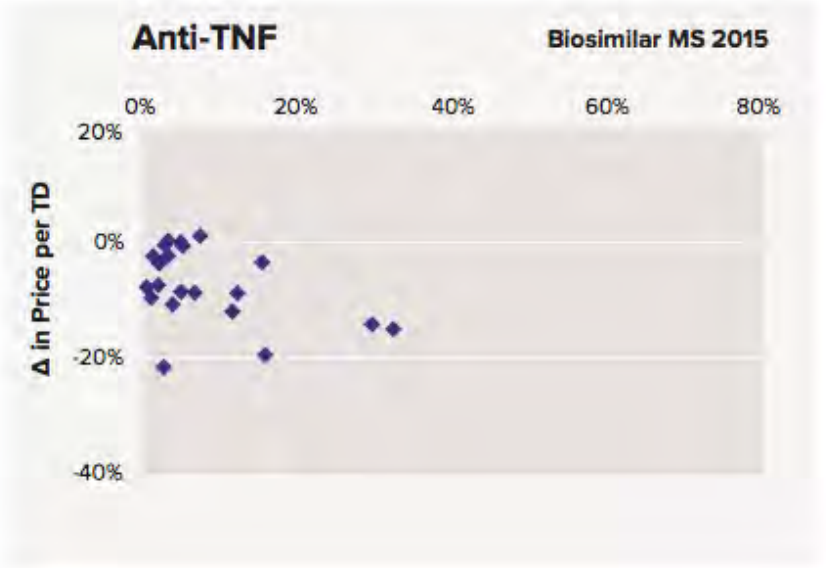


EPO indicates epoetin; G-CSF, granulocyte colony-stimulating factor.

Demonstrating Value for Biosimilars: A Conceptual Framework Sotiris Rompas, PhD; Thomas Goss, PharmD; Sally Amanuel, BSc, MA, MBA; Victoria Coutinho, BSc, PhD; Zhihong Lai, PhD; Paola Antonini, MD, PhD; Michael F. Murphy, MD, PhD Am Health Drug Benefits. 2015;8(3):129-139

Penetración no se relaciona con bajada coste



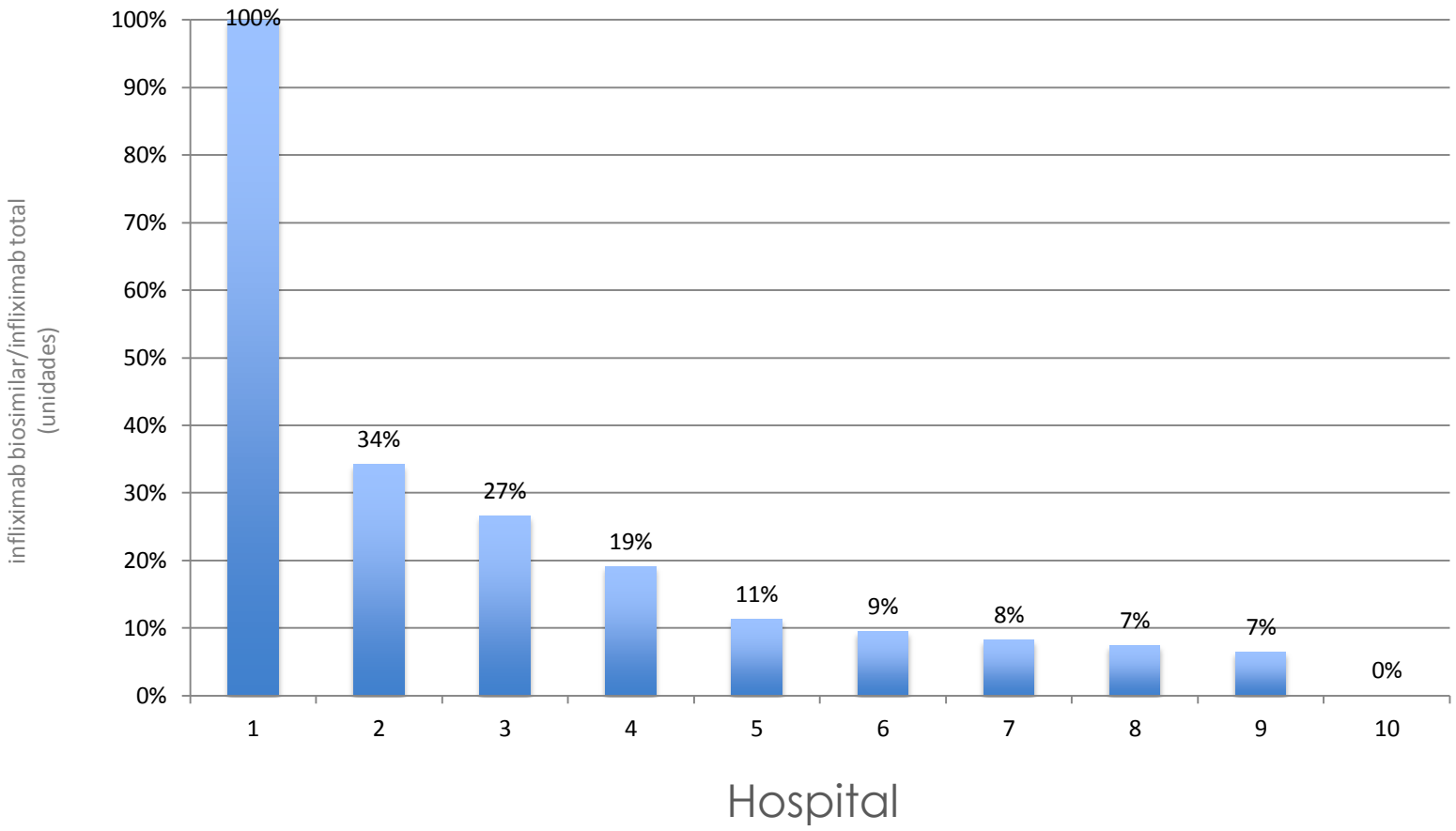


Precios más bajos permiten mayor uso

Exhibit 6

	Epoetins	Price per TD 2015/ Year before Biosimilar entrance	TD per capita (Year before Biosimilar entrance)	Volume TD 2015/ Year before Biosimilar entrance
Low historical usage	Romania	-36%	0.036	460%
	Bulgaria	-46%	0.125	120%
	Poland	-49%	0.027	186%
High historical usage	Ireland	-18%	0.523	-32%
	Austria	-36%	0.942	-28%
	Germany	-45%	0.412	-25%

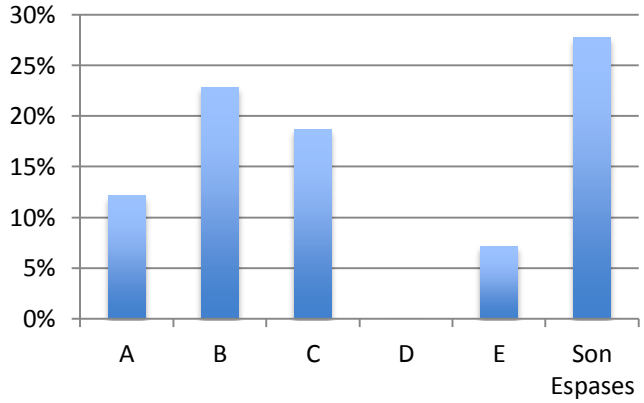
Penetración biosimilares en España



Datos propios Grupo Oligopsonio en 10 hospitales españoles: % utilización infliximab biosimilar 1 año después de la comercialización.

Penetración biosimilares en Baleares

Compras Mayo 2015 - Abril 2016	A	B	C	D	E	Son Espases
med	n	n	n	n	n	n
INFLIXIMAB 100MG VIAL IV/Inflectra	110	100				422
INFLIXIMAB 100MG VIAL IV/Remsima		140	89		160	227
INFLIXIMAB 100MG VIAL IV/Remicade	796	810	387	921	2.080	1.689
total INFLIXIMAB	906	1.050	476	921	2.240	2.338
biosimilares	110	240	89	-	160	649
% biosimilares	12%	23%	19%	0%	7%	28%



Datos propios 6 hospitales Baleares: % utilización infliximab biosimilar 1 año después de la comercialización.

Responder Responder a todos Reenviar

INFLIXIMAB

Lucio Pallares Ferreres

Para: lucio.pallares@ssib.es Sanchez; Iciar Martinez Lopez; Pedro Ventayol Bosch

CC: Jordi Forteza-Rey Borralleras

jueves, 21 de enero de 2016 8:25

- Respondiste el 21/01/2016 8:34.

Buenos días,

En relación con los pacientes de la Unidad de Enfermedades Autoinmunes Sistémicas, Medicina Interna, que requieren para su tratamiento administración de INFLIXIMAB, nosotros pautaremos la molécula (Infliximab), dejando a criterio del Servicio de Farmacia la selección comercial del mismo (Remicade u otro).

Un cordial saludo,

Dr. Lucio Pallares Ferreres
Unitat Malalties Autoimmunes Sistèmiques
Hospital Universitari Son Espases
Servei de Medicina Interna
Nivell 3Q, Sala 329
Ext 75032
Tel (+34) 871 205 547
Fax (+34) 871 909 723
Ctra. de Valldemossa 79, 07010 Palma. Mallorca
Mail: husd.umas@ssib.es

comportamiento original

- Sacar otra molécula que modifica el mercado
- Bajar precios
- No bajan precios
- Descuentos por aumento volumen
- El original es más barato que el biosimilar

Incentivos a la prescripción

- Acuerdos beneficio compartido
- Procedimiento y metodología intercambio
- Refuerzos actividad-consultas
- Registro resultados

Pacientes

- Formación
- Asociaciones de pacientes
- Programas soporte

Promoción

- Promoción activa
- Investigación

Colaboración

Confianza

Compromiso

Visión futuro