



QuintilesIMS™

I farmaci biosimilari in Europa e in Italia

IL VALORE DEI FARMACI BIOSIMILARI NELLA GOVERNANCE DELLA SPESA

Roma, 1 Marzo 2017



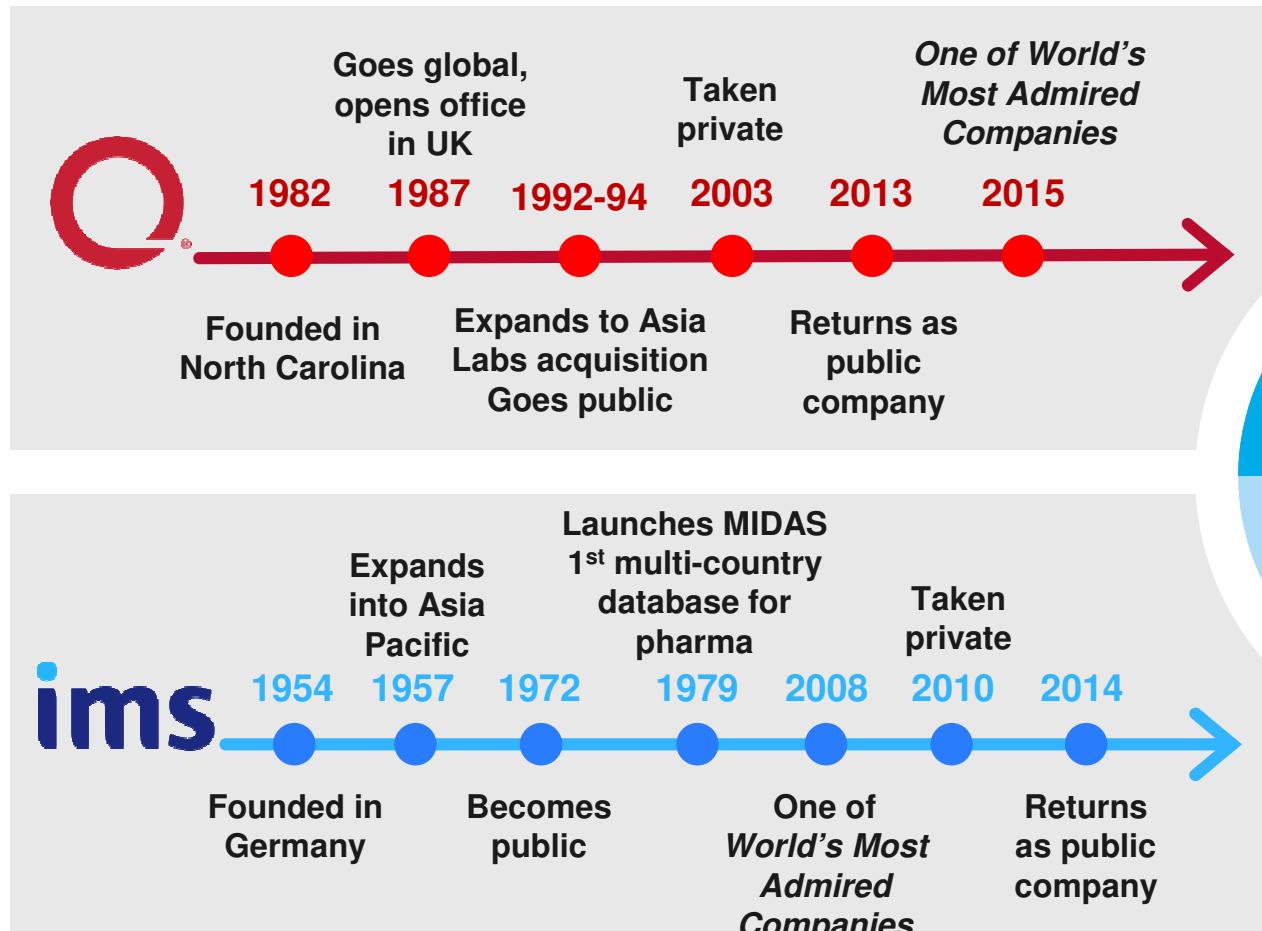
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Oggi siamo una nuova azienda



Convergence of Two Great Companies





Creating solutions for you to drive healthcare *forward*



Tap into our superior global resources & experience



I farmaci biosimilari in Italia e in Europa



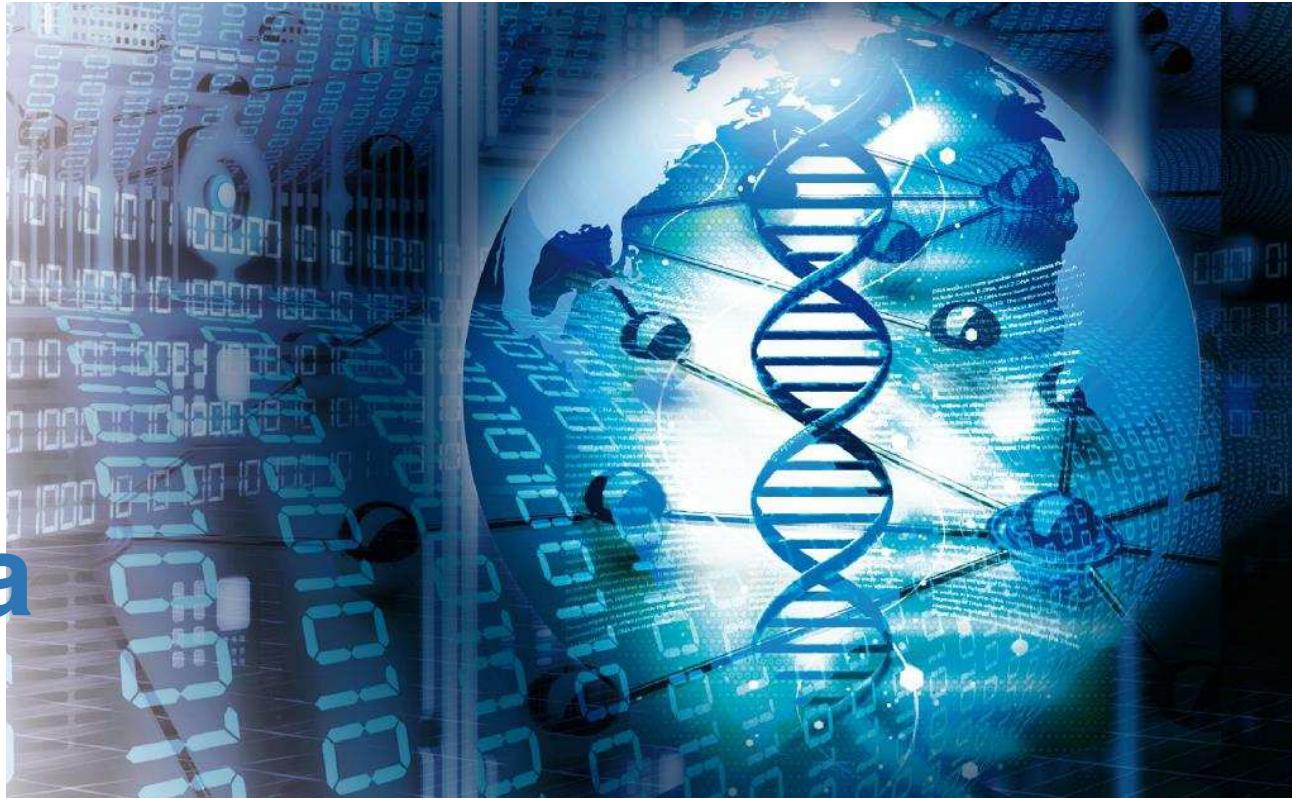
AGENDA

- 1 La sfida della innovazione**
- 2 Biosimilari in Italia**
- 3 Il mercato in Europa**
- 4 Il contributo alla sostenibilità**

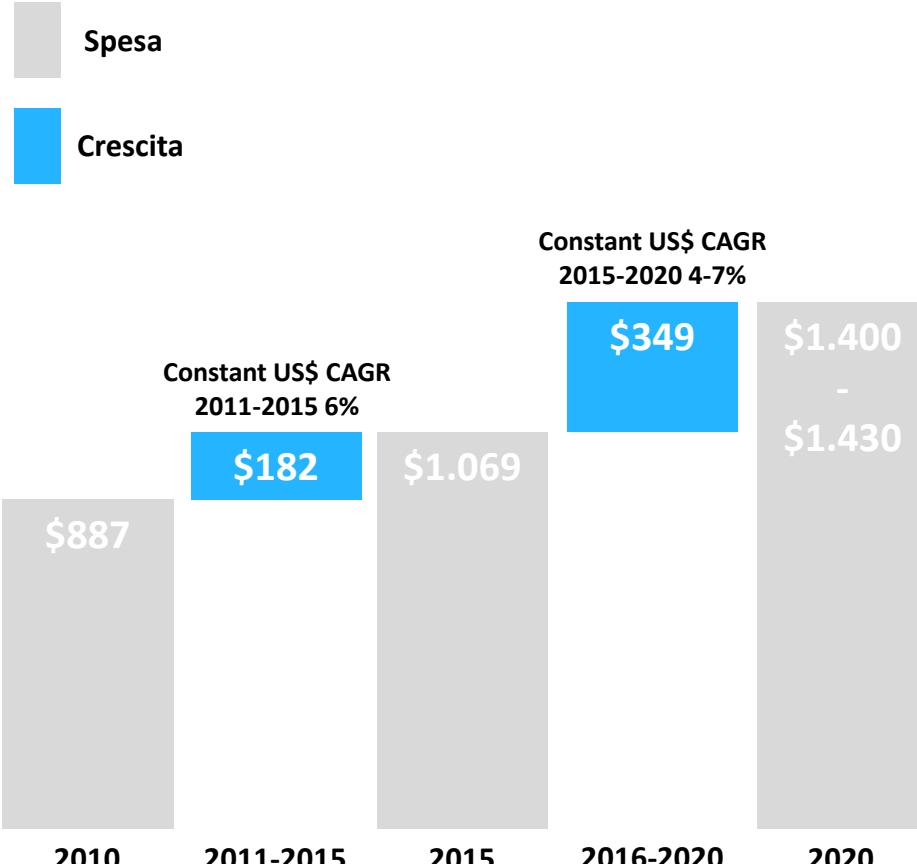


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La sfida della innovazione



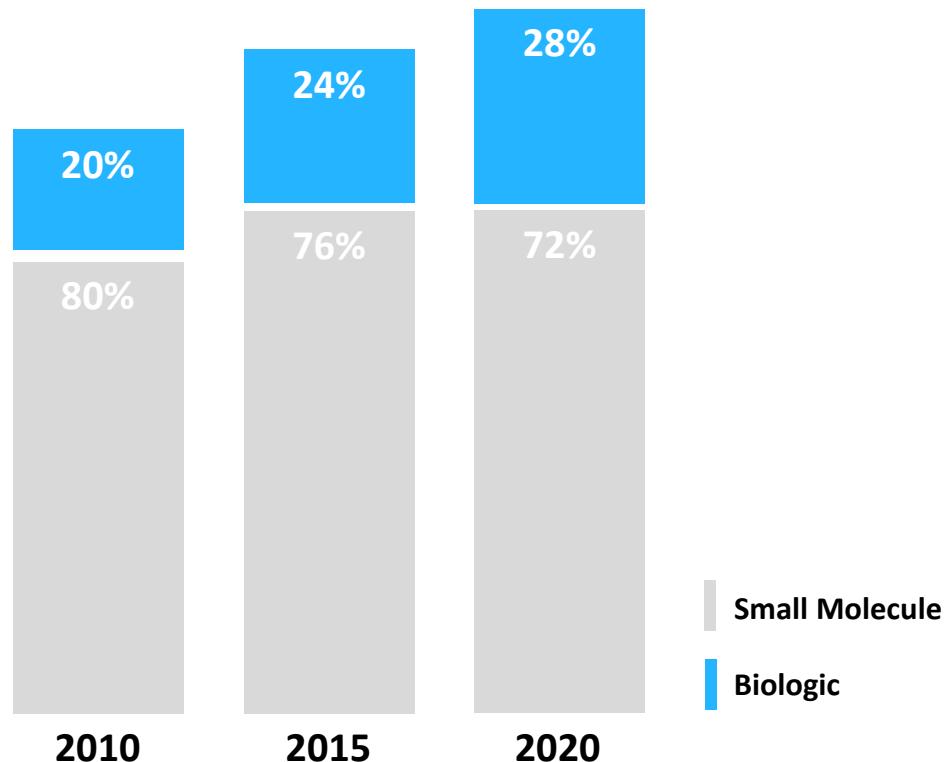
Il mercato globale supererà nel 2020 i 1.400 miliardi di dollari



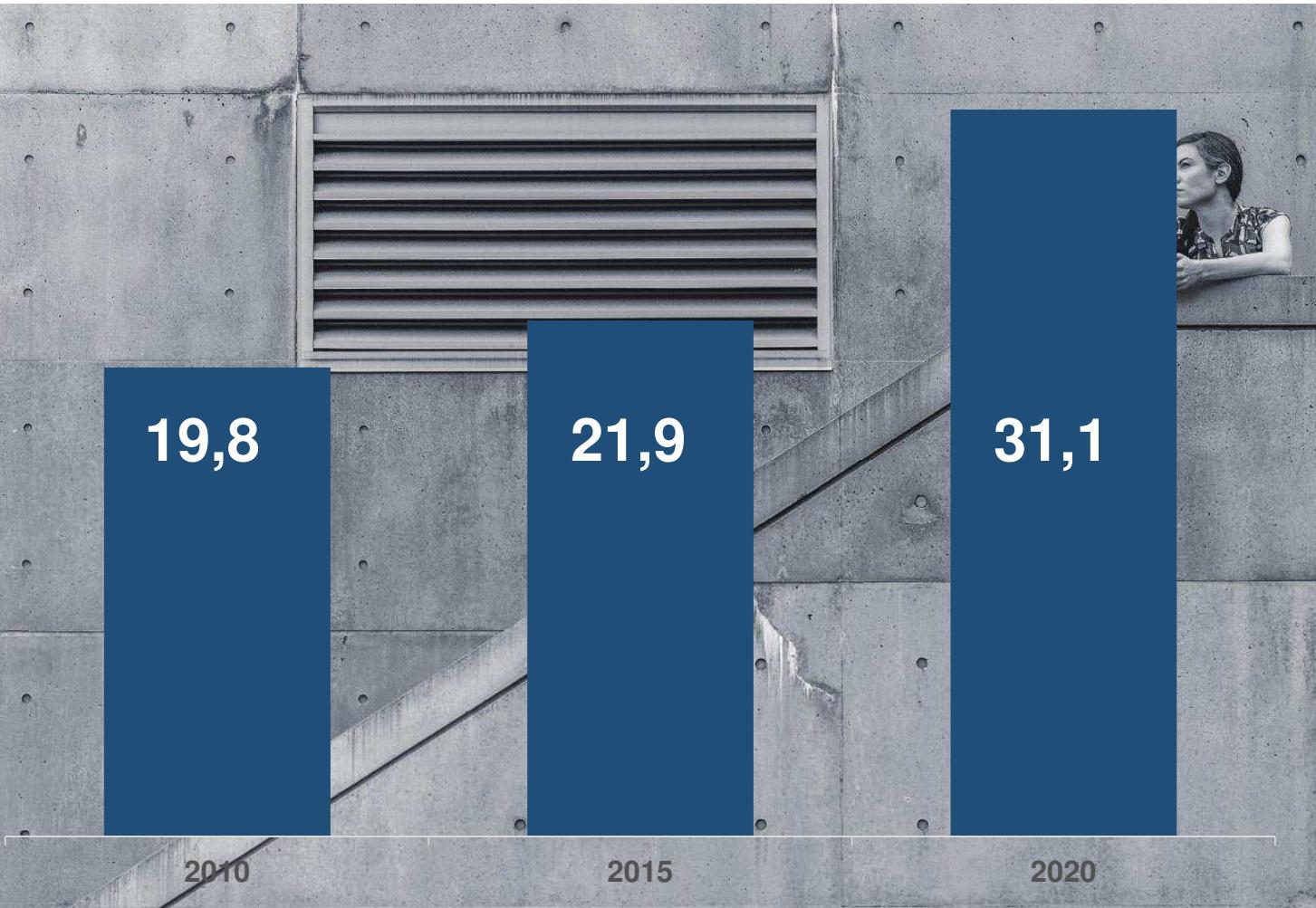
Fonte: Global Medicines Use in 2020. Report by IMS Institute for Healthcare Informatics

I farmaci biologici trainano la crescita

Biologic vs small molecule sales



Spesa per oncologia* > 135 Mld. nel 2020 – 31 Mld. US\$ in EU5



In Italia l'oncologia pesa > 16% del totale spesa farmaceutica. Prevista una crescita annua composta a cinque anni del 5-7%.

Generici: si riduce la possibilità di efficienza economica



-52,3%



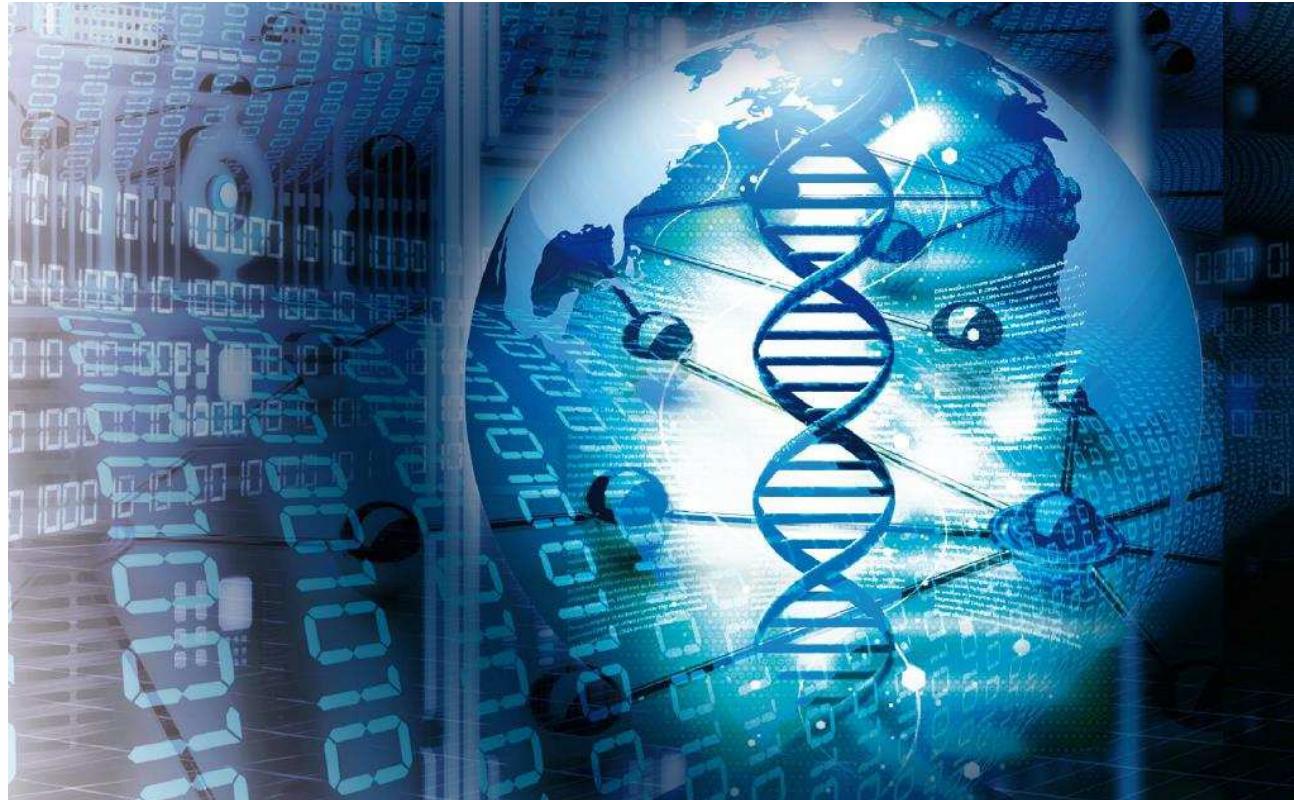
-35,5%



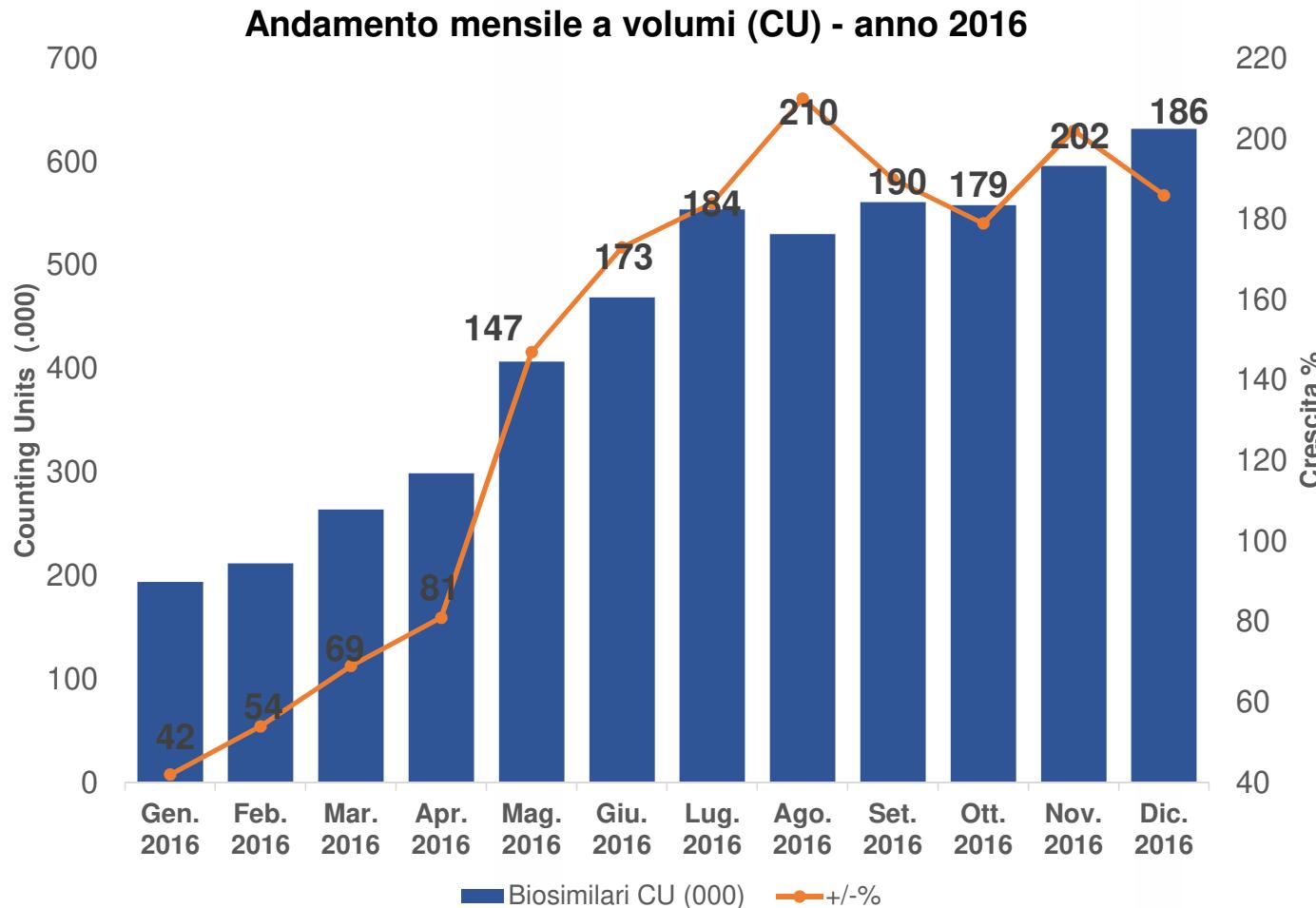
-47,7%

 % reduction in spending exposed to LOE 2015-20 vs 2009-14

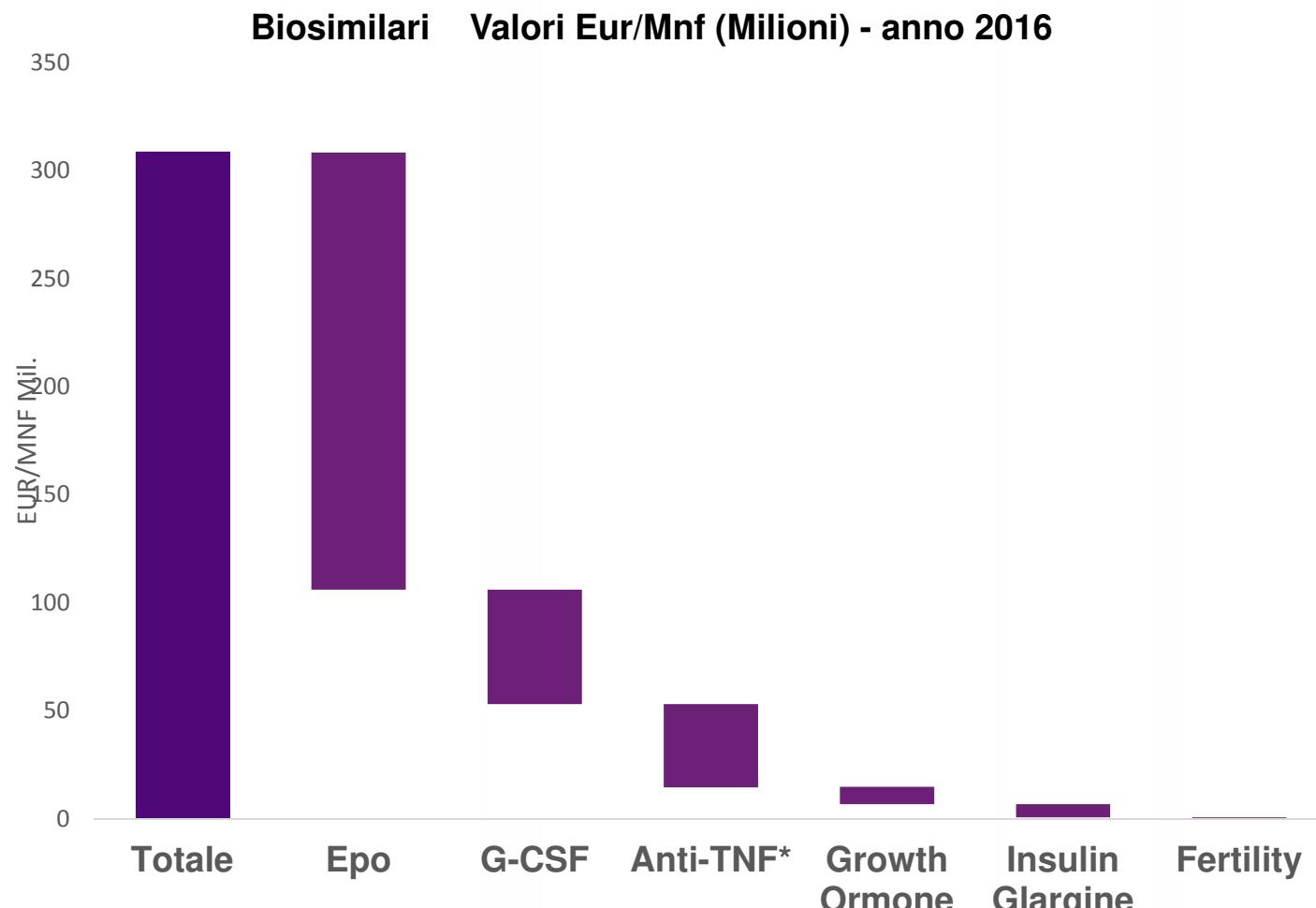
2 Biosimilari In Italia



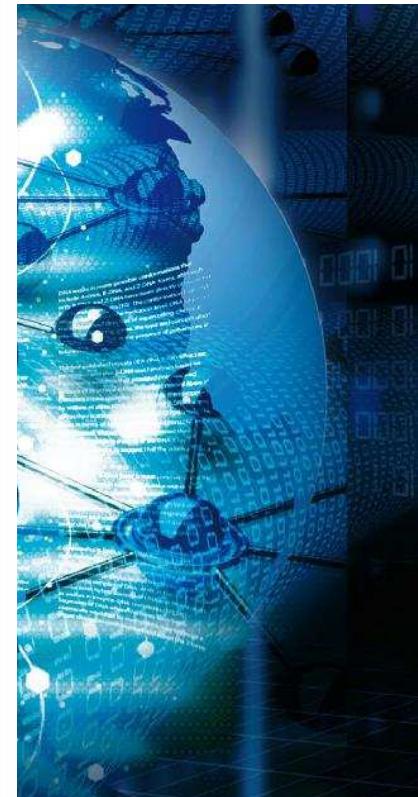
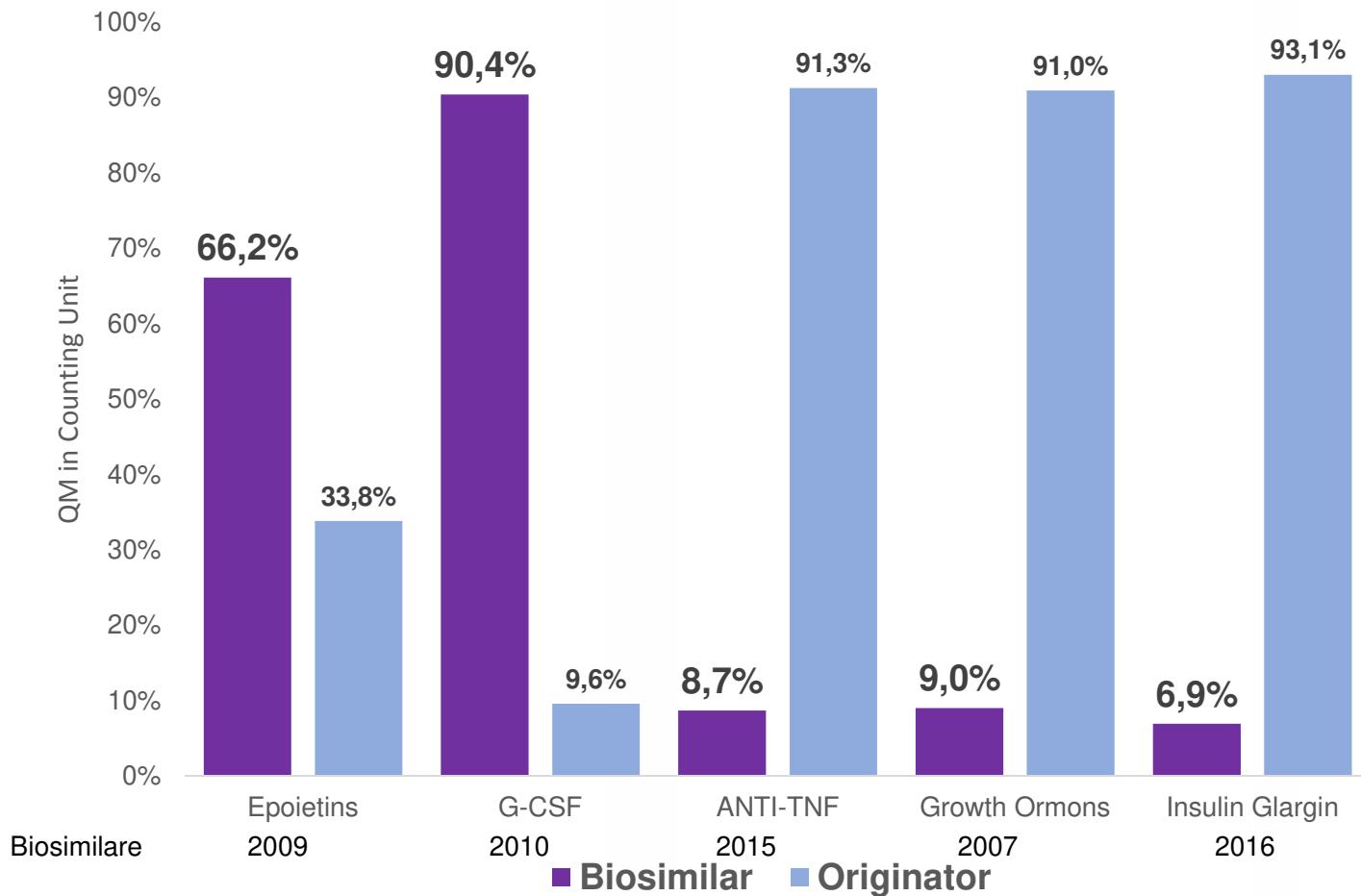
In Italia il consumo di biosimilari è triplicato nell'ultimo anno



Nel 2016 l'Epo assorbe il 66% del mercato in valori



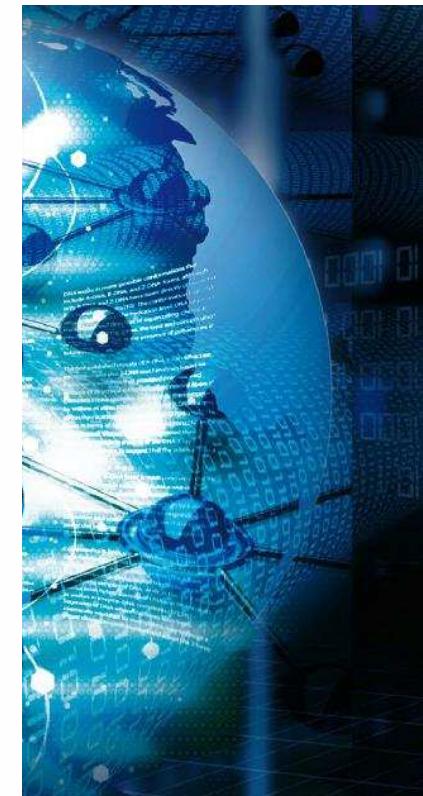
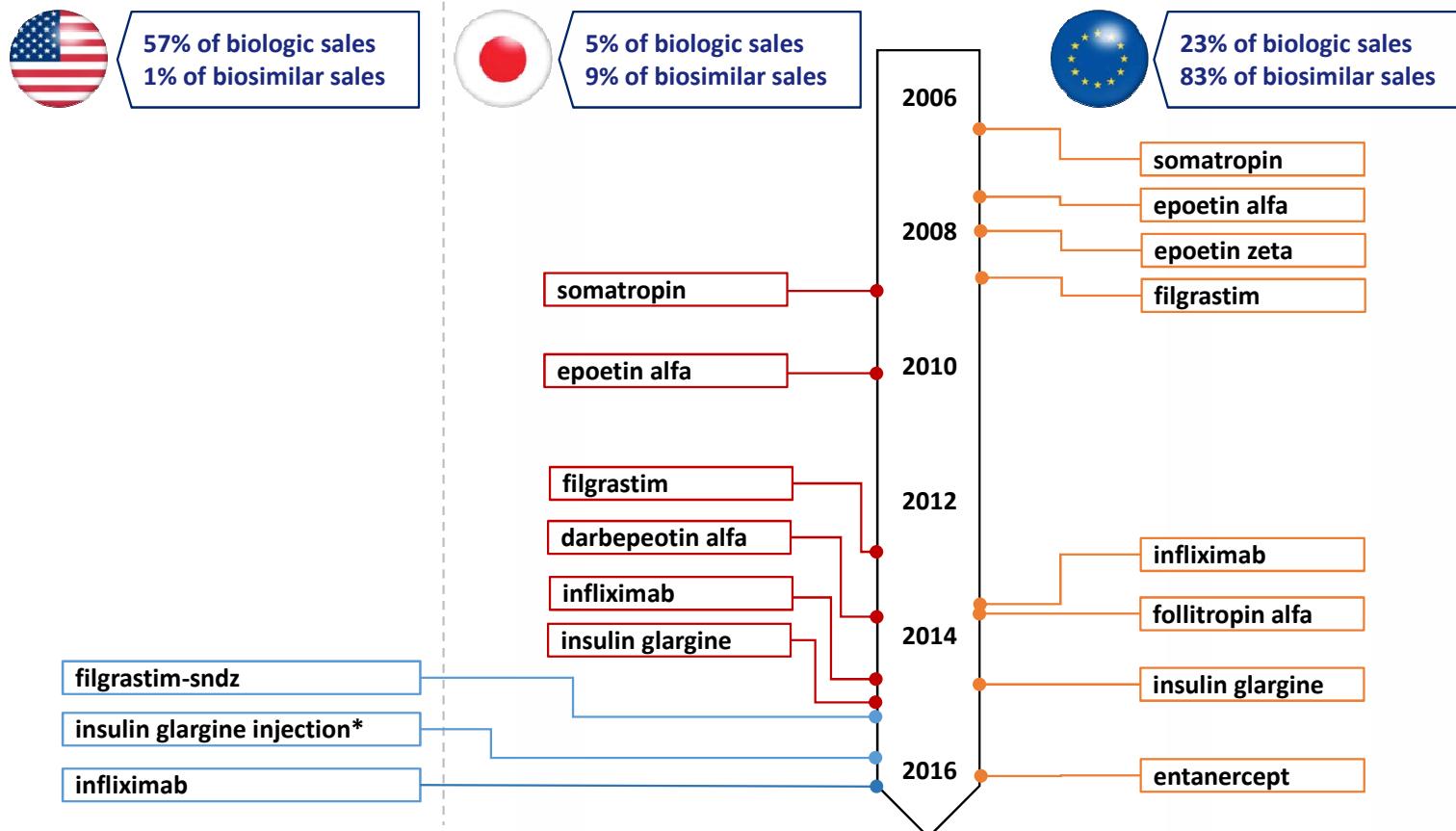
La quota dei biosimilari varia secondo l'area terapeutica, il numero di prodotti e la permanenza sul mercato



3 Biosimilari Europa

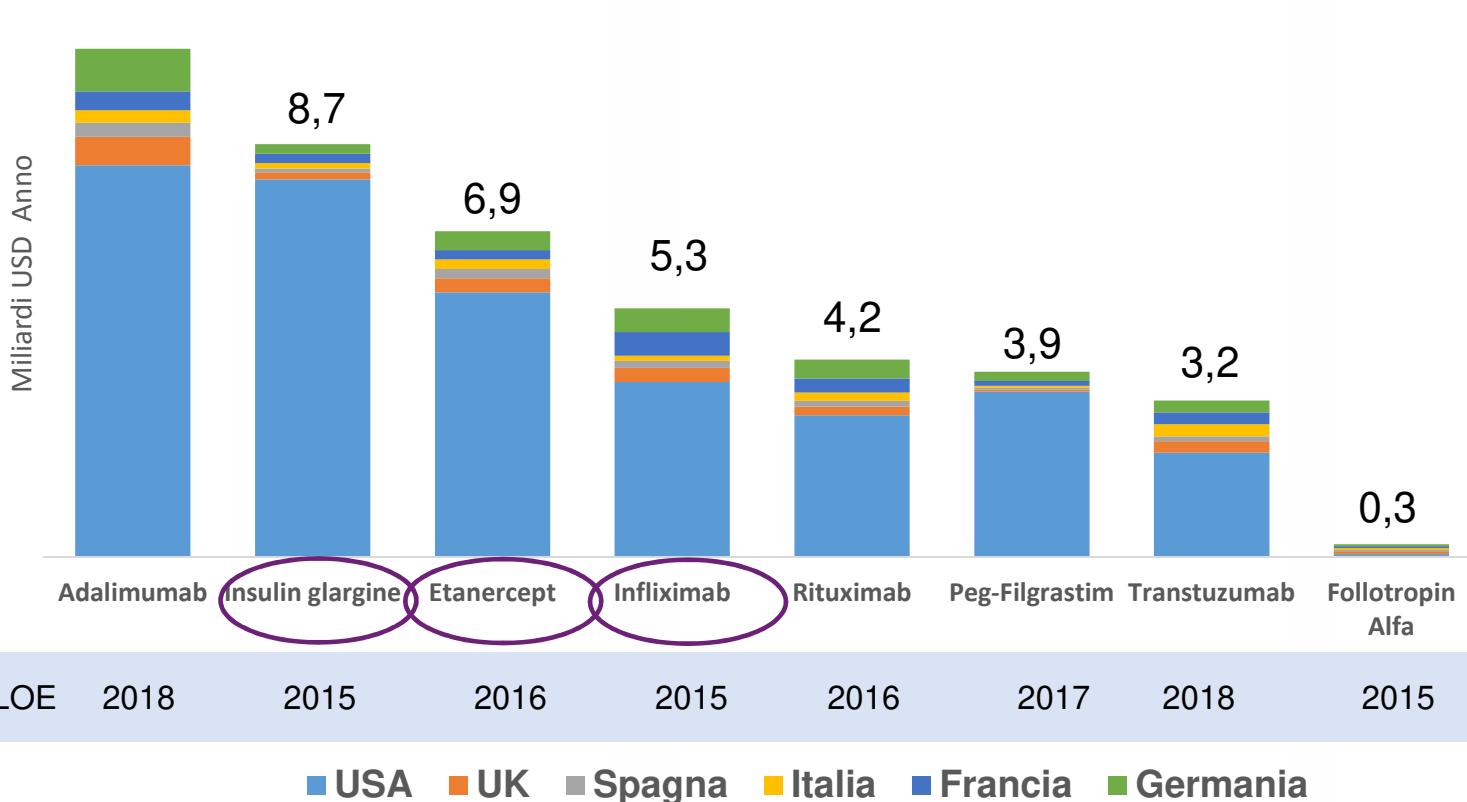


L'Europa concentra l'83% del mercato dei farmaci biosimilari



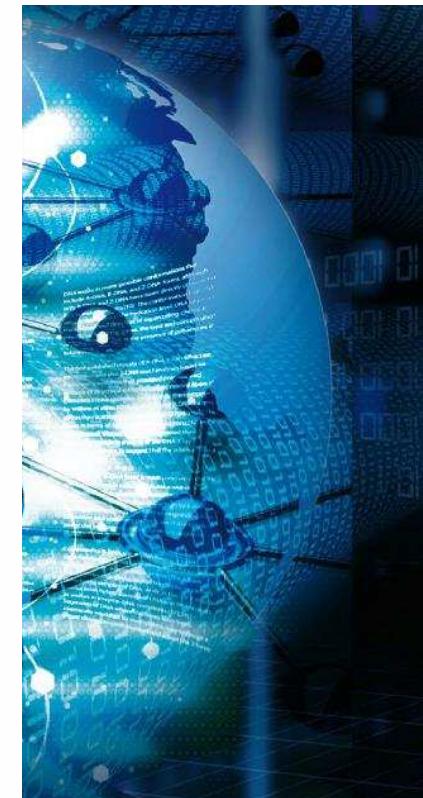
US, Japan, Europe Biosimilar molecule approvals to date

Solo tre biologici in scadenza recente hanno un biosimilare

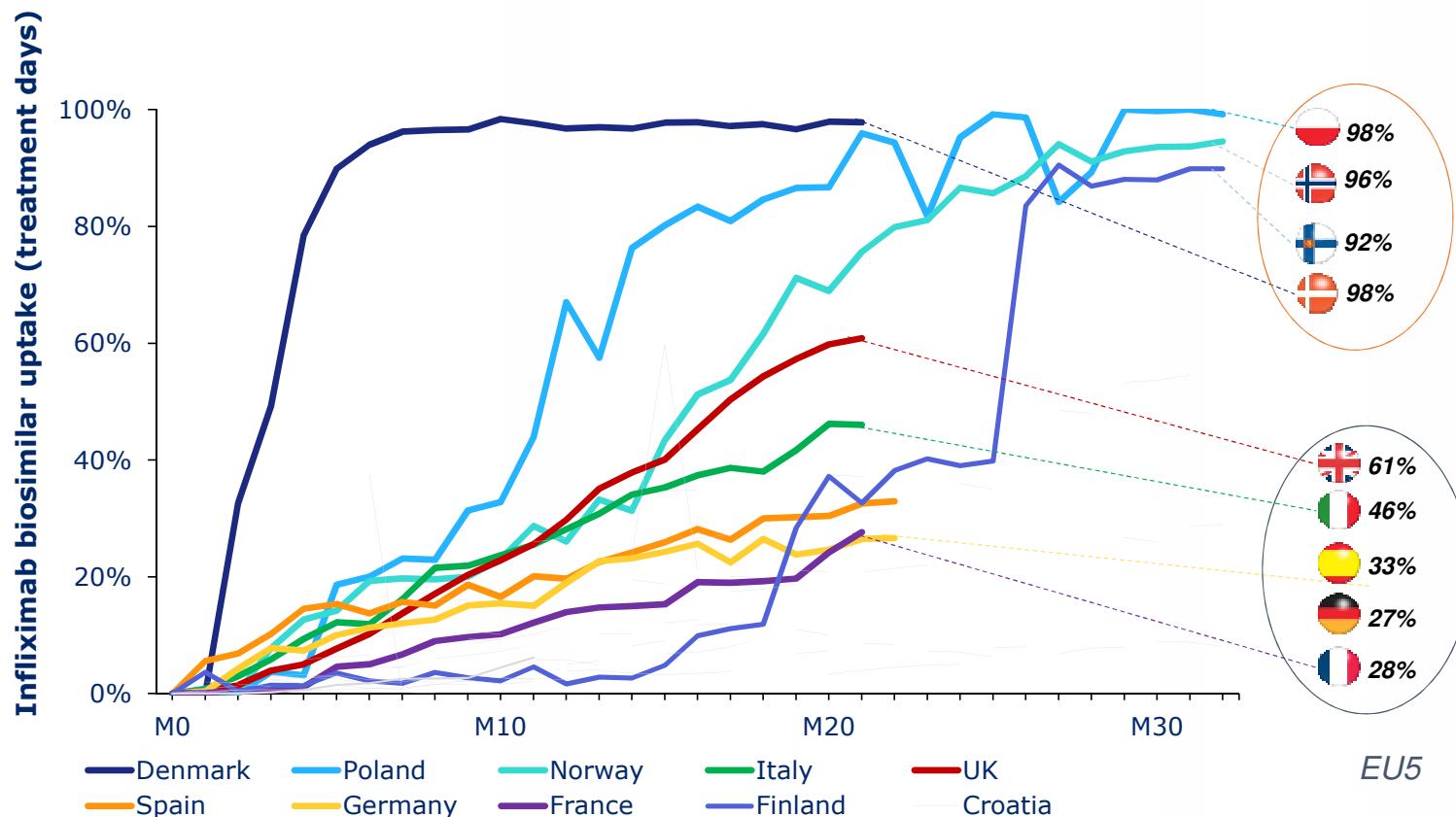


INFLIXIMAB:

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Biosimilars
        

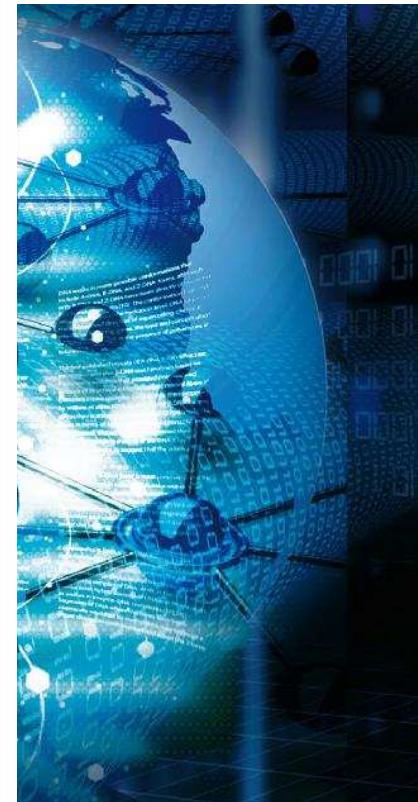


L'Italia è diventato il secondo mercato fra i top 5 europei: 46% di biosimilare



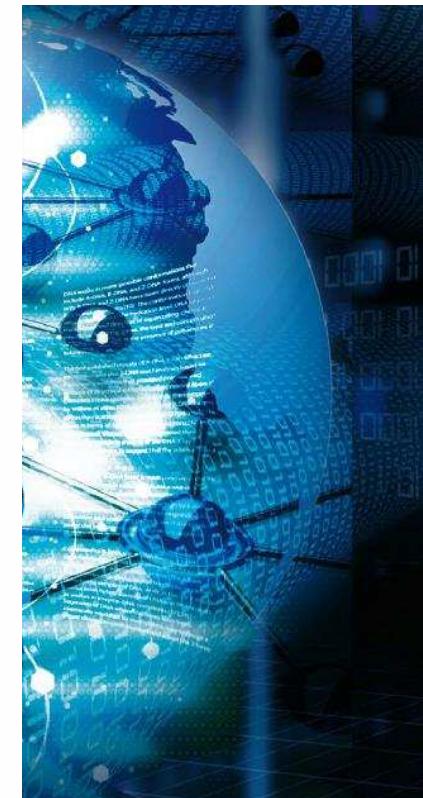
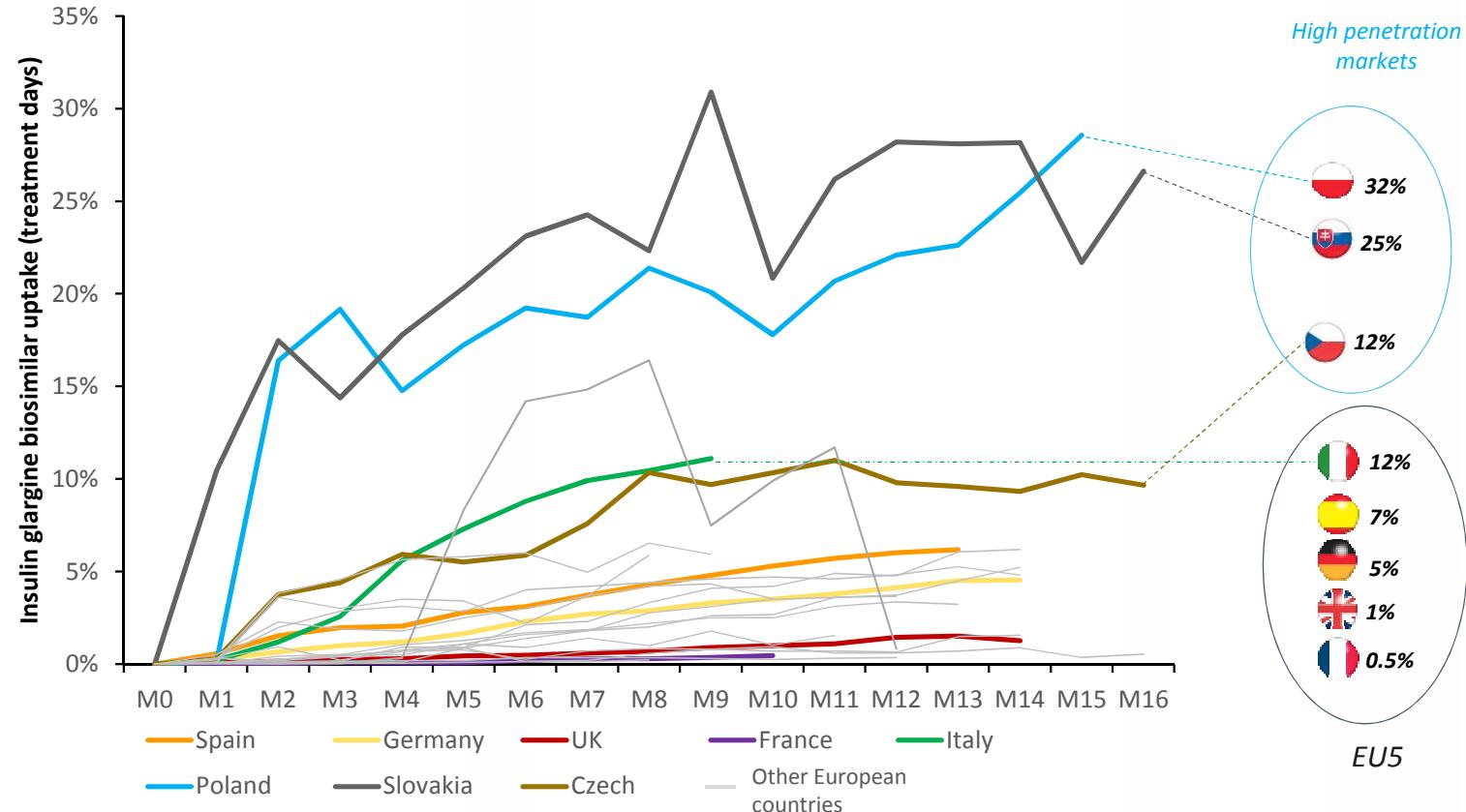
INSULIN GLARGINE:

Originator
 LANTUS®
 SANOFI
Biosimilars
 abasaglar®
 Lilly



L'Italia è al primo posto fra i top 5 europei: 12% di biosimilare

Europe: Insulin glargine biosimilar market share in treatment days

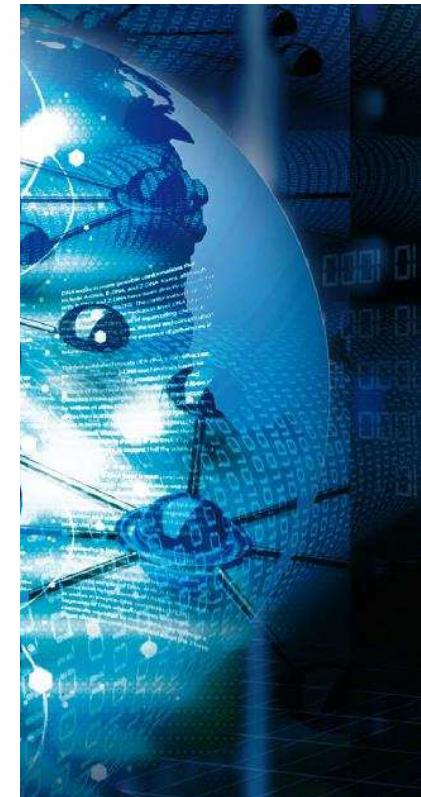


ETANERCEPT:

Originator

 
Biosimilars

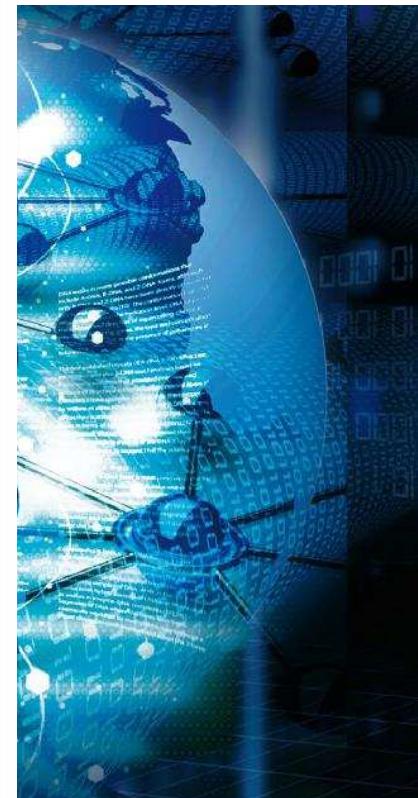
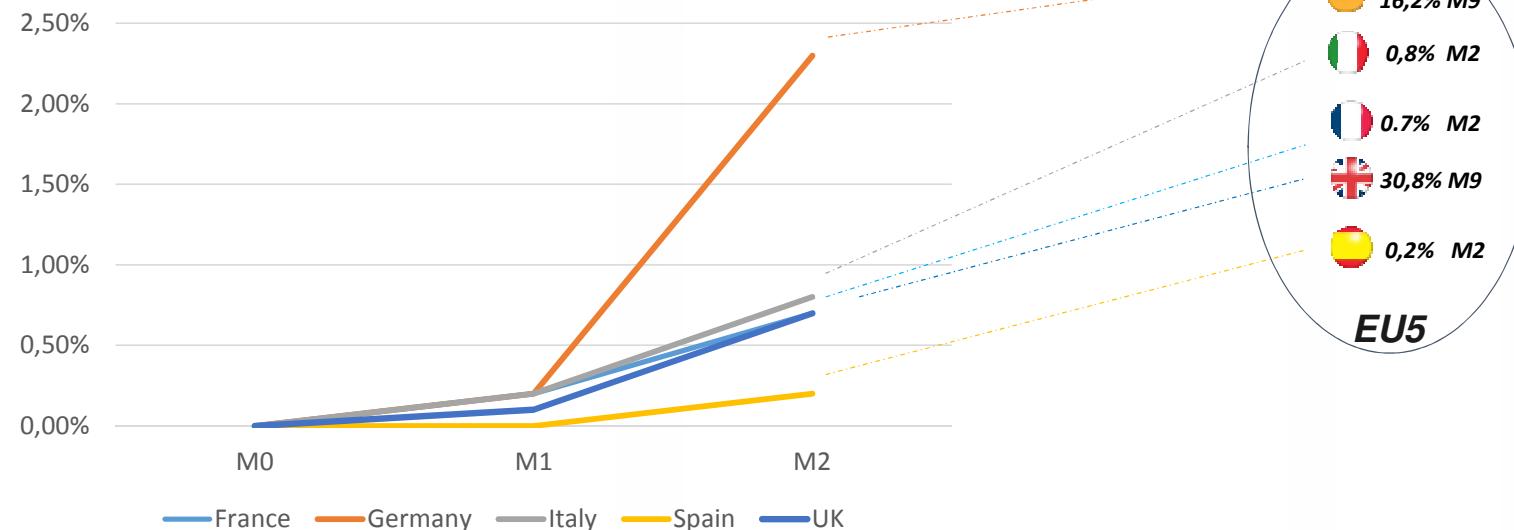


Etanercept: il nord Europa guida per market share biosimilari

L'Italia in linea fra gli EU5 a pochi mesi dal lancio

Europe: Etanercept biosimilar market share in treatment days (M2)



Biosimilar share (*Etanercept months after launch)	Denmark (M7)*	Sweden (M8)*	Germany (M9)*	UK (M9)*	Italy (M2)	Spain (M2)	France (M2)
Etanercept	78,7%	38,8%	16,2%	30,8%	0,8%	0,2%	0,7%
Infliximab	94,0%	17,3%	15,1%	20,4%	46%	33%	28%

I paesi maturi europei mostrano finora medio potenziale per i biosimilari

Europe, Japan & Canada- Biosimilar share of molecule treatment days

Country	Biosimilar treatment day share (November 2016)		
	infliximab	insulin glargine	etanercept
UK	60.9%	1.1%	30.8%
France	27.7%	0.5%	0.7%
Germany	26.7%	4.9%	16.2%
Italy	46.0%	11.6%	0.8%
Spain	32.9%	6.6%	0.2%
Finland	92.1%	0.9%	-
Norway	95.6%	1.8%	69.0%
Poland	97.7%	31.5%	0.0%
Denmark	97.8%	4.0%	78.7%
Japan	3.1%	29.9%	-
Canada	1.0%	0.8%	0.0%

High uptake
Low uptake



Ogni paese ha leve di sviluppo diverse

**Drivers:**

- Economic imperative
- Physician backing

Barriers:

- Originator strategy
- Hospital-Retail budget responsibility

**Drivers:**

- Regional tenders
- Heavy promotion - agency encouraged

Barriers:

- Medicines agency guidance
- Originator pricing

**Drivers:**

- Naïve patients tenders

Barriers:

- Medicines agency guidance
- Reluctance to switch from patient and physician groups

**Drivers:**

- Regional quotas
- Government initiatives, pharma dialogue

Barriers:

- Hospital-Retail budget responsibility
- Originator strategy

**Drivers:**

- Prescription quotas
- Physician incentives

Barriers:

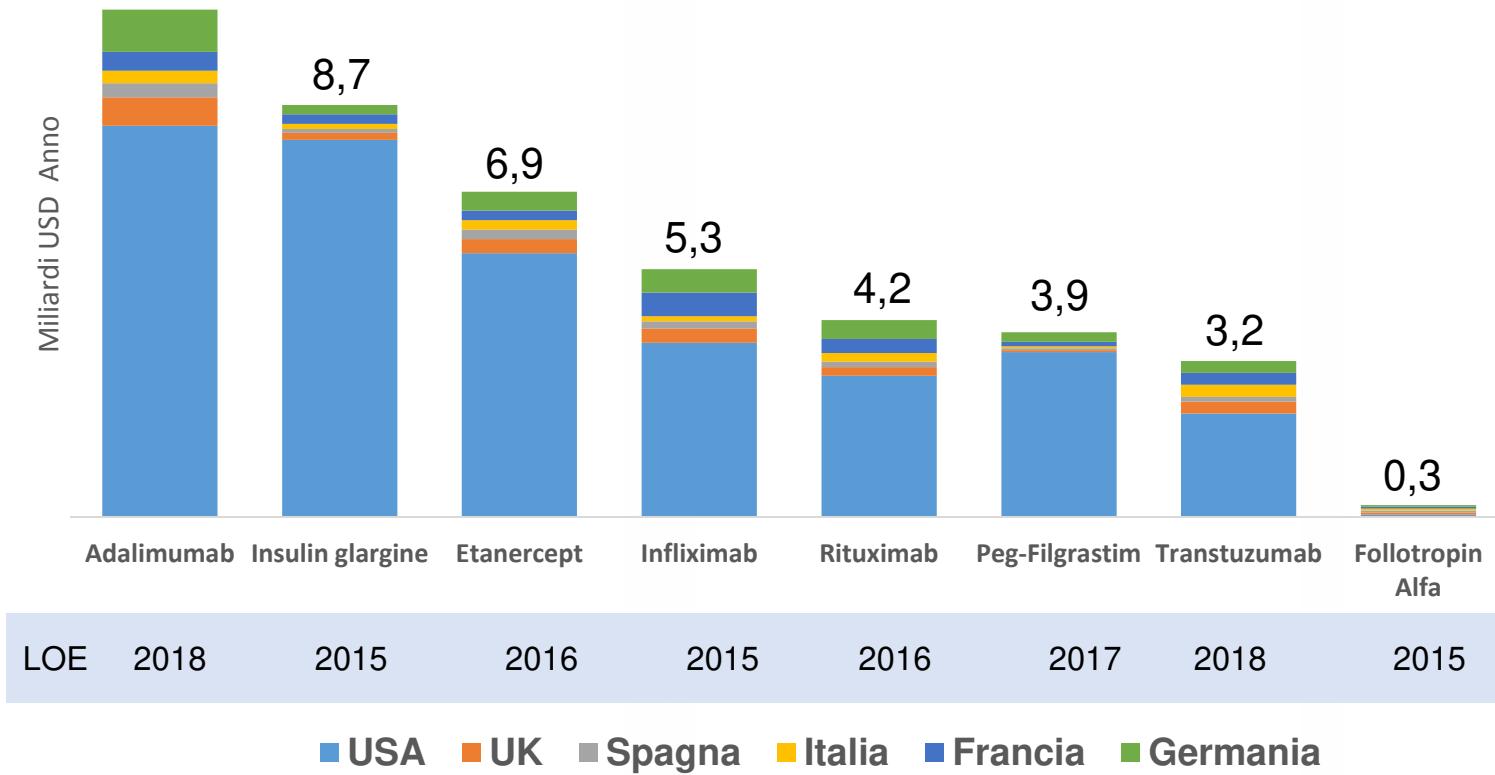
- Regional guidance
- Originator pricing strategies



4 Contributo alla sostenibilità



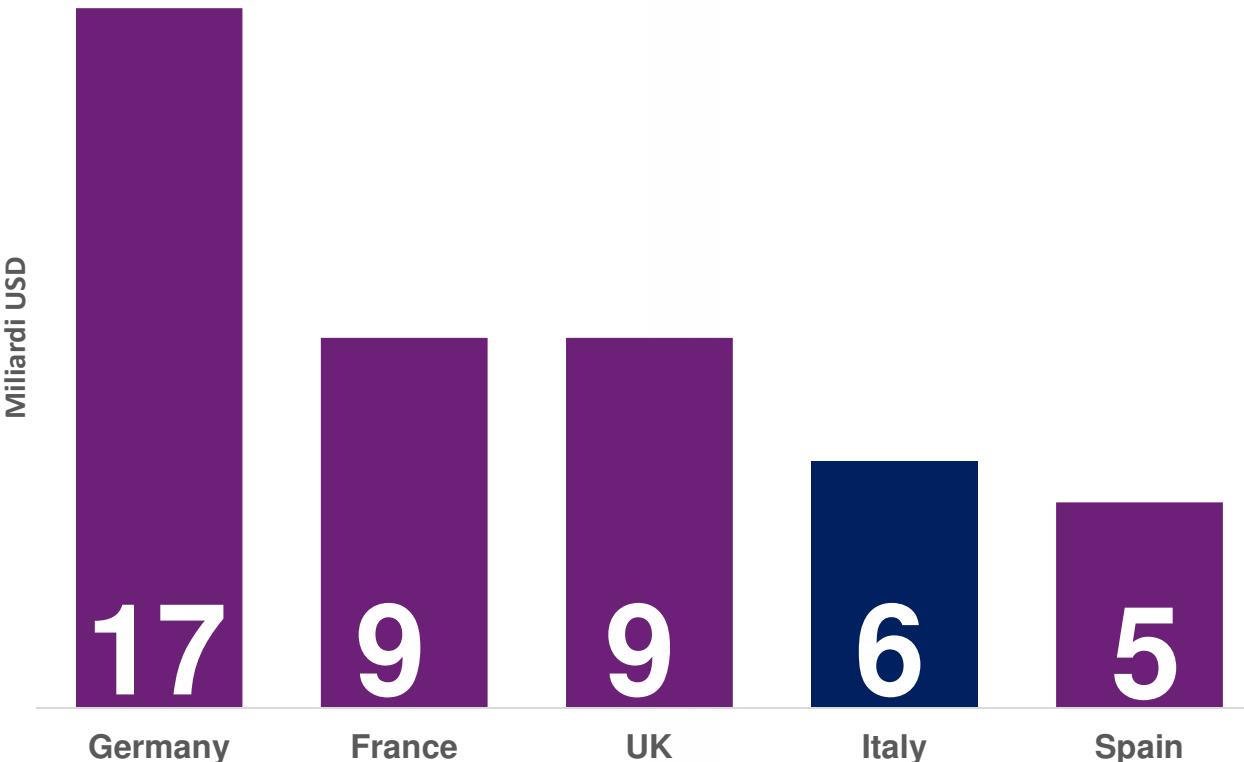
Biologici in scadenza brevettuale 2015-2020: ~ 50 mld. (USD)



Biologici in scadenza - in Europa quasi 50 miliardi in 5 anni

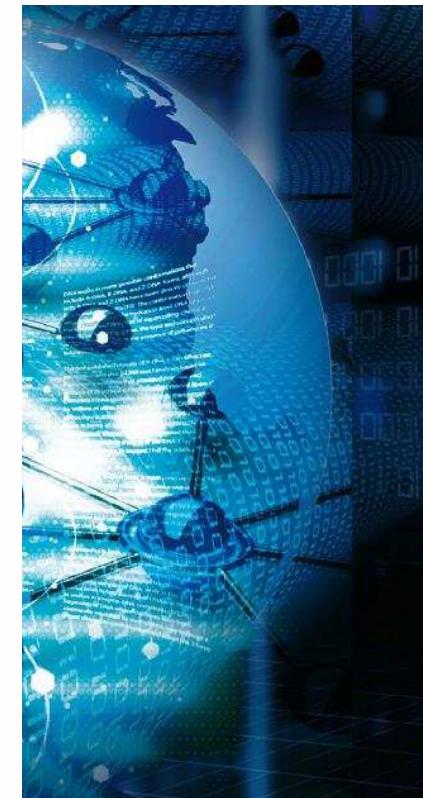
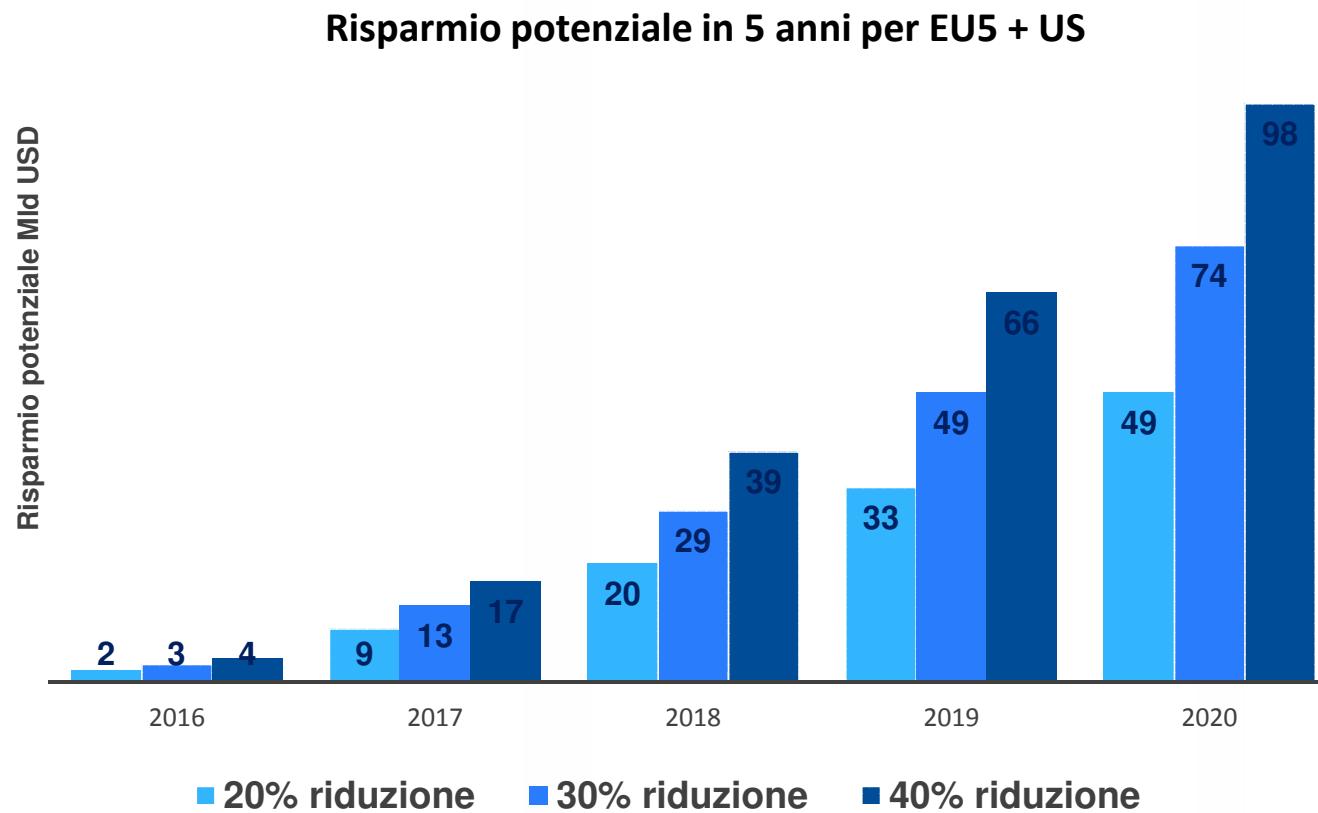


6 Miliardi in Italia



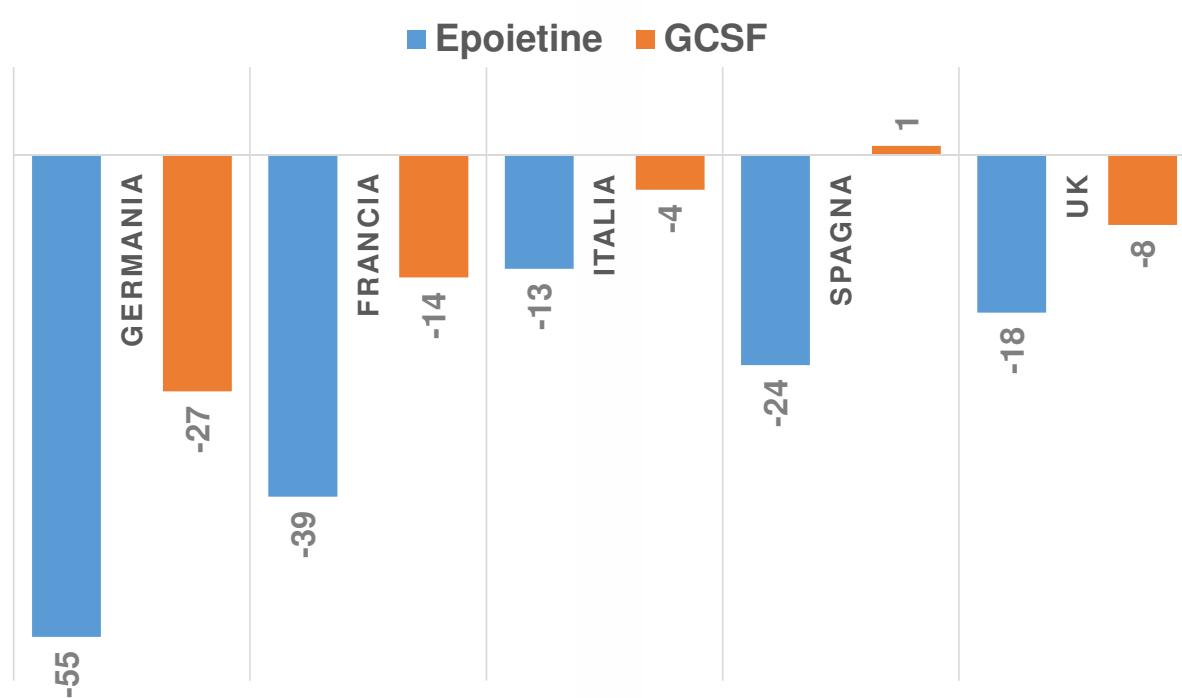
Risparmio possibile per effetto della concorrenza del biosimilare

Potenziale risparmio di **10 miliardi in 5 anni in EU5** (calcolato su 30% riduzione dei prezzi)



La concorrenza del biosimilare può ridurre i costi della terapia

Case history

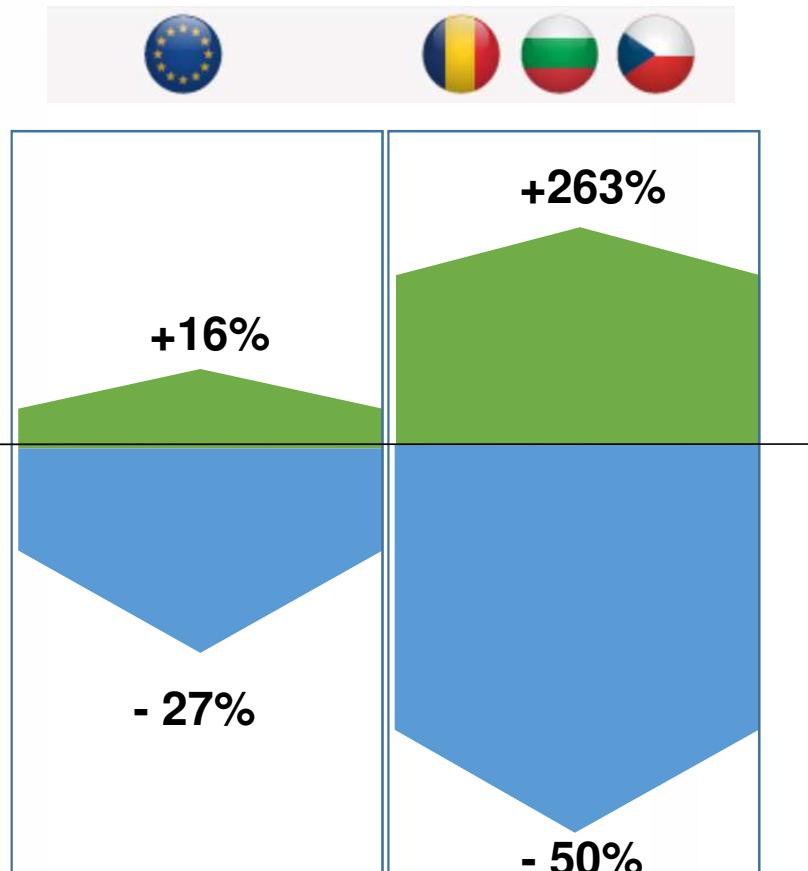


Fonte: IMS Institute of Healthcare Informatics; *The Impact of Biosimilar Competition*

La concorrenza del biosimilare può incrementare l'accesso

Case history

Aumento medio dei volumi*
(giorni di trattamento)



*variazioni dalla data di lancio

Fonte: IMS Institute of Healthcare Informatics; The Impact of Biosimilar Competition

CONCLUSIONI

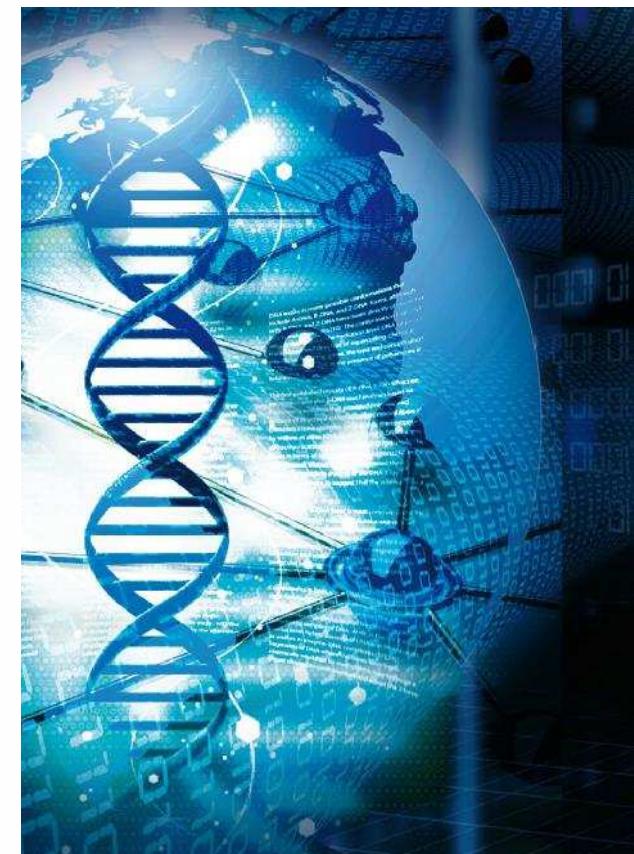
I farmaci biologici rappresentano un sfida alla sostenibilità

L'Europa è la regione più matura per i farmaci biosimilari ma ogni Paese ha linee guida ed approcci diversi

Una normativa chiara e linee guida coerenti a ogni livello (europeo, nazionale e regionale) contribuirebbero a massimizzare le opportunità

E' determinante l'autonomia prescrittiva del medico e adeguata informazione clinica verso prescrittori, payers e pazienti

I biologici di prossima scadenza offrono ulteriori importanti potenzialità di contenimento dei costi e ampliamento dell'accesso



GRAZIE

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