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Biosimilars Substitution Impact

Market Insights

Situation Analysis

&

Strategic Options

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The purpose of this study is to help pharma companies define an optimal strategy considering the expected extension of biosimilars authorized to be substituted by retail pharmacists

Introduction

Context

- The art. 54 of the LFSS[1] 2024 published in December 2023 authorizes the substitution by retail pharmacists of biosimilars, two years after their market entry, unless the ANSM[2] gives a negative opinion
- This change in the retail market environment should have different impacts on companies marketing biosimilars according to their product portfolio and their current presence at retail pharmacy level

Objective

- The objective of this study is to evaluate:
  - The likely changes re. the substitution of biosimilars over the 2024 – 2027 period, on the retail market
  - The possible impacts on the behavior of involved stakeholders
  - The specific strategic implications for pharma companies depending on their competitive position and ambition

Methodology

- Desk research (professional magazines, Smart Pharma Consulting and other experts' reports)
- Market database analysis (2019 – 2023)
- Interviews of 38 key stakeholders to gather insights re. their vision, opinion and likely behavior:
  - 6 professional associations
  - 9 Pharma companies operating on the retail biosimilars market
  - 20 retail pharmacists and 3 VTOs[3]
- Market scenario building and strategic options development and evaluation for pharma companies on the retail biosimilar market

Sources: Smart Pharma Consulting

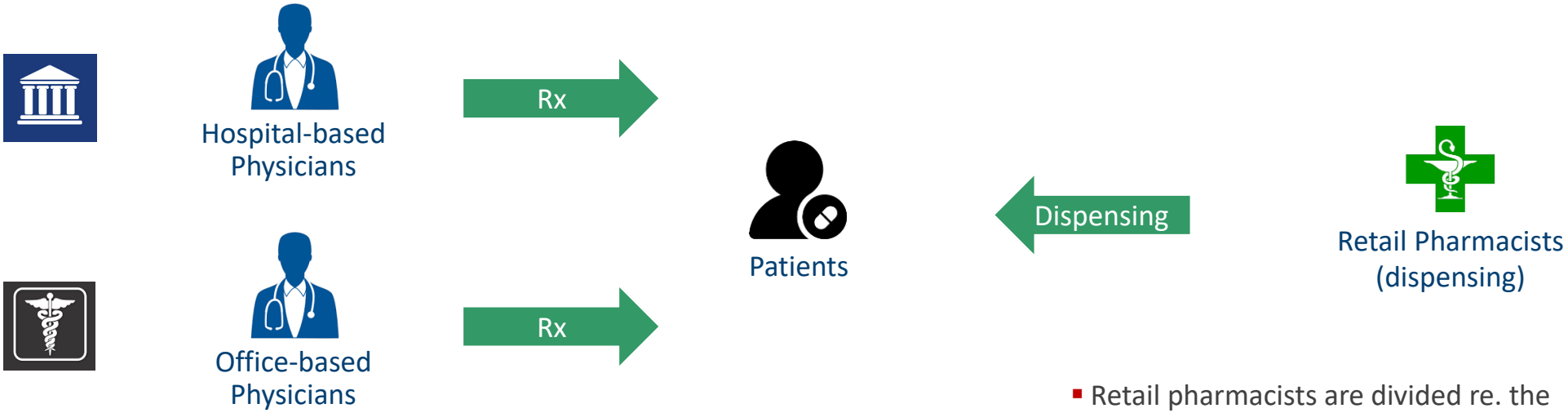
[1] Loi de Financement de la Sécurité Sociale (Social Security Financing Act) – [2] Agence Nationale de Sécurité du Médicament (National Agency for the Safety of Medicines and Health Products) – [3] Voluntary Trade Organizations (pharmacy groups)

So far, the development of the biosimilars retail market has been mostly driven by the prescription of hospital and office-based physicians which is encouraged by health authorities

Stakeholders involved in the French biosimilars market

Health Authorities & Payers[1]

- Health authorities and payers have introduced a series of measures to convince hospital and office-based physicians to prescribe more biosimilars, either as an initial treatment or as a switch



- Prescriptions of biosimilars by physicians depend on patients and the products

- Patients and PAGs[2] still wary re. the Rx of biosimilars

- Retail pharmacists are divided re. the substitution of biological drugs…
- … which is only allowed for filgrastim and pegfilgrastim as of May 2024

Sources: Smart Pharma Consulting analyses

[1] National Health Insurance Fund – [2] Patients Advocacy Groups

The French retail biosimilars market requires from pharma companies strategies, tactics and organizational models to succeed that are different from the hospital market segment ones

Specificities of the retail biosimilars market

Definition	▪ Prescribed by hospital and/or office-based specialists, purchased and delivered by retail pharmacies only (e.g., follitropin alfa, somatropin) or by hospital pharmacies too (e.g., epoetin, filgrastim)
Pricing	▪ Ex-factory price initially set by the CEPS at -40% below the price of the original biologic before its price is cut, following biosimilars entry
Purchasing	▪ The level of rebates to retail pharmacies is legally limited to a maximum of 2.5% of the ex-factory price which is in general granted by wholesalers[1] ▪ Limited price pressure on retail sales
Medico marketing activities	▪ Medical activity carried out by MSLs to reassure prescribers about the quality of the biosimilars ▪ Promotional activity carried out by marketers and med reps to be prescribed to in- and out-patients

Sources: Smart Pharma Consulting analyses

[1] Pharma companies are not used to giving discounts to retail pharmacists for their biosimilars

Substitution of biosimilars by retail pharmacists is yet allowed for filgrastim and pegfilgrastim, and should be extended to additional biologics, from 2024 onwards

Regulations related to biosimilars

Biosimilar drugs[1]

- A biosimilar drug is any biological drug that has the **same qualitative** and **quantitative** composition of **active substance** and the same pharmaceutical **form** as an original biologic…
- … but does not fulfill the conditions for being regarded as a generic due to differences related to **raw material variability** or **manufacturing processes** requiring the achievement of additional **preclinical** and **clinical data** under regulatory conditions…
- … demonstrating that the biosimilar:
  - Is **similar** to the original biologic
  - **Does not differ** significantly from the originator in terms of **quality**, **efficacy** and **safety**

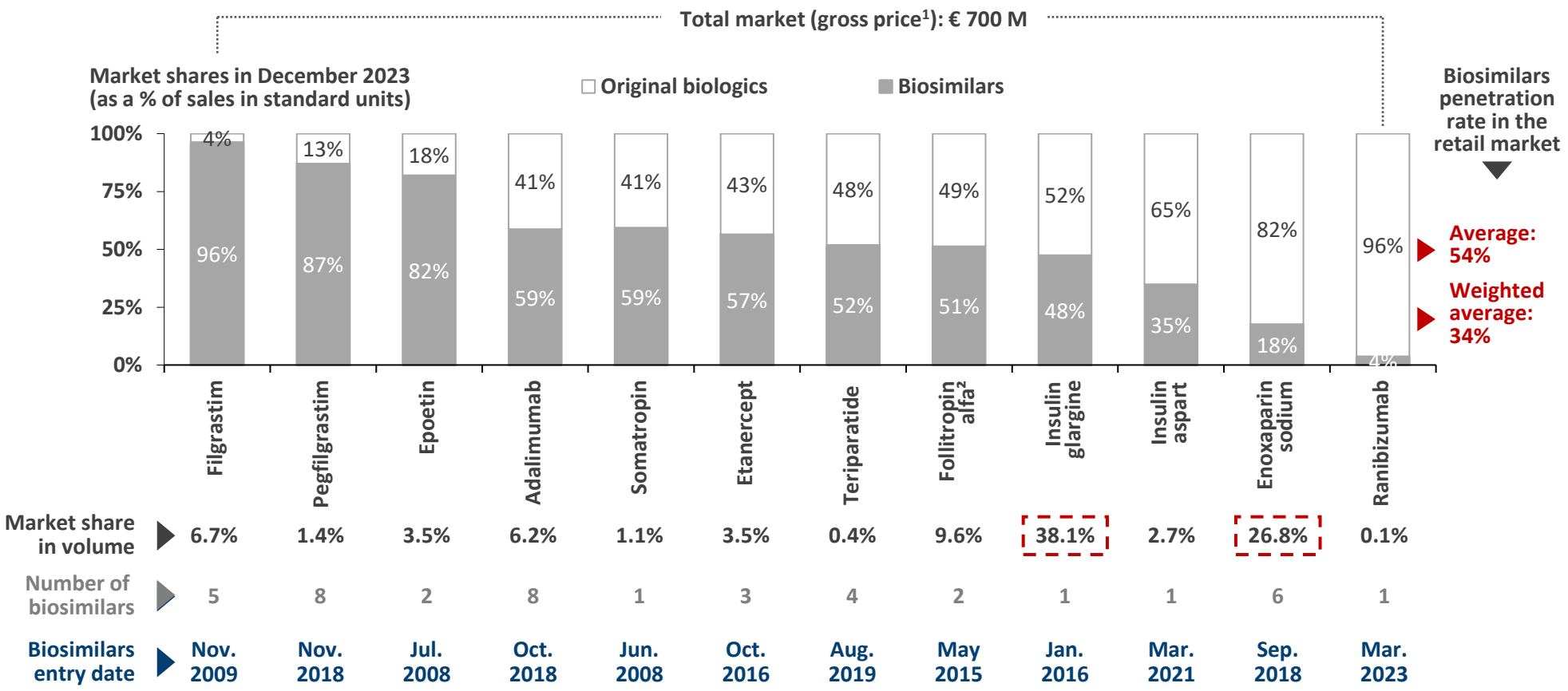
Inter-changeability	▪ The ANSM has specified in **May 2016** that **inter-changeability** was **possible** between biologic drugs belonging to the **same similar biologic group**
Biosimilar register	▪ The ANSM[2] has created in 2017 **similar biologic groups**, each of them defined by an **original biologic** and its corresponding **biosimilars**, listed by brand name
Biosimilar substitution right	▪ France **allowed** the **substitution** of biosimilars in **December 2013**, but in the absence of implementation decrees, this law has never been implemented ▪ After having been abrogated in 2020, the substitution right has been reintroduced in 2022, with a decree authorizing the substitution by retail pharmacists of 2 products: **filgrastim** and **pegfilgrastim** ▪ The Article 54 of the PLFSS 2024 stipulates that **two years after** the publication of the **reimbursement** listing of the **first biosimilar**, in a given group, a **decree** will **authorize** the **substitution by retail pharmacists** within this group, **unless the ANSM issues** an **opinion to the contrary** before the end of these two years ▪ **Substitution** is possible, provided: – The biological products belong to the **same similar biologic group** – The **prescriber** has **not explicitly prohibited**, in writing, the substitution of the prescribed drug – The **retail pharmacist** has **informed the prescriber, the patient** and **recorded the details** of the biosimilar delivered – The biological product delivered **does not induce higher costs**[3]

Sources: Public Health Code – Official Gazette – ANSM – Smart Pharma Consulting analyses

[1] A specific legal framework for biosimilars was introduced in Europe on March 31st, 2004, and the first biosimilar was authorized by the European Commission in April 2006 – [2] "Agence nationale de sécurité du médicament": National Agency for the Safety of Medicines and Health Products – [3] For the National Health Insurance Fund

In December 2023, the weighted average retail biosimilars penetration rate was limited to ~34%, pulled down by insulin glargine and enoxaparin sodium which accounted for ~65% of the volumes

Retail biosimilars penetration rate (2023)

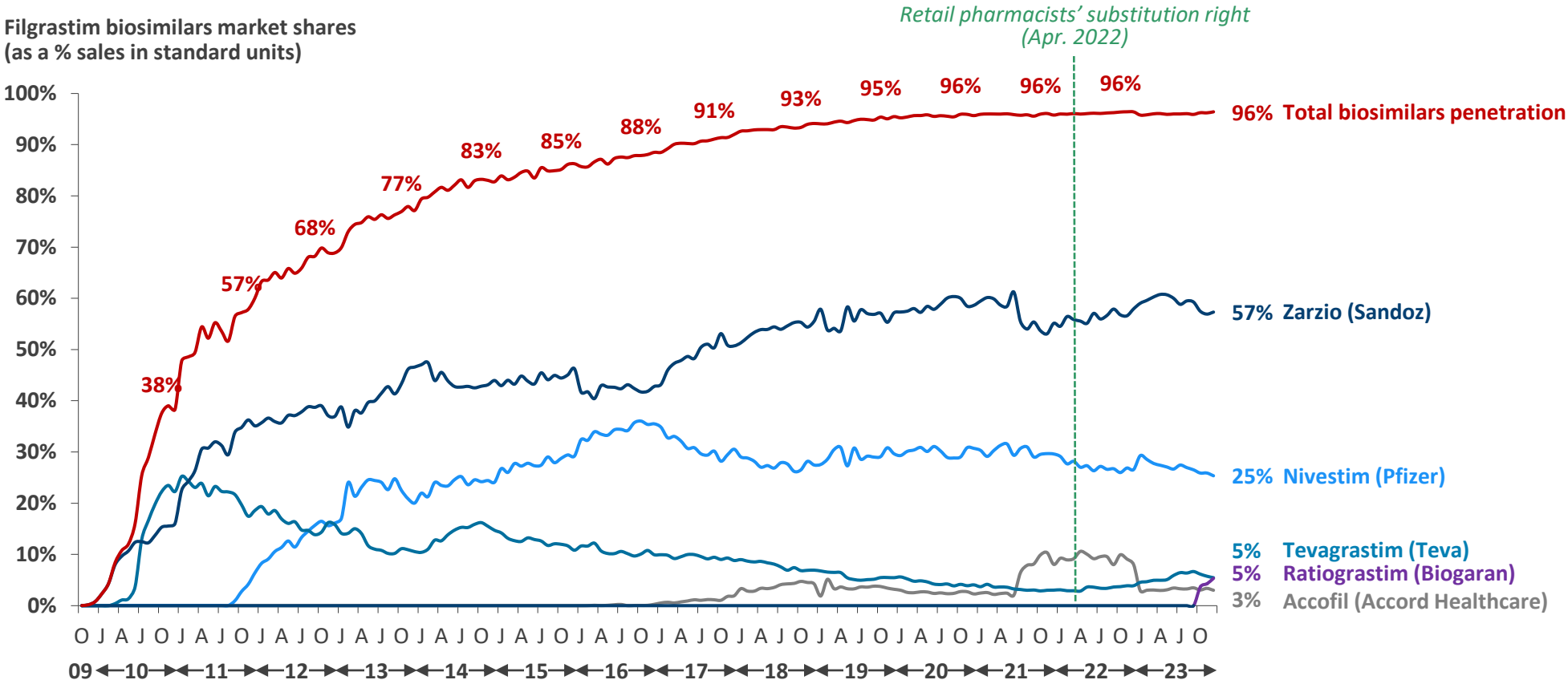


Sources: GERS (December 2023) – Smart Pharma Consulting analyses

[1] Ex-factory prices before taxes – [2] In equivalent 900 UI standard units

Retail pharmacists' substitution right had no significant impact on both biosimilar penetration (which already reached ~96% before the authorization) and market shares amongst biosimilars

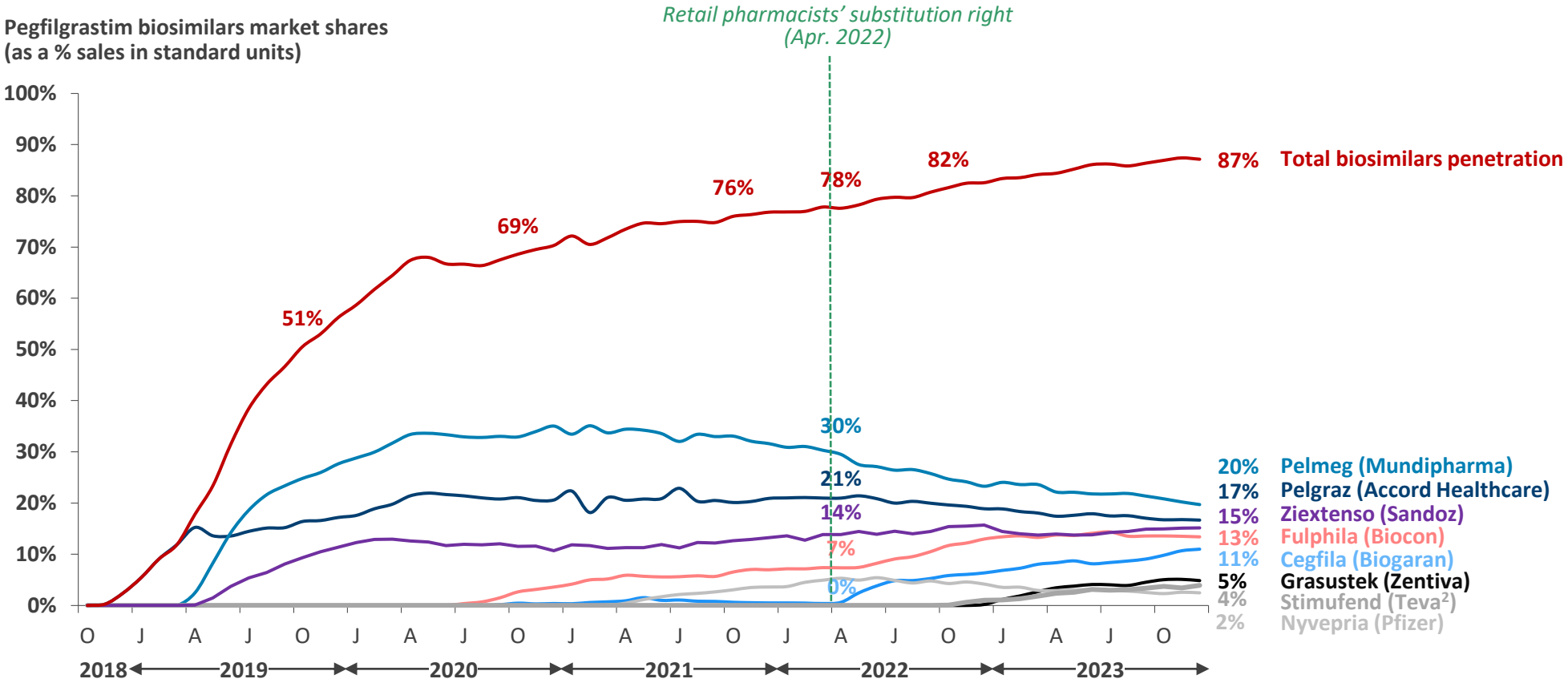
Filgrastim biosimilars penetration in volume (retail market)



Sources: ANSM – GERS (December 2023) – Smart Pharma Consulting analyses

Retail pharmacists' substitution right led to a strong uptake of Biogaran (+11 pts MS) and Biocon[1] (+6 pts MS) to the detriment of Mundipharma (-10 pts MS) and Accord Healthcare (-4 pts MS)

Pegfilgrastim biosimilars penetration in volume (retail market)

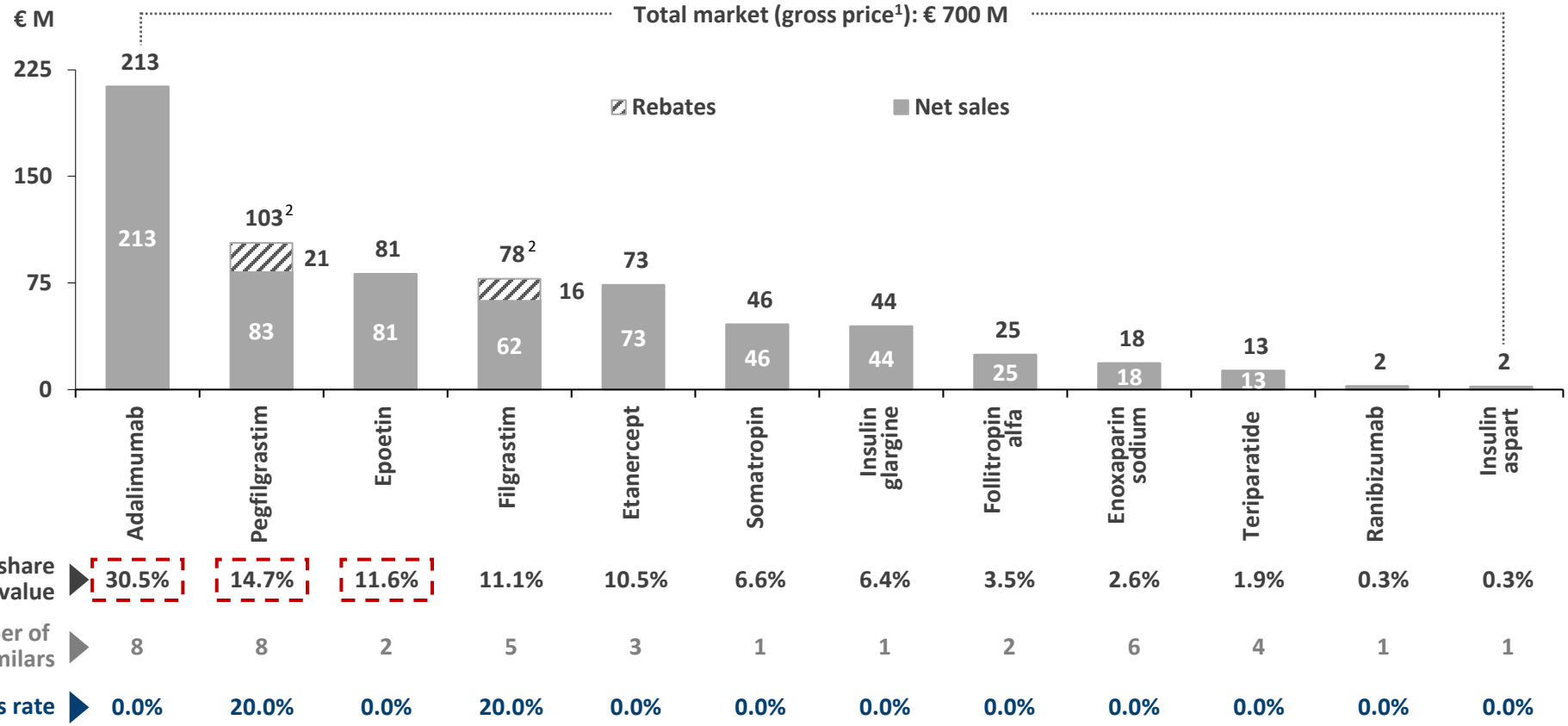


Sources: ANSM – GERS (December 2023) – Smart Pharma Consulting analyses

[1] Since December 2023. Previously marketed by Viatris – [2] Belonging to Fresenius Kabi but marketed by Teva

In 2023, adalimumab, pegfilgrastim and epoetin led the French biosimilars retail market, accounting together for ~57% of the market in value

Retail biosimilars market size (2023)



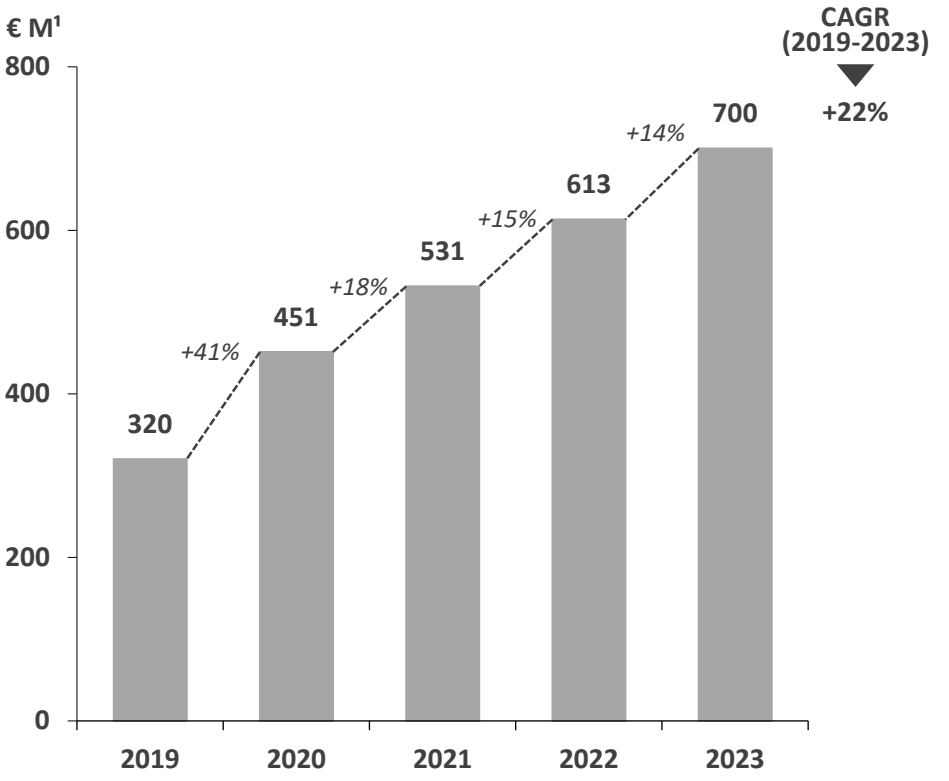
Sources: GERS (December 2023) – Smart Pharma Consulting analyses

[1] Ex-factory prices before taxes – [2] Average discounts estimated at 20% in 2023

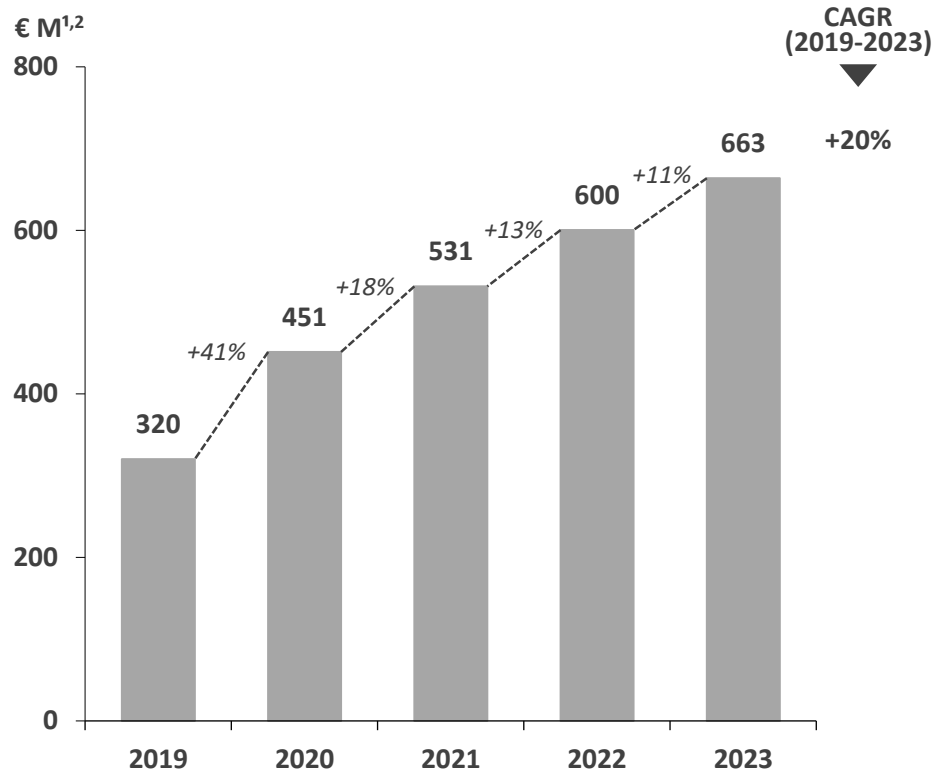
In 2023, biosimilars retail sales reached € 700 M in gross value and an estimated € 663 M in net value, representing a +22% and a +20% CAGR between 2019 and 2023, respectively

Retail biosimilars market evolution (2019 – 2023)

Gross price



Net price



Sources: GERS (December 2023) – Smart Pharma Consulting analyses

[1] Ex-factory prices before taxes – [2] Assuming the following discounts on biologics substitutable (i.e., filgrastim and pegfilgrastim): 10% from April 2022 to December 2022 and 20% in 2023

In May 2024, the price difference between original biologics and their biosimilars ranges from -32.9% (for pegfilgrastim) to +11.9% (for epoetin)

Price differences between retail original biologics and biosimilars (2024)

INN	Original biologics	Date of 1st biosimilar commercialization	Original biologic price[1] in € (May 24)	Biosimilar price[1] in € (May 24)	Price difference (May 24)
Pegfilgrastim	Neulasta (Amgen)	November 2018	594.78	399.13	**-32.9%**
Follitropin alfa	Gonal-F (Merck)	May 2015	194.88	139.49	**-28.4%**
Ranibizumab	Lucentis (Novartis)	March 2023	377.78	283.34	**-25.0%**
Tocilizumab	Roactmera (Roche)	Feb. 2024	589.72	442.29	**-25.0%**
Insulin aspart	Novorapid (NovoNordisk)	March 2021	12.27	9.60	**-21.8%**
Adalimumab	Humira (AbbVie)	October 2018	438.96	367.95	**-16.2%**
Somatropin	Genotonorm (Pfizer)	June 2008	1,290.57	1,134.04	**-12.1%**
Filgrastim	Neupogen (Amgen)	November 2009	54.58	50.49	**-7.5%**
Enoxaparin	Lovenox (Sanofi)	September 2018	22.98	22.06	**-4.0%**
Insulin glargine	Lantus (Sanofi)	January 2016	32.44	31.51	**-2.9%**
Teriparatide	Forsteo (Lilly)	August 2019	176.18	172.73	**-2.0%**
Etanercept	Enbrel (Pfizer)	October 2016	466.85	457.76	**-1.9%**
Epoetin	Eprex (Janssen)	July 2008	153.21	171.42	**+11.9%**[2]

Sources: National Health Insurance tariffs (May 2024) – Smart Pharma Consulting analyses

[1] For each INN, unit ex-factory price before discounts and taxes of the most sold SKU in 2023 – [2] The fact that the original biologic has a lower price than its biosimilars results from Janssen pricing strategy to encourage physicians to remain loyal to their brand and to the negotiation with the CEPS. However, this gap should be reduced in the short-term since the CEPS is currently negotiating a price decrease for the corresponding biosimilars of Sandoz and Pfizer

The ANSM has established a timetable to assess similar biologic groups so that to tell the MoH – which at end will decide – the biologics for which it does not recommend substitutability

Assessment of biosimilars' substitutability by the ANSM – 2024 Timetable[1]

Timetable	INN	Indications	Original Biologics	Biosimilars	Sales (2023)
April 24	Ranibizumab	AMD[2]	Lucentis (Novartis)	Ranivisio – Byooviz – Ximluci	€ 2 M*
	Aflibercept	AMD[2]	Eylea (Bayer)	Yesafili	NA**
May 24	Adalimumab	RA[3] – Psoriasis – IBD[4]	Humira (AbbVie)	Amgevita – Amsparity – Hukyndra – Hulio – Hyrimoz – Idacio – Imraldi – Yuflyma	€ 213 M
	Etanercept	RA – Psoriasis	Enbrel (Pfizer)	Benepali – Erelzi – Nepexto	€ 73 M
	Teriparatide	Osteoporosis	Forsteo (Lilly)	Livogiva – Movymia – Sondelbay – Terrosa	€ 13 M
June 24	Insulin aspart	Diabetes	Novorapid (NN[5])	Insulin aspart Sanofi	€ 2 M
	Insulin glargine		Lantus (Sanofi)	Abasaglar	€ 44 M
	Insulin lispro		Humalog (Lilly)	No Bx launched	NA*
	Epoetin	Cancer – CKD[6]	Eprex (Janssen)	Binocrit – Retacrit	€ 81 M
	Follitropin α	Functional anovulation	Gonal-F (Merck)	Bemfola – Ovaleap	€ 25 M
	Enoxaparin	Angina – infarction – DVT[7]	Lovenox (Sanofi)	Enoxaparin Arrow – Enoxaparin Becat – Enoxaparin Biogaran – Enoxaparin Crusia – Enoxaparin Teva – Inhixa	€ 18 M

** Recently launched – ** Not yet launched*

Sources: ANSM – SmPCs – Smart Pharma Consulting analyses

[1] A tocilizumab biosimilar (Tyenne) has been added to the biosimilars repertory on December 29, 2023, but is not to be assessed this year – [2] Wet age-related macular degeneration – [3] Rheumatoid arthritis – [4] Inflammatory bowel disease including Crohn's disease and ulcerative colitis – [5] Novo Nordisk – [6] Chronic kidney disease – [7] Deep vein thrombosis

All the biologics assessed by the ANSM should become substitutable but with restrictions for some of them, while certain prescribers will write "No substitution" on their prescription

Retail market: Estimates of substitutability barriers

INN	Treatment duration	Forms / dosages differences	Physicians' positions		ANSM position re. substitutability	Bx penetration dynamics
			Bx prescription[1]	Substitution		
Adalimumab	2-3 years	Different dosages / pack size / excipients	59%	At initiation	Restricted to initiations	**Limited acceleration**
Enoxaparin	5 to 35 days	Not all dosages	18%	No objection	Allowed	**High acceleration**
Epoetin	≥ 4 months	Similar injector Same dosage	82%	Not in nephrology	Allowed	**Limited acceleration**
Etanercept	2-3 years	Different dosages	57%	At initiation	Restricted to initiations	**Limited acceleration**
Follitropin α	4 months	Different injectors Different dosages	51%	Not favorable[3]	Restricted to initiations	**No acceleration**
Insulin aspart	Life-long	Different injectors (pen – cartridge)	35%	No objection	Allowed	**Medium acceleration**
Insulin glargine	Life-long	Similar injector Same dosage	48%	No objection	Allowed	**Medium acceleration**
Insulin lispro	Life-long	NA	Bx not marketed	No objection	Allowed	**Medium acceleration**
Ranibizumab	Several years	Different injectors (PFS – injectable solution)	4%[2]	If as convenient[4]	Allowed	**Limited acceleration**
Teriparatide	≤ 18 months	Pen with or without cartridge	52%	No objection	Allowed	**Medium acceleration**

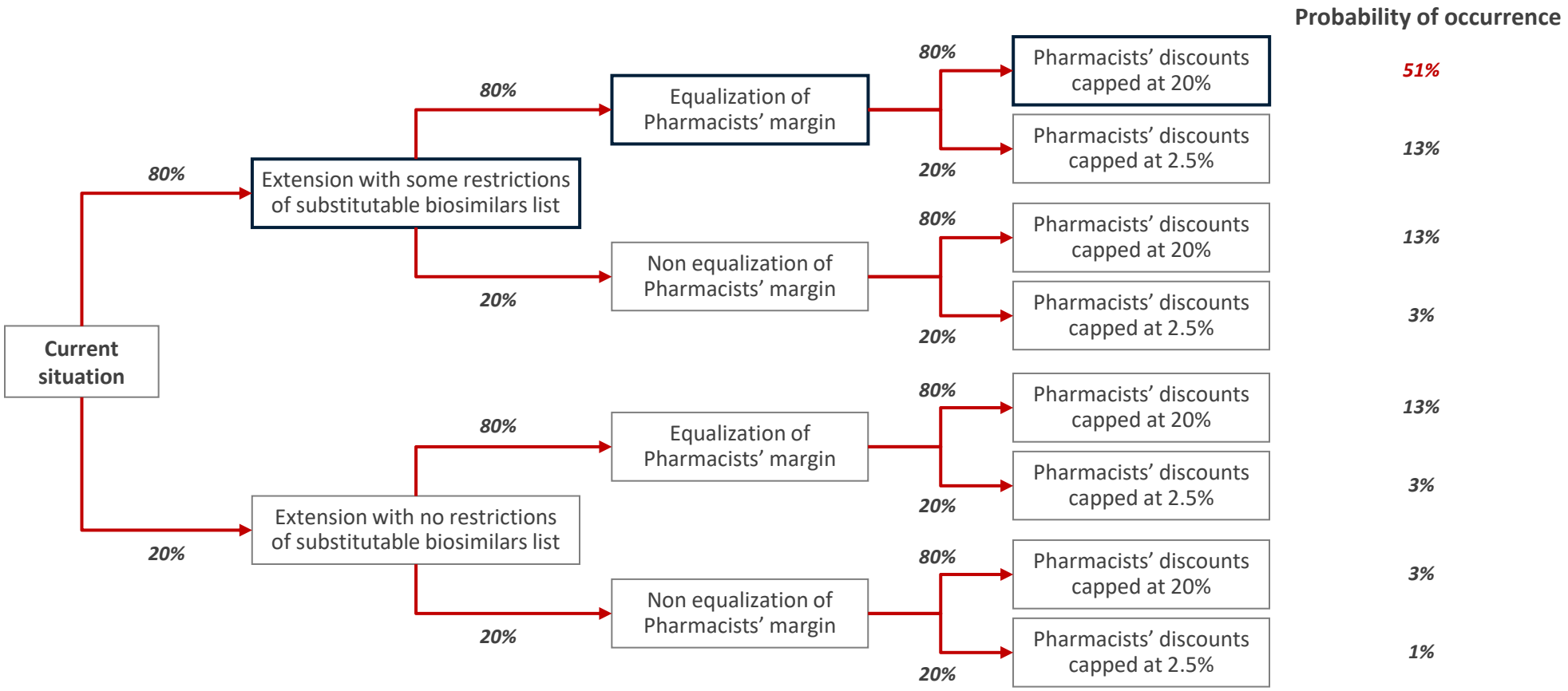
Note: The Human Growth Hormone (HGH) somatropin for which a biosimilar (Omnitrope), marketed in France since 2008, in a previous evaluation, the ANSM has expressed a negative opinion re. its substitutability, under the pression of PAGs and physicians

Sources: GERS data – EMA – ANSM – Vidal (May 2024) – Key stakeholders' interviews – Smart Pharma Consulting analyses

[1] As of December 2023 in standard units – [2] Recently launched – [3] Success rate of 30% only for IVF (In-Vitro Fertilization) – [4] Injected by prescribers who in general run after time

Based on market research and analysis, we assume that most of biosimilars, with restrictions for some of them will be substitutable, margins will be equalized, and discount capped at ~20%

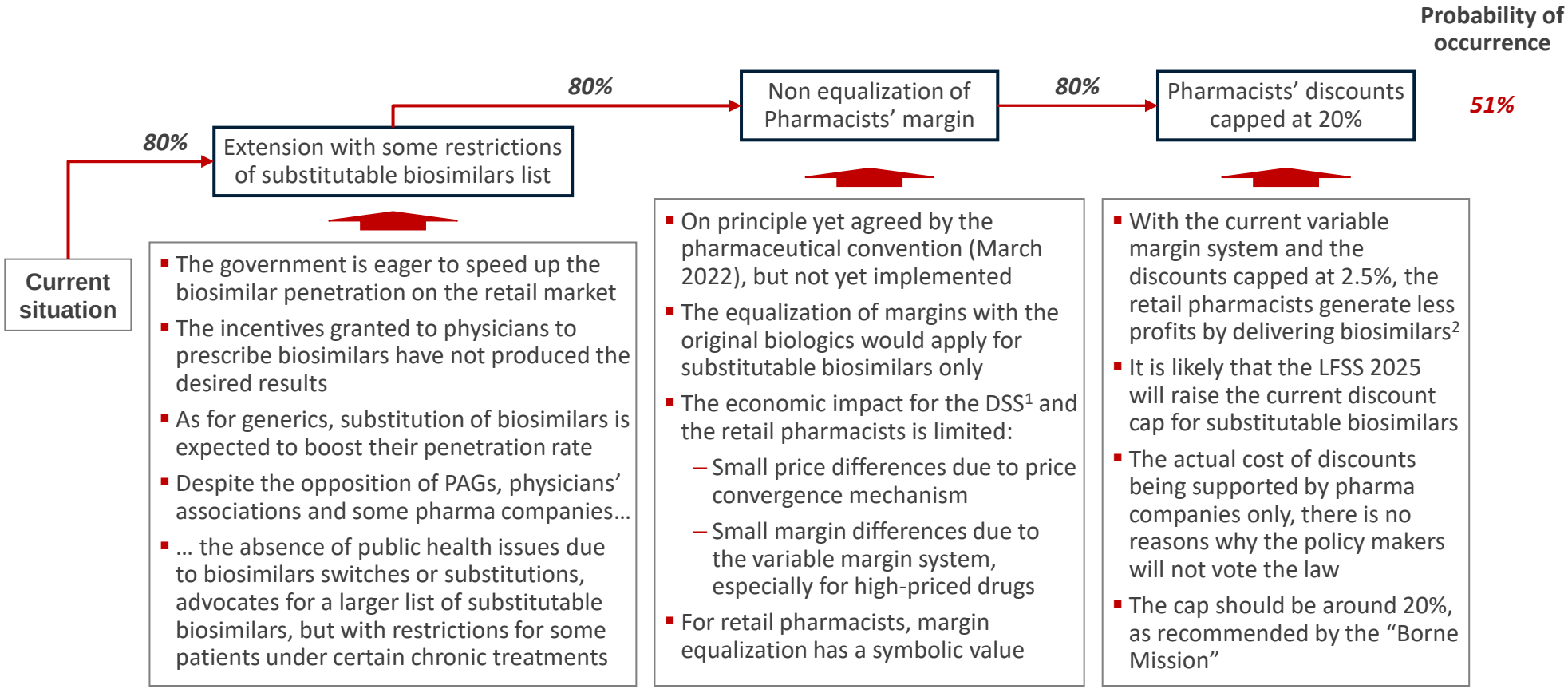
Market changes driven by health authorities – Scenario building (2024 – 2027)



Sources: Stakeholders interviews – Smart Pharma Consulting analyses

Based on market research and analysis, we assume that most of biosimilars, with restrictions for some of them, will be substitutable, margins will be equalized, and discounts capped at ~20%

Retail market: Rationale supporting the most likely market scenario

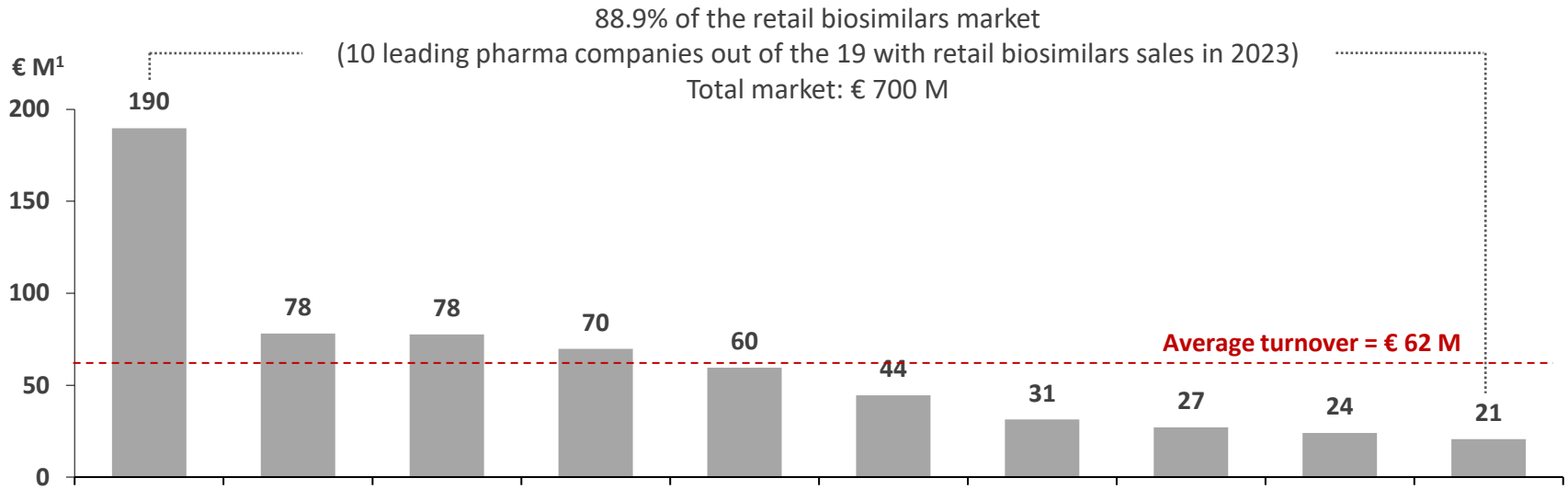


Sources: Stakeholders interviews – Smart Pharma Consulting analyses

[1] Directorate of the Social Security – [2] Officially. Currently, pharma companies offer rebates of 20-25% for pegfilgrastim and filgrastim

In 2023, Sandoz, Biogen, Amgen and Viatris generated individually € 70 M or more retail sales and represented together ~59% of the French retail biosimilars market in value

Top 10 companies on the retail biosimilars market – In value (2023)



	Sandoz	Biogen	Amgen	Viatris[2]	Pfizer	Lilly	Celltrion	Mundipharma	Accord Healthcare	Biogaran
Market share	27.1%	11.2%	11.1%	10.0%	8.5%	6.4%	4.5%	3.9%	3.4%	3.0%
Biosimilars weight in the retail portfolio	28.6%	42.3%	14.8%	4.0%	4.3%	7.0%	36.0%[3]	63.9%	41.1%	1.5%
2022-2023 evolution	+14.2%	+9.5%	+4.8%	+25.4%	-7.1%	+7.1%	+260.7%	-24.8%	-15.1%	+110.9%

Note: Other companies operating on the French biosimilars market as of May 2024: Arrow, EG Labo, Fresenius Kabi, Gedeon Richter, Rovi, Samsung Bioepis, Sanofi, Teva, Theramex and Zentiva

Sources: GERS (December 2023) – Smart Pharma Consulting analyses

[1] Ex-factory price, before taxes and discounts – [3] Company founded in November 2020 by the merger of Mylan, Mylan Medical and Pfizer Upjohn activities. In December 2023, Viatris transferred its biosimilars portfolio to Biocon Biologics (excluding Inhixa, its biosimilar of enoxaparin sodium) – [3] Remsima SC, which accounted for 64% of Celltrion retail sales in 2023, does not have the biosimilar status, unlike its IV form available at hospital

14 of the biosimilars players have a weak competitive position at retail pharmacies, the two best established ones have a limited portfolio, while Sandoz and Teva have well balanced position

Mapping of pharma companies marketing biosimilars in the retail market

Number of proposed Biosimilars[1]	Weak	Medium	Strong
6		Sandoz	
5			
4	Pfizer	Teva	
3	Accord Healthcare, Biocon, Biogen		Biogaran
2	Fresenius Kabi, Sanofi, Theramex	Arrow, EG Labo	
1	Amgen, Celltrion, Gedeon Richter, Mundipharma, Lilly, Rovi, Samsung Bioepis	Zentiva	Viatris

Competitive position at retail pharmacy level

R&D-based companies – Generics and/or biosimilars companies – Mature brand companies

Sources: Smart Pharma Consulting analyses

[1] As of May 2024

The development of the substitutable biosimilars market segment will lead to important challenges irrespective of the group the pharma companies belong to

Typology of pharma companies marketing biosimilars

	Group 1	Group 2	Group 3
Features	Weak competitive position at retail pharmacy level	Medium competitive position at retail pharmacy level	Strong competitive position at retail pharmacy level
Players	▪ Amgen – Biogen – Lilly – Pfizer – Sanofi ▪ Accord – Biocon – Celltrion – Gedeon Richter – Rovi – Samsung Bioepis – Theramex ▪ Fresenius Kabi – Mundipharma	▪ Arrow ▪ EG Labo ▪ Sandoz ▪ Teva ▪ Zentiva	▪ Biogaran ▪ Viatris
Key challenges	▪ If prescribed by physicians, they would probably be substituted in favor of biosimilars marketed by company having a medium / strong competitive position at retail pharmacies' level ▪ They will not benefit from the substitution of original biologics	▪ The companies with a broader portfolio (e.g., Sandoz, Teva) are well-positioned to reinforce their competitive positive at retail pharmacies' level ▪ Those with a narrow portfolio will be at risk on both their generics and biosimilars businesses	▪ They cannot take advantage of their strong position due to their limited biosimilars portfolio ▪ Could be "attacked" on the generics business by companies with a medium competitive position but a broader biosimilars portfolio

R&D-based companies – Generics and/or biosimilars companies – Mature brand companies

Sources: Smart Pharma Consulting analyses

To keep on playing on the retail substitutable biosimilars market, Group 1 pharma companies should partner with retail pharmacies, through third parties

Group 1: Strategic options

	Group 1	Strategic options
Features	Weak competitive position at retail pharmacy level	Stop marketing biosimilars that are substitutable or likely to be substituted
Players	▪ Amgen – Biogen – Lilly – Pfizer – Sanofi ▪ Accord – Biocon – Celltrion – Gedeon Richter – Rovi – Samsung Bioepis – Theramex ▪ Fresenius Kabi – Mundipharma	Milk biosimilars once they become substitutable
Key challenges	▪ If prescribed by physicians, they would probably be substituted in favor of biosimilars marketed by company having a medium / strong competitive position ▪ They will not benefit from the substitution of original biologics	Partner with a CSO, a generics or an OTC company well-established at retail pharmacy level Stand alone

R&D-based companies – Generics and/or biosimilars companies – Mature brand companies

Sources: Smart Pharma Consulting analyses

The strategy of Group 2 pharma companies will depend on the size of their portfolio, and their ability and willingness or not to be a leading player on the substitutable biosimilars market

Group 2: Strategic options

	Group 2
Features	Medium competitive position at retail pharmacy level
Players	▪ Arrow ▪ Teva ▪ EG Labo ▪ Zentiva ▪ Sandoz
Key challenges	▪ The companies with a broader portfolio (e.g., Sandoz, Teva) are well-positioned to reinforce their competitive positive ▪ Those with a narrow portfolio will be at risk on both their generics and biosimilars businesses

Strategic options

- Do nothing
- In-license and/or sell substitutable biosimilars on behalf of pharma companies having a weak position
- Out-license and/or subcontract the sale of substitutable biosimilars to pharma companies with a narrow portfolio but a strong position

R&D-based companies – Generics and/or biosimilars companies – Mature brand companies

Sources: Smart Pharma Consulting analyses

To remain competitive on the retail substitutable biosimilars market, Group 3 pharma companies should either sell on behalf of, or in-license from, biosimilars manufacturers

Group 3: Strategic options

	Group 3	Strategic options
Features	Strong competitive position at retail pharmacy level	Do nothing
Players	▪ Biogaran ▪ Viatris	Sell substitutable biosimilars on behalf of pharma companies having a weak competitive position
Key challenges	▪ Cannot take advantage of their strong position due to their limited biosimilars portfolio ▪ Could be "attacked" on the generics business by companies with a medium competitive position but a broader biosimilars portfolio	Build up a broad / broader portfolio of substitutable biosimilars through BD&L initiatives

R&D-based companies – Generics and/or biosimilars companies – Mature brand companies

Sources: Smart Pharma Consulting analyses

Pharma companies will require medical reps only to promote non-substitutable biosimilars to physicians and pharmacy reps only to sell substitutable biosimilars to retail pharmacists

Biosimilars substitutability: Implications for pharma companies (1/2)

- 2 years from the publication of the **reimbursement** listing of the **first biosimilar**, in a similar biologic group

Non-substitutable biosimilars → **ANSM**

- Market share driven by the prescription of physicians

Medico-marketing & sales activities targeted at physicians only

Pharma companies' promotional activities

ANSM → Negative opinion → **Non-substitutable biosimilars**

- Market share driven by the prescription of physicians

Medico-marketing & sales activities targeted at physicians only

Pharma companies' promotional activities

ANSM → Absence of opinion → **Substitutable biosimilars**

Sales activities targeted at pharmacists & selected physicians[1]

- Market share driven by the substitution of retail pharmacists:
  - From original biologics to biosimilars
  - From biosimilars to biosimilars

Sources: Smart Pharma Consulting analyses

[1] Physicians who are reluctant to biosimilars' substitution and who will be inclined to indicate "Non substitutable" on their prescriptions of biosimilars

The sales activities of pharma companies at retail pharmacists should not start before it becomes substitutable

Biosimilars substitutability: Implications for pharma companies (2/2)

	Physicians	Pharmacists
Non substitutable phase	▪ Promotional activity at targeted physicians… ▪ … to strengthen physicians' preference for the marketed biosimilars	NO ACTION
Substitutable phase	▪ Promotional activity stopped… ▪ … or restricted to physicians who are opposed to biosimilars' substitution… ▪ … and willing to prevent substitution by indicating on their prescription, next to the name of the biologic[1] prescribed, "Non-substitutable"	▪ Sales activity to get the biosimilar listed… ▪ … and preferentially substituted at the expense of the original biologic or of another biosimilar

Sources: Smart Pharma Consulting analyses

[1] *Either the original biologic or a biosimilar*

The optimal strategies of pharma companies marketing biosimilars would depend on their competitive position at retail pharmacies, each product status and the diseases it addresses

Key Takeaways

1. Regulatory environment

- Filgrastim and pegfilgrastim are substitutable since April 2022
- From 2024 onwards, expansion of the list with existing drugs[1]
- For new biosimilars, a period of 2 years will precede the possibility to substitute biologics[1]

2. Physicians' behavioral trends

- Physicians, especially hospital-based, are used to initiate treatments with biosimilars…
- … but are more reserved regarding switching and substituting chronic treatments when patients' disease is well controlled[2]

3. Pharmacists' behavioral trends

- Pharmacists do not anticipate difficulties to substitute biologics for naïve patients
- For patients under a chronic therapy, they will substitute depending on each patient
- If opportunities to substitute are rare, pharmacists should not be very pro-active

4. Patients' behavioral trends

- Naïve patients should in large proportion accept biosimilar substitution, but…
- … if yet treated and well-controlled, they will have to be convinced by pharmacists
- Even if they accept, they may have trouble to adjust if the delivery device is different

5. Pharma companies' strategic options & recommendations

- During the two years before biosimilars become substitutable, they should be promoted to physicians[3]
- Certain substitutable biosimilars should still be promoted[3]
- Agreements with retail pharmacists and VTOs[4] they belong to, are essential to succeed on the biosimilar substitutable market
- To do so, company marketing biosimilars strategies would depend on their competition position at retail pharmacies:
  - If weak: partner with a company yet well-established, a CSO[5] or leave the market
  - If medium: in-license or sell biosimilars of companies having a weak position or out-license / subcontract to a 3rd party having a strong position
  - If strong: pharma companies should either sell on behalf of, or in-license from, biosimilars manufacturers

Sources: Smart Pharma Consulting analyses

[1] Unless the ANSM issues a negative opinion. The ANSM can also restrict the substitutability (e.g., to naïve patients only) – [2] In this case they can and should prevent substitution by indicating on their prescription "Non-Substitutable" – [3] Especially for chronic disease treatments – [4] Voluntary Trade Organizations (pharmacy groups) – [5] Contract Sales Organization

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Biosimilars Substitution Impact

Situation Analysis & Strategic Options

This position paper analyzes the current market segment situation and estimates its perspectives of evolution

Thus, the following topics are covered:

- Regulatory framework
- Key stakeholders' analysis (health authorities – healthcare professionals – pharma companies)
- Scenario building and likely impacts
- Strategic options assessment
- Recommendations

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Best regards

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