



# Estimated savings from biosimilar use

Francesca Poma, IQVIA

#sanita2030



[www.sanita2030.it](http://www.sanita2030.it)





## Agenda

- **Italian biosimilar market overview**
- **Estimated savings from biosimilars**

#sanita2030



[www.sanita2030.it](http://www.sanita2030.it)

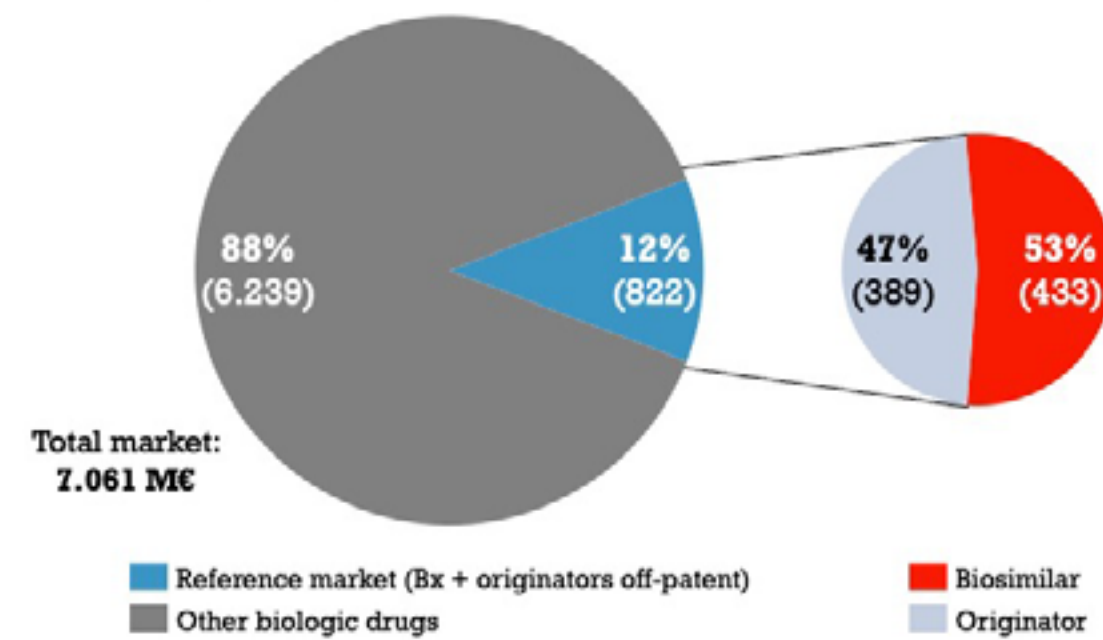






### Biosimilars still represent a minority share (6%) of the Italian biologics market

**Biologics market**  
 (Value - PMP, M€, 2022)



- In 2022, the **total share** of biosimilars in the biologics market was **6%**
- **Bx share is 53% of the reference market;** reference market includes **biosimilars** and their **off-patent originators**

#sanita2030

Source: IQVIA REGDTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing

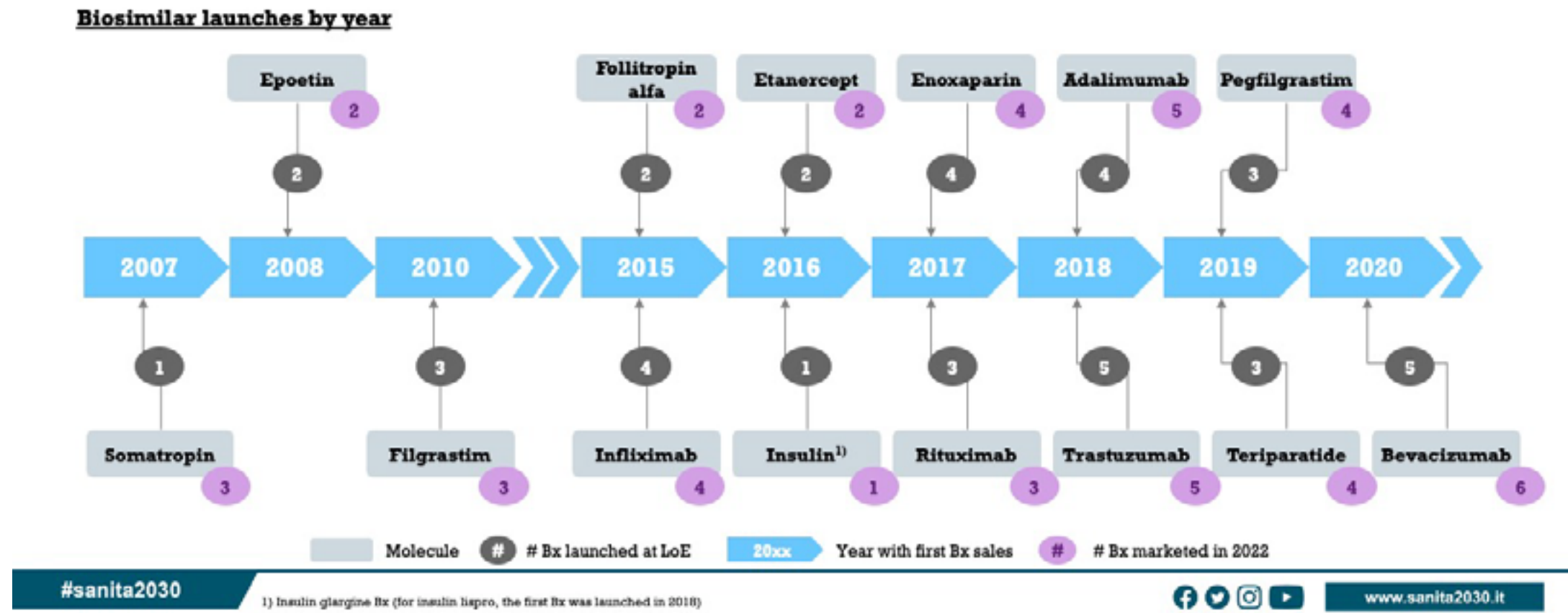


www.sanita2030.it





### Most biosimilars launched between 2015 and 2020







## Almost all top 20 biologics are still protected by patent

### Top 20 biologics marketed in Italy

Ranking	Product	Molecole	Manufacturer	Launch year	Sales 2022	% bio market
1	Keytruda	Pembrolizumab	Merck Sharp Dohme	2015	429	6%
2	Darzalex	Daratumumab	Janssen-Cilag	2017	365	5%
3	Opdivo	Nivolumab	Bristol-Myers Squibb	2015	194	3%
4	Trulicity	Dulaglutide	Eli Lilly	2016	192	3%
5	Perjeta	Pertuzumab	Roche	2013	148	2%
6	Stelara	Ustekinumab	Janssen-Cilag	2010	134	2%
7	Soliris	Eculizumab	Alexion Pharma	2008	127	2%
8	Ocrevus	Ocrelizumab	Roche	2018	122	2%
9	Cosentyx	Secukinumab	Novartis Farma	2016	113	2%
10	Tysabri	Natalizumab	Biogen	2007	111	2%
11	Dupixent	Dupilumab	Sanofi	2018	109	2%
12	Ozempic	Semaglutide	Novo Nordisk	2019	90	1%
13	Entyvio	Vedolizumab	Takeda	2016	81	1%
14	Inhixa	Enoxaparin (Bx)	Techedo Pharma	2017	78	1%
15	Eylea	Aflibercept	Bayer	2013	76	1%
16	Taltz	Ixekizumab	Eli Lilly	2017	71	1%
17	Hemlibra	Emicizumab	Roche	2018	66	1%
18	Orencia <sup>1</sup>	Abatacept	Bristol-Myers Squibb	2008	66	1%
19	Repatha	Evolocumab	Amgen	2016	66	1%
20	Kadcyla	Trastuzumab emtansine	Roche	2014	63	1%
<b>Top 20 products</b>					<b>2.701</b>	<b>38%</b>

#sanita2030

Source: IQVIA REGDTV\_ALL\_BO\_OD; FMP ("Prezzo medio ponderato"): average actual price for hospital/LIA purchasing  
 1) Expired patent, no biosimilars marketed



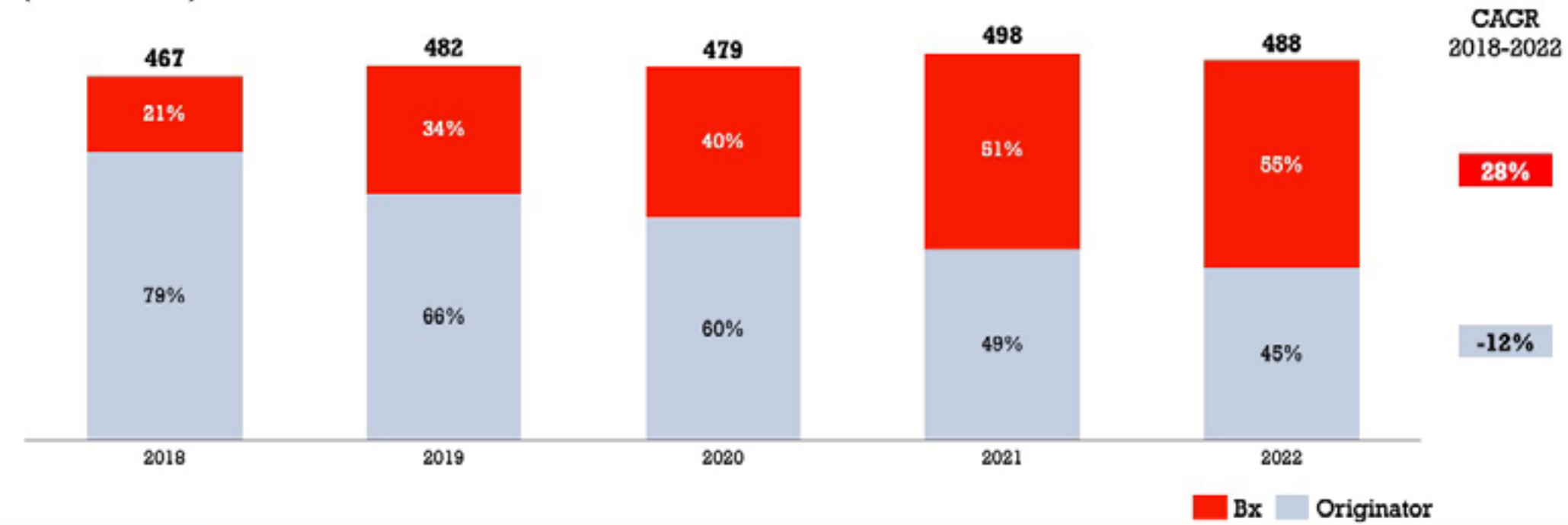
www.sanita2030.it





The reference market has remained flat in volume, with an increasing Bx share

**2018-2022 biosimilar penetration**  
 (Volume – M DOT)



#sanita2030

Source: IQVIA REODTV\_ALL\_BIO\_OD; DOT ("Days of treatment"): Number of days of therapy estimated considering the volume sold



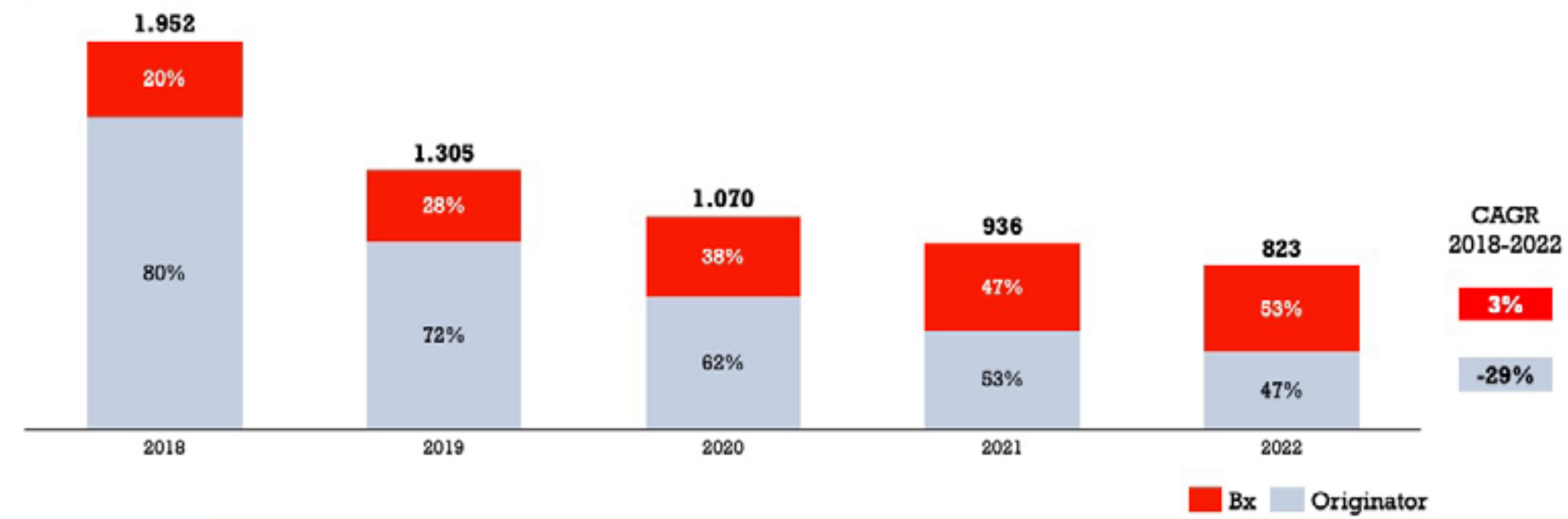
www.sanita2030.it





In value (net prices), the reference market declined between 2018 and 2022

**2018-2022 biosimilar penetration**  
 (Value – PMP, M€)



#sanita2030

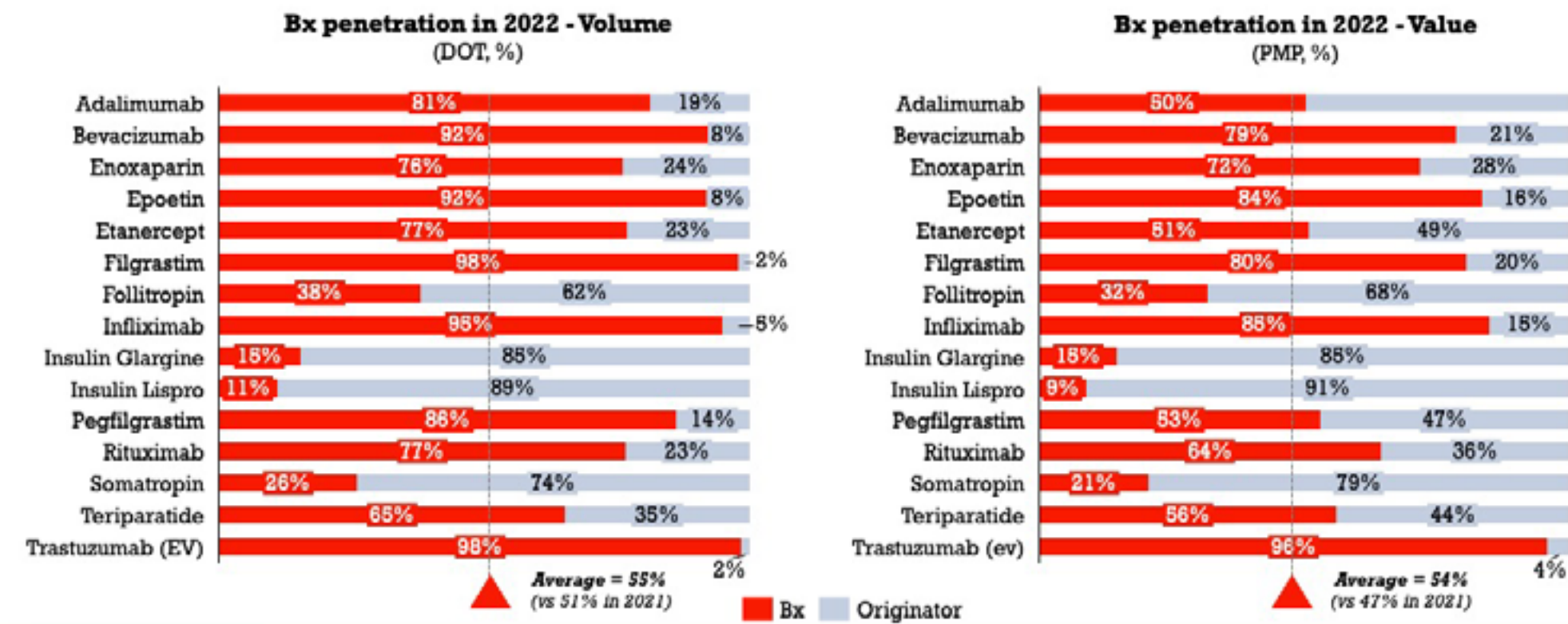
Source: IQVIA REODTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



www.sanita2030.it



In 2022, biosimilar share has reached 55% in volume and 54% in value



#sanita2030

Source: IQVIA REODFV\_ALL\_BIO\_OD; D-DOT ("Days of treatment"): Number of days of therapy estimated considering the volume sold; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



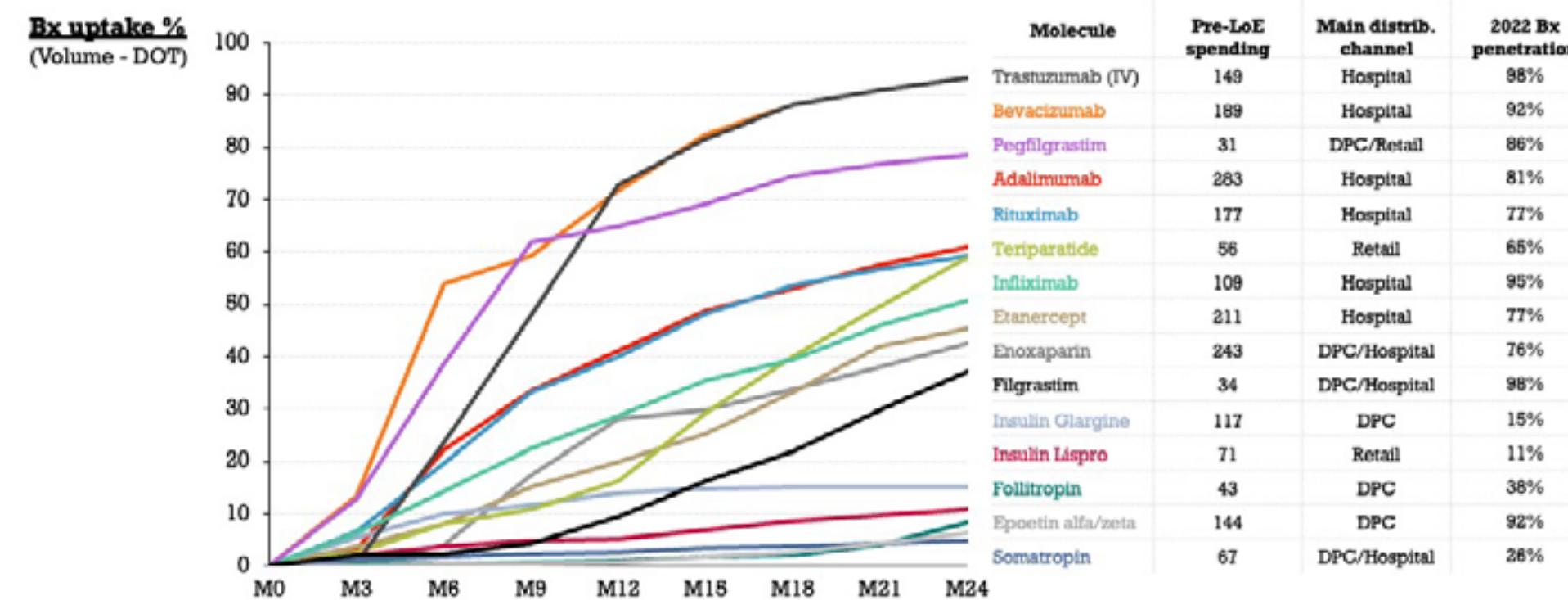
www.sanita2030.it







### Trastuzumab, bevacizumab and adalimumab Bx had the fastest uptake



#sanita2030

Source: IOVIA REGDTV\_ALL\_BIO\_OD; DOT ("Days of treatment"): Number of days of therapy estimated considering the volume sold



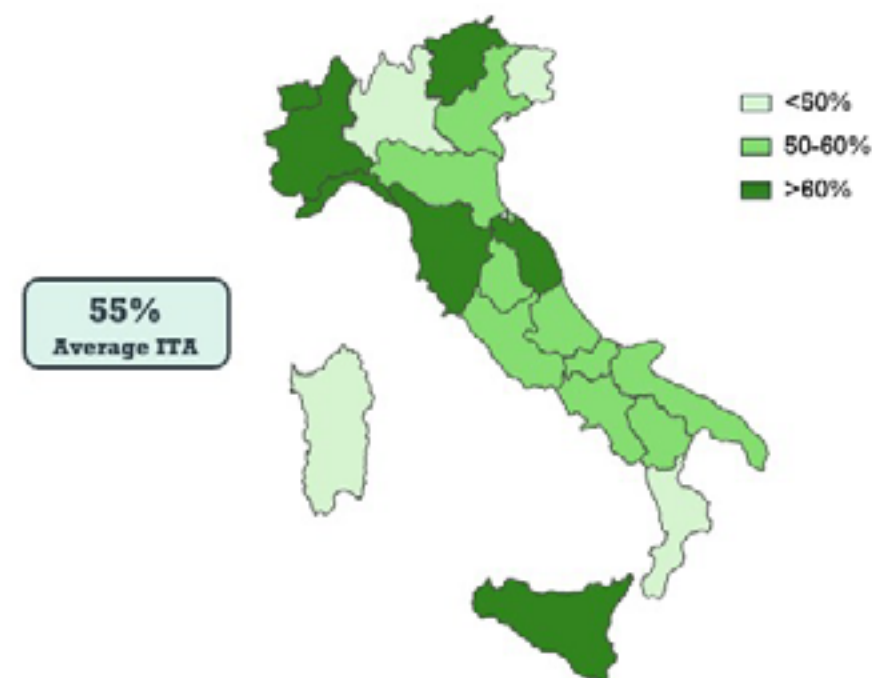
www.sanita2030.it



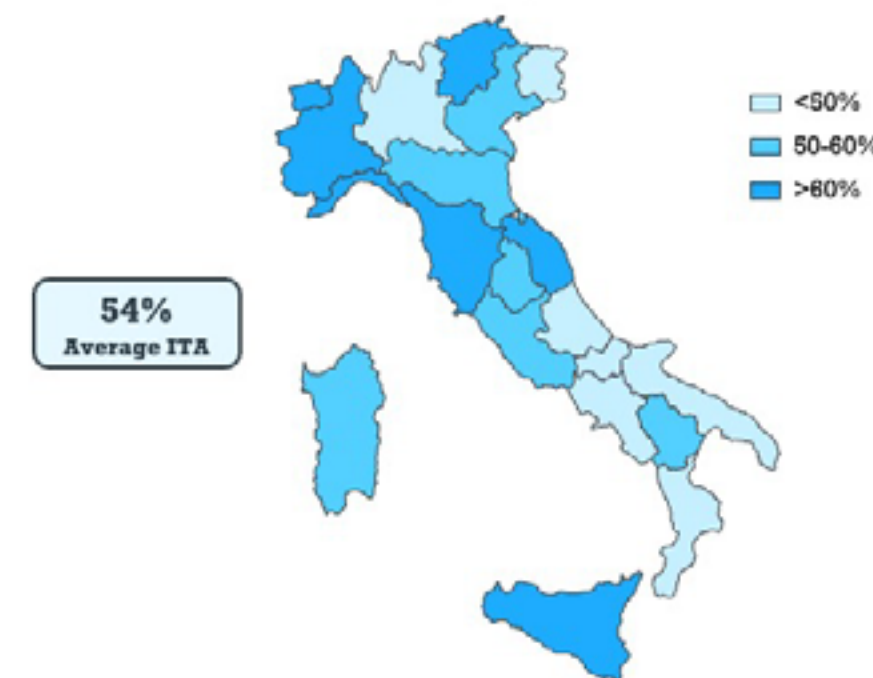


### Bx penetration varies across regions

**Bx penetration in 2022 - Volume**  
 (DOT, %)



**Bx penetration in 2022 - Value**  
 (PMP, %)



#sanita2030

Source: IQVIA REODTV\_ALL\_BIO\_OD; DOT ("Days of treatment"): Number of days of therapy estimated considering the volume sold.  
 PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



www.sanita2030.it







## Agenda

- Italian biosimilar market overview
- **Estimated savings from biosimilar use**

#sanita2030

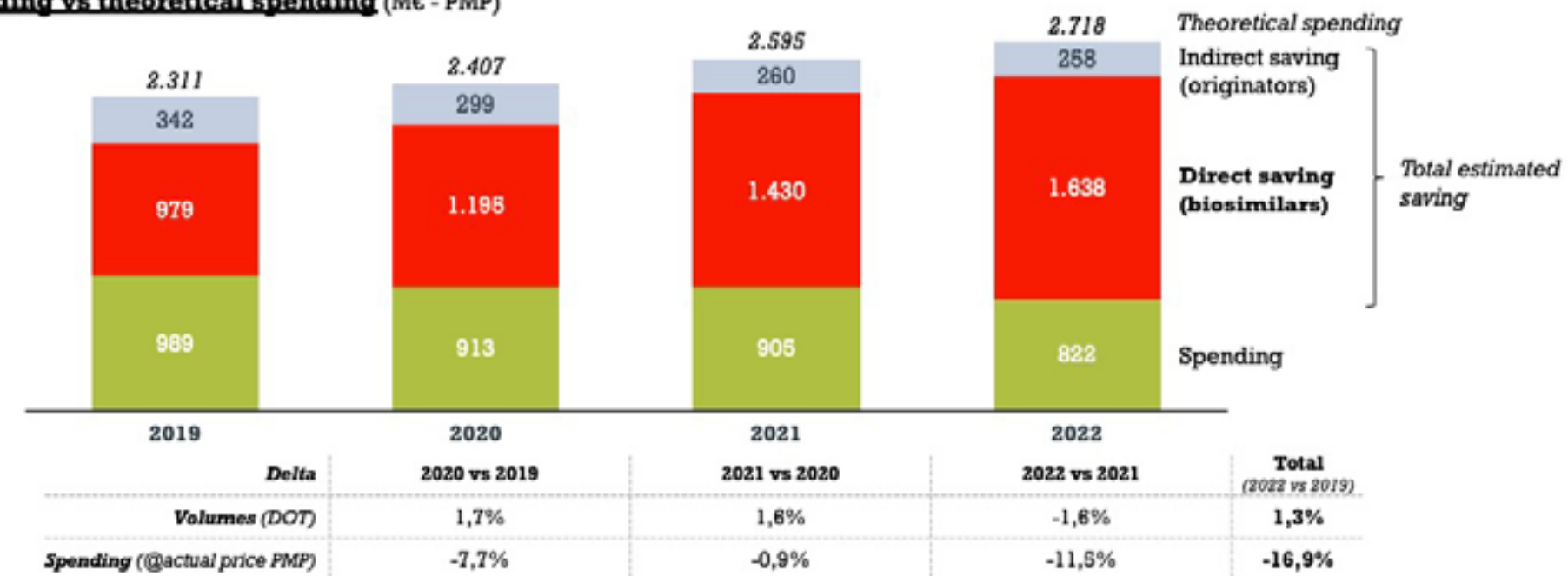


[www.sanita2030.it](http://www.sanita2030.it)



### Estimated direct savings from biosimilar use were EUR 1,6Bn in 2022

**Actual spending vs theoretical spending (M€ - PMP)**



Methodology: theoretical spending calculated considering actual volume of products and originators' pre-LoE Ex-MDF price; indirect saving calculated as difference between originators' theoretical spending and originators' actual spending; direct saving calculated as difference between biosimilars' theoretical spending and biosimilars' actual spending

#sanita2030

Source: IOVIA REGD TV\_ALL\_BIO\_OD; DOT ("Days of treatment"): Number of days of therapy estimated considering the volume sold; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



www.sanita2030.it







### Epoetin and adalimumab Bx contributed for ~50% of total direct savings

**Yearly estimated direct saving by molecule**

Molecule	Direct saving by molecule (MC)			
	2019	2020	2021	2022
Adalimumab	10%	14%	17%	19%
Bevacizumab			4%	8%
Enoxaparin	5%	5%	5%	4%
Epoetin	40%	35%	31%	29%
Etanercept	7%	7%	7%	7%
Filgrastim	14%	11%	8%	8%
Follitropin	0%	0%	0%	0%
Infliximab	7%	7%	7%	7%
Insulin glargine	1%	1%	1%	0%
Insulin lispro	0%	0%	0%	0%
Pegfilgrastim		2%	2%	2%
Rituximab	5%	5%	5%	6%
Somatropin	1%	1%	1%	1%
Teriparatide		0%	0%	1%
Trastuzumab (IV)	10%	12%	10%	9%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

Methodology: theoretical spending calculated considering actual volume of products and originators' pre-LoE Ex-MNF price; direct saving calculated as difference between biosimilars' theoretical spending and biosimilars' actual spending

#sanita2030

Source: IOVIA REODTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



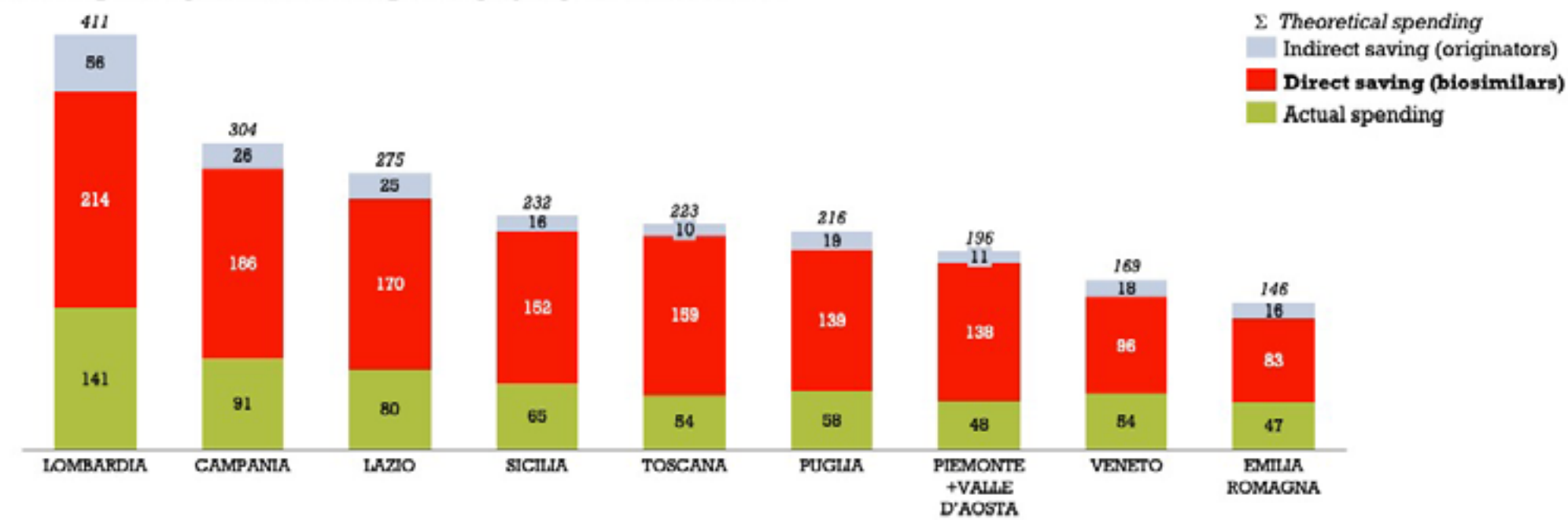
[www.sanita2030.it](http://www.sanita2030.it)





## Lombardia, Campania and Lazio had the highest savings in absolute terms

**Actual spending vs theoretical spending by region** (M€ - PMP, 2022)



Methodology: theoretical spending calculated considering actual volume of products and originators' pre-LoE Ex-MDF price; indirect saving calculated as difference between originators' theoretical spending and originators' actual spending; direct saving calculated as difference between biosimilars' theoretical spending and biosimilars' actual spending

#sanita2030

Source: IQVIA RECDTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



www.sanita2030.it

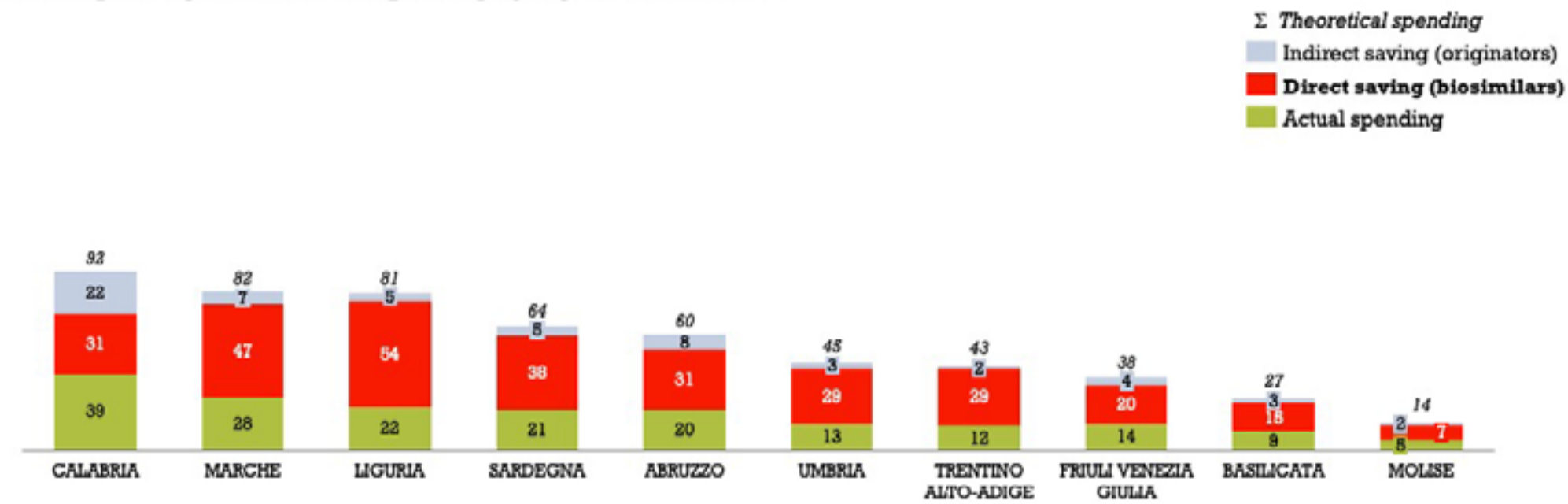






## In smaller regions, highest total savings occurred in Marche and Liguria

**Actual spending vs theoretical spending by region** (M€ - PMP, 2022)



Methodology: theoretical spending calculated considering actual volume of products and originators' pre-LoE Ex-MDF price; indirect saving calculated as difference between originators' theoretical spending and originators' actual spending; direct saving calculated as difference between biosimilars' theoretical spending and biosimilars' actual spending

#sanita2030

Source: IQVIA REODTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing

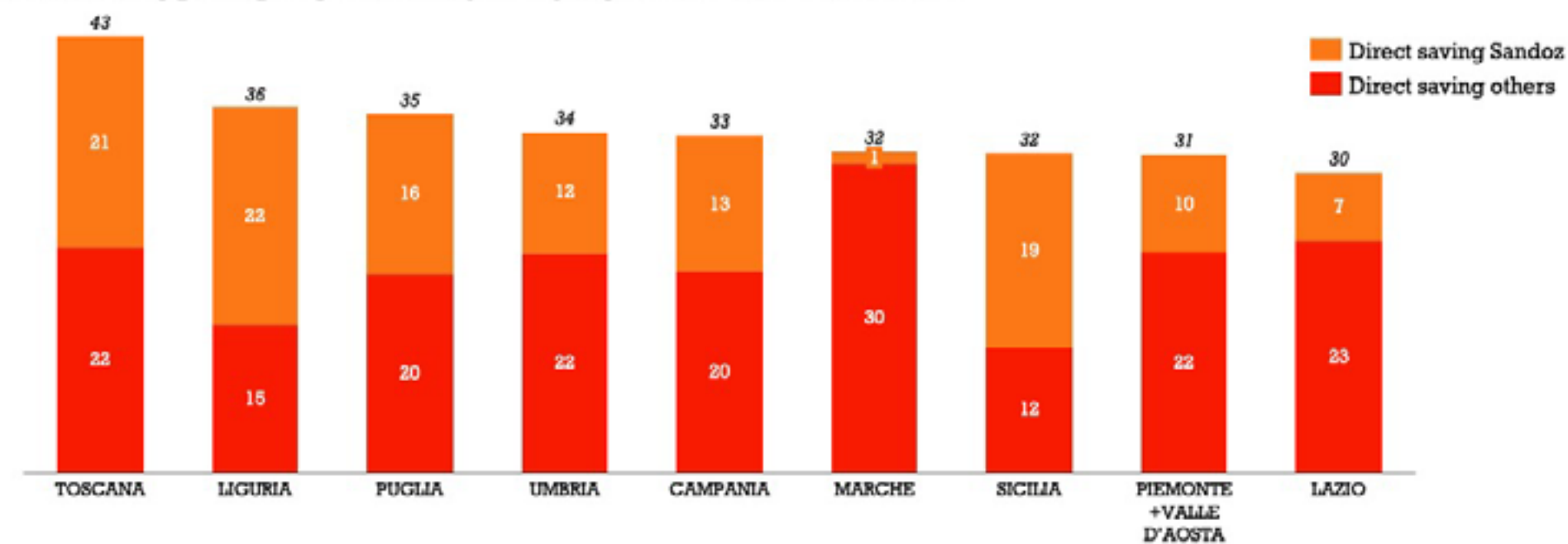


www.sanita2030.it



### Estimated direct savings per capita vary across regions (1/2)

**Direct saving per capita generated by Bx, by region** (€/regional population, 2022)



Methodology: theoretical spending calculated considering actual volume of products and originators' pre-LoE Ex-MNF price; direct saving calculated as difference between biosimilars' theoretical spending and biosimilars' actual spending

#sanita2030

Source: IQVIA REODTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



www.sanita2030.it

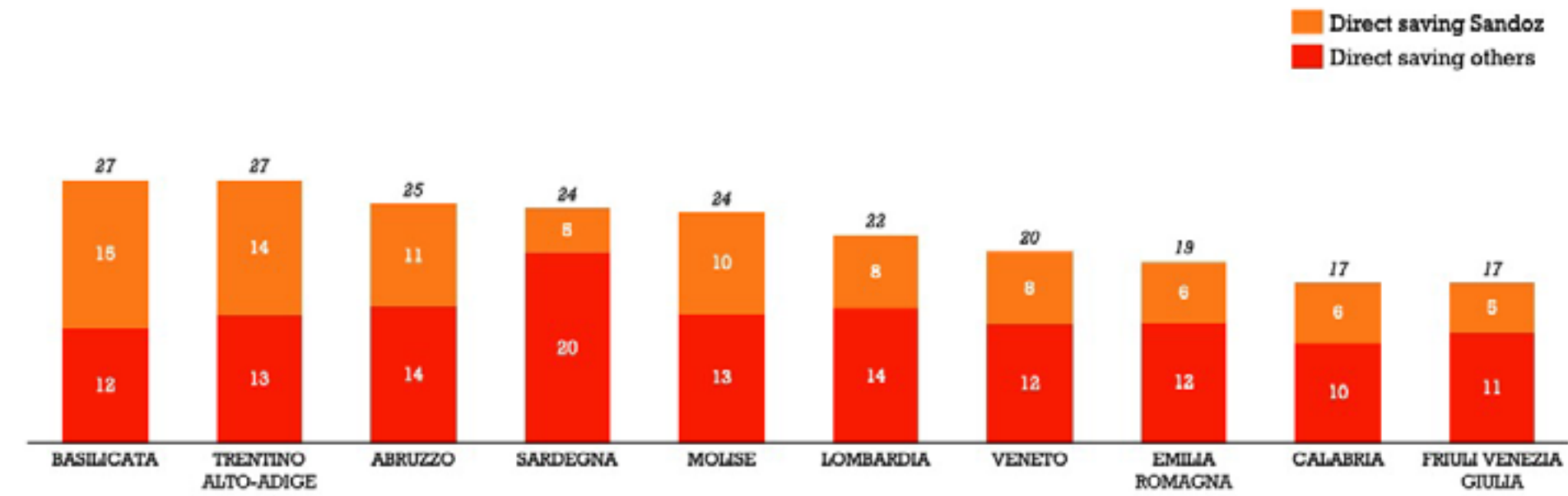






## Estimated direct savings per capita vary across regions (2/2)

**Direct saving per capita generated by Bx, by region** (€/regional population, 2022)



Methodology: theoretical spending calculated considering actual volume of products and originators' pre-LoE Ex-MNF price; direct saving calculated as difference between biosimilars' theoretical spending and biosimilars' actual spending

#sanita2030

Source: IQVIA RECDTV\_ALL\_BIO\_OD; PMP ("Prezzo medio ponderato"): average actual price for hospital/LHA purchasing



www.sanita2030.it



<https://secure.constellation.iqvia.com/Biosimilars>



### **Delitti in materia di violazione del diritto d'autore (Art. 25-novies, D.Lgs. n. 231/2001) [articolo aggiunto dalla L. n. 99/2009]**

- Messa a disposizione del pubblico, in un sistema di reti telematiche, mediante connessioni di qualsiasi genere, di un'opera dell'ingegno protetta, o di parte di essa (art. 171, legge n.633/1941 comma 1 lett. a) bis)
- Reati di cui al punto precedente commessi su opere altrui non destinate alla pubblicazione qualora ne risulti offeso l'onore o la reputazione (art. 171, legge n.633/1941 comma 3)
- Abusiva duplicazione, per trarne profitto, di programmi per elaboratore; importazione, distribuzione, vendita o detenzione a scopo commerciale o imprenditoriale o concessione in locazione di programmi contenuti in supporti non contrassegnati dalla SIAE; predisposizione di mezzi per rimuovere o eludere i dispositivi di protezione di programmi per elaboratori (art. 171-bis legge n.633/1941 comma 1)
- Riproduzione, trasferimento su altro supporto, distribuzione, comunicazione, presentazione o dimostrazione in pubblico, del contenuto di una banca dati; estrazione o reimpiego della banca dati; distribuzione, vendita o concessione in locazione di banche di dati (art. 171-bis legge n.633/1941 comma 2)
- Abusiva duplicazione, riproduzione, trasmissione o diffusione in pubblico con qualsiasi procedimento, in tutto o in parte, di opere dell'ingegno destinate al circuito televisivo, cinematografico, della vendita o del noleggio di dischi, nastri o supporti analoghi o ogni altro supporto contenente fonogrammi o videogrammi di opere musicali, cinematografiche o audiovisive assimilate o sequenze di immagini in movimento; opere letterarie, drammatiche, scientifiche o didattiche, musicali o drammatico musicali, multimediali, anche se inserite in opere collettive o composite o banche dati; riproduzione, duplicazione, trasmissione o diffusione abusiva, vendita o commercio, cessione a qualsiasi titolo o importazione abusiva di oltre cinquanta copie o esemplari di opere tutelate dal diritto d'autore e da diritti connessi; immissione in un sistema di reti telematiche, mediante connessioni di qualsiasi genere, di un'opera dell'ingegno protetta dal diritto d'autore, o parte di essa (art. 171-ter legge n.633/1941)
- Mancata comunicazione alla SIAE dei dati di identificazione dei supporti non soggetti al contrassegno o falsa dichiarazione (art. 171-septies legge n.633/1941)
- Fraudolenta produzione, vendita, importazione, promozione, installazione, modifica, utilizzo per uso pubblico e privato di apparati o parti di apparati atti alla decodificazione di trasmissioni audiovisive ad accesso condizionato effettuate via etere, via satellite, via cavo, in forma sia analogica sia digitale (art. 171-octies legge n.633/1941).

**[Torna all'inizio](#)**