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September 2018

The Impact of Biosimilar Competition in Europe

Contents

Introduction

This document sets out to describe the effects on price, volume and market share following the arrival and presence of biosimilar competition in Europe, as defined by the countries listed in the Appendices. The report consists of a set of Key Performance Indicators (KPIs) to monitor the impact of biosimilars in European markets, using full year 2017 data.

This report has been prepared by IQVIA at the request of the European Commission services with initial contributions from EFPIA, Medicines for Europe, and EuropaBio. The information and views set out in this report are those of its authors and are not to be attributed to, nor necessarily reflect the views of, the European Commission or any of its services.

The European Medicines Agency (EMA) has a central role in setting the rules for biosimilar submissions, approving applications, establishing approved indications and monitoring adverse events, and if necessary issuing safety warnings. We have, when appropriate, quoted their information and statements.

Definitions

The report uses some basic terms defined as follows:

- **Accessible category:** products within the same ATC4 code including the following three product categories:
  - **Referenced Medicinal Product:** Original product, granted market exclusivity at the start of its life, exclusivity has now expired and the product has been categorised as referenced.
  - **Non-Referenced Medicinal Product:** Original product, granted market exclusivity at the start of its life, exclusivity has now expired and the product has never been categorised as a Referenced Medicinal product, or may have been referenced but the referencing biosimilar has not been launched.
  - **Biosimilar Medicinal Product:** Product, granted regulatory approval, demonstrating similarity to the Reference Medicinal Product in terms of quality characteristics, biological activity, safety and efficacy.
- **Non-accessible category:** products within the same ATC4 code as the accessible category products, and are typically second generation products; this category may include products with different dosing schedules and / or route of administration to those in the accessible category.
- **Total market:** includes both the Accessible and the Non-accessible product markets.

The **KPIs** used in the report focus on price and volume trends

- **Launch date:** date of first recorded sales of Biosimilar Medicinal Product in the country.
- **Price indicators:**
  - **Price:** the price level used is gross ex-manufacturer price (list price), which values the product at the level that the manufacturer sells out, without taking into account rebates or discounts.
  - **Price evolution:** price per Treatment Day (TD) in 2017 versus year before biosimilar entry.
- **Volume indicators:**
  - **Volume:** volume is measured in Treatment Days (also known as Defined Daily Dose) which is a measure of the average dose prescribed as defined by the WHO.
  - **Biosimilar market share:** number of biosimilar treatment days as a share of (i) biosimilar + referenced product(s) volume, (ii) accessible market volume and (iii) total market volume.
  - **Volume evolution:** number of Treatment Days in 2017 versus year before biosimilar entry.
  - **Volume per capita 2017:** number of Treatment Days consumed in 2017 normalised by population size.
  - **Volume per capita year before biosimilar entrance:** number of Treatment Days consumed the year before the entrance of biosimilars, normalised by population size.

Caveats

The indicators are intended to give a broad overview of the uptake and the implications on price and volume evolution after introduction of biosimilar medicines. There are differences in perspective between payers, providers, and different types of manufacturers. In focusing on the payers there are a few key caveats that need to be made when interpreting the results:

- **Pricing and discounts:** the report is based on publicly available LIST prices. Discounting occurs, especially in contracting with hospitals and in countries using tenders for biological drug procurement, which can lead to larger price fluctuations than is visible through the reported IQVIA data.
- **Approved indications and efficacy:** not all products in a specific product group in the accessible, non-accessible or total market have the same approved indications and can have differences in efficacy and individual patient outcomes. Biosimilars normally receive the same indications as the referenced products and are expected to have the same safety and efficacy.
- **Volume estimates:** the pack volumes reported are based on IQVIA collected data which may have been unknowingly impacted by issues such as parallel exporting. The volumes have been converted to daily doses using the published World Health Organization (WHO) defined daily doses (DDD) which can introduce bias. Consumption measures are therefore not adjusted for clinical practice guidelines, patient characteristics, indications for which the molecule is used, or other factors that may result in different volumes utilised on a per patient Treatment Day basis.
- **Long-term vs. one-off use:** hospital-only vs. retail: no distinction is made in this report between biologicals for long-term (repeat use) and one-off use, nor between hospital-only and retail products, although competitive conditions and scope for biosimilar uptake are likely to differ in the various scenarios.

Key Observations

1. The entrance of biosimilars increases price competition

1a. Competition drives down price

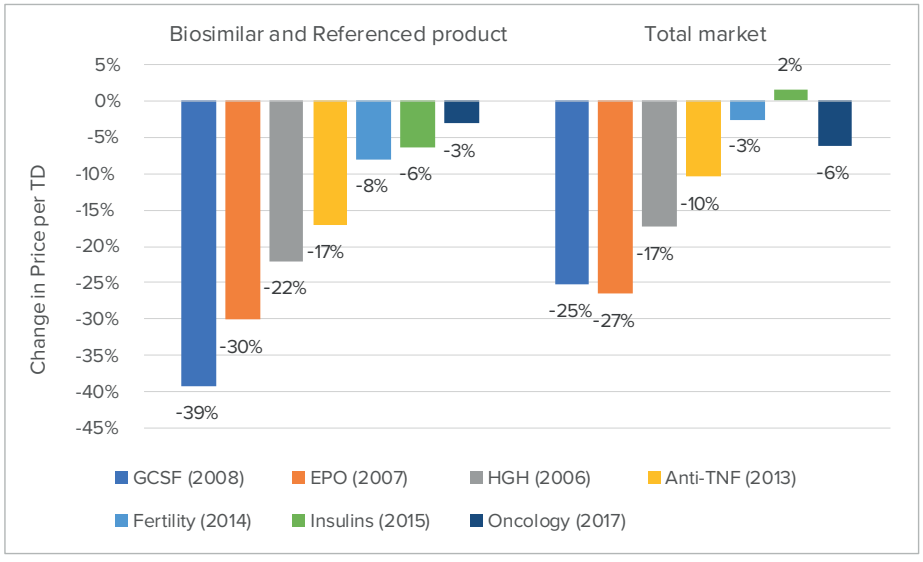
The rationale behind the introduction of biosimilars is to increase price competition, an effect of which is often reduced prices. The seven established therapy areas with biosimilar competition show a consistent picture of reduced average list prices in European countries (see Exhibit 1).

The increased competition resulting from biosimilars entering the market affects not just the price of the respective biosimilars referenced product, but also the price of the whole product class. It can have almost as large an impact on the total market price as it has on the biosimilar/referenced product price. In the case of EPO's in Portugal, the price decease of the total market was -66%.

List price reductions vary considerably across Europe within a class, and between classes. The variation in change in price per treatment day between the classes is largely dependent on the length of time biosimilars have been on the market.

Countries may also have high price reductions, through non-published discounting. However, such reductions are not visible in the data in this report, therefore, the biosimilars value is understated. In addition, the highest reduction may not equal the lowest price. This report does not examine in detail the scope for further biosimilar uptake or price reductions in countries and what the underlying obstacles are.

Exhibit 1: Change in Price per treatment day since introduction of biosimilars (year of first biosimilar launch)

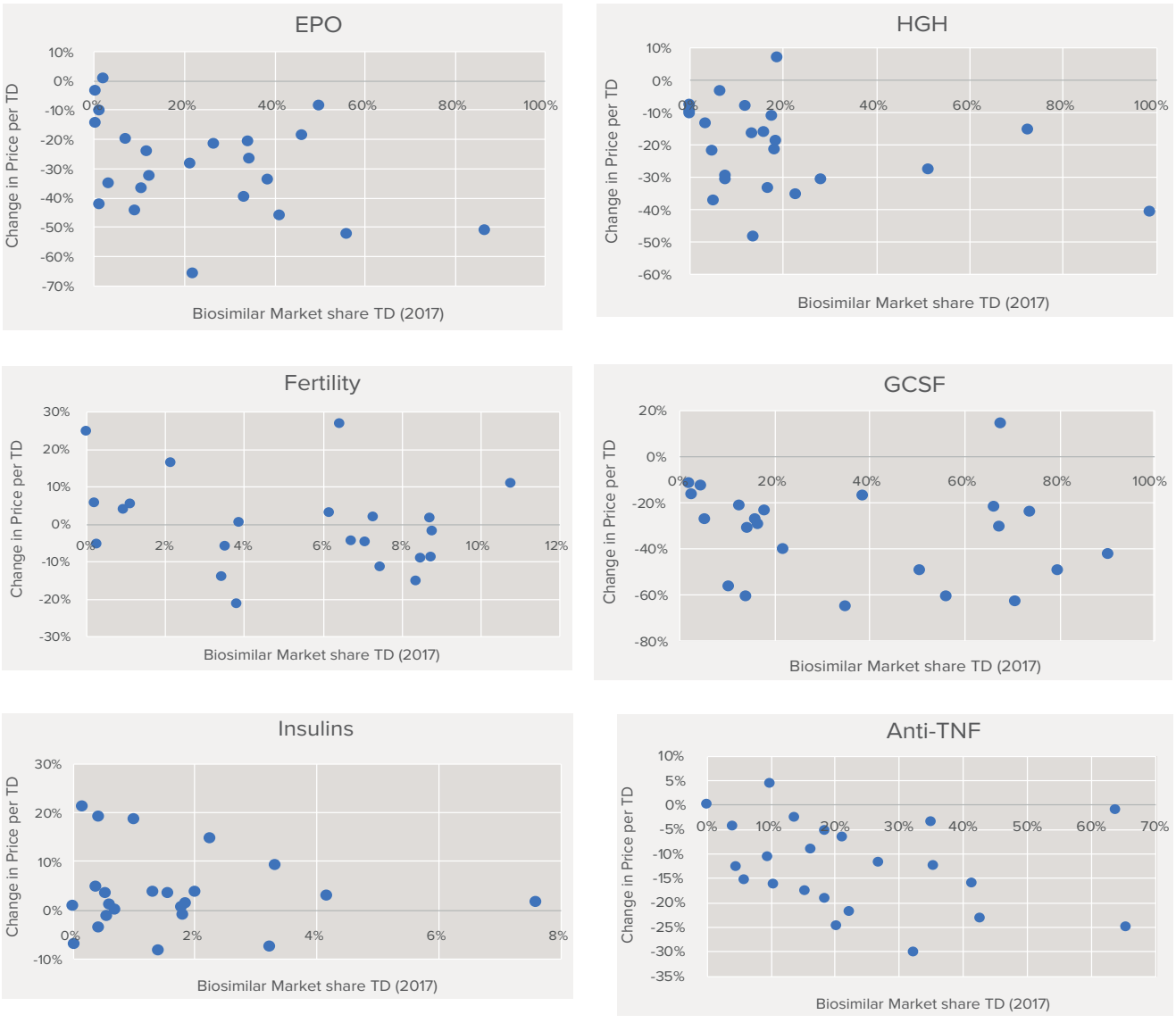


1b. The correlation between biosimilar market share and price is weak

The correlation between biosimilar volume market share of the total market and price reduction (at list price level) of the total market is weak, as can be seen by the established biosimilar classes. For all the seven established classes we can see the same pattern; in some countries savings can be achieved even if the biosimilar market share is low.

Price reduction can be achieved through price regulation interventions and/or commercial decisions of manufacturers. Even if the biosimilar product does not end up being the product sold, it is likely an essential step to generate a more competitive environment, which leads to lower prices. However, in the long term, low biosimilar uptake could lead to fewer new biosimilars being developed, reducing the overall competitive pressure. To ensure competition and market attractiveness, appropriate country incentives must be in place.

Exhibit 2: Biosimilar market share in 2017 vs Change in price per treatment day (2017/year before biosimilar entrance), by country

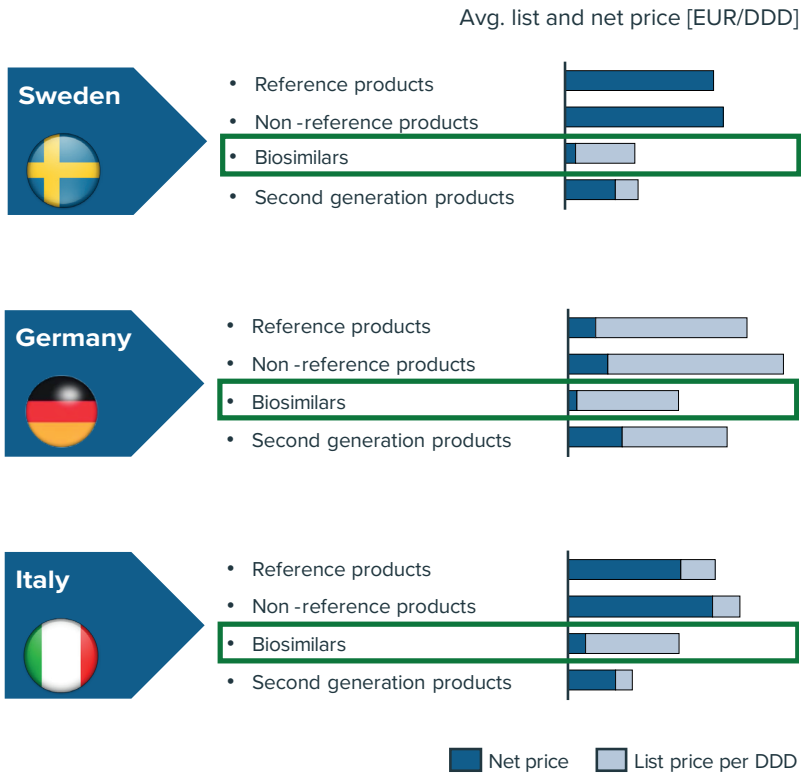


1c. Savings are much larger in some situations due to rebates

This report is based on publicly available list prices; however, discounting does occur and can lead to larger price fluctuations, and higher price savings than is visible through the reported IQVIA data.

In the case study below, the net prices for GCSF in a few countries are reported. Biosimilar discounts can be 80-90% off the originator list price and the net prices are in fact similar across the countries analysed. The originator has focused its defense on switching users to the second-generation product and offering rebates. In some markets, the non-referenced products are also discounted. Therefore, the competition is fierce and very low net prices are often available in a market.

Exhibit 3: Case study GCSF in European markets



Source: IQVIA consulting, Q1 2017; Net prices in Sweden and Italy are based on actual transacted costs in the regional systems; Net prices in Germany are based on a large sample of hospital pharmacies

2. Biosimilars have the potential to improve patient access of the total market

2a. Lower prices, amongst other factors, can increase patient access

Some level of price-elasticity is expected to be observed for biosimilars. However, this report shows different levels of impact to lowered prices for different countries and different classes.

For most classes, there is a significant increase in consumption since biosimilar entry in countries which had low starting volumes. There are also some countries which already had high usage of classes before biosimilar entry, such as Norway with Anti-TNF's, which still show a significant increase in consumption.

Therefore, lowered prices can impact usage, but there are other factors to consider:

- New indications or restriction of indications (for example the EPO safety warnings)
- General economic conditions imposing use restrictions
- Changes in diagnosis and prevalence of diseases

It is important to note that a price-only policy does not generate access; country policies which stimulate biosimilar penetration are required to increase patient access.

Exhibit 4: Countries with the highest change in volume treatment day (2017/year before biosimilar entrance)

Anti-TNF	Price per TD 2017/ Yr before BS entrance	Volume TD 2017/ Yr before BS entrance	TD/capita (Year before Biosimilar entrance)
Austria	4%	407%	0.17
Bulgaria	-25%	242%	0.10
Portugal	-19%	82%	0.26
Norway	-1%	71%	1.07
Poland	-30%	69%	0.04

G-CSF	Price per TD 2017/ Yr before BS entrance	Volume TD 2017/ Yr before BS entrance	TD/capita (Year before Biosimilar entrance)
Bulgaria	-60%	1893%	0.00
Romania	-63%	489%	0.00
Slovakia	-65%	426%	0.01
Slovenia	-56%	249%	0.02
Norway	-12%	152%	0.03

EPO			
Poland	-37%	418%	0.03
Greece	-51%	103%	0.02
Italy	-8%	41%	0.82
UK	-10%	32%	0.24
Czech	-34%	30%	0.09

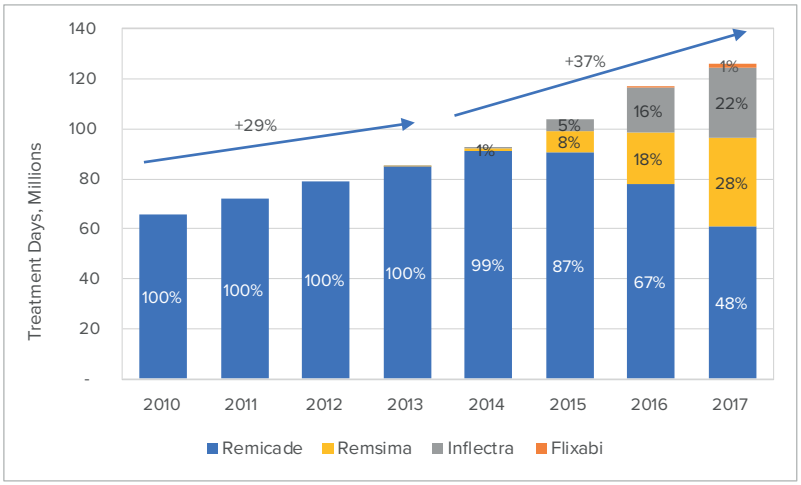
HGH			
Romania	-31%	145%	0.02
Poland	-41%	102%	0.04
UK	-16%	94%	0.04
Czech	-31%	85%	0.08
Ireland	-10%	75%	0.04

2b. There is demand elasticity in the market

Case study: Infliximab treatment days

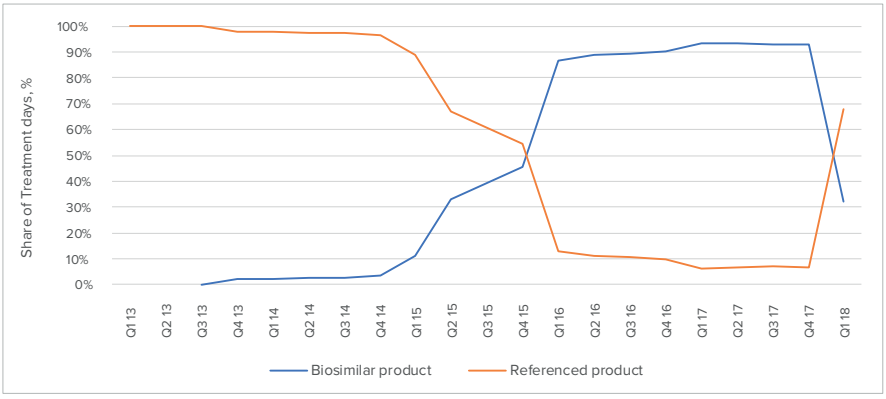
Since the launch of infliximab biosimilars in Europe in September 2013, there has gradually been an increase in the total number of infliximab treatment days, increasing at a faster rate than before biosimilar entry. In 2017, biosimilar products accounted for over half of the infliximab treatment days.

Exhibit 5. Number of treatment days for Infliximab products in Europe (% change in treatment days)



However, locally the dynamics can look very different. For example, in Finland, patients are starting to be switched from the biosimilar product back to the referenced product, Remicade. One of the factors driving this is that the originator is actively competing on price.

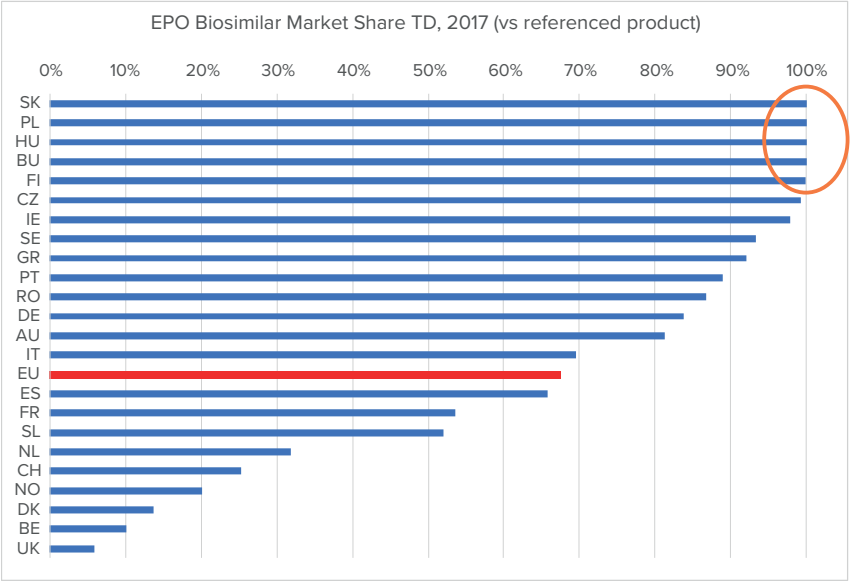
Exhibit 6: Infliximab share of treatment days (%) in Finland



3. In some countries, biosimilars have completely taken over the (biosimilar and referenced product) market

In classes where biosimilars have been on the European market for several years, there are now many examples of countries where the referenced product is no longer available and biosimilars have 100% market share of treatment days (vs biosimilar and referenced products). It must be noted that this analysis only considers the biosimilar and referenced products, not the total market.

These are often countries with low GDP/capita in Europe, where the incentive to switch to biosimilars may be high. It must be noted that some of the countries analysed had very low use of the reference product before the launch of the biosimilar, meaning access to the biologic product was granted by biosimilars entering the market.



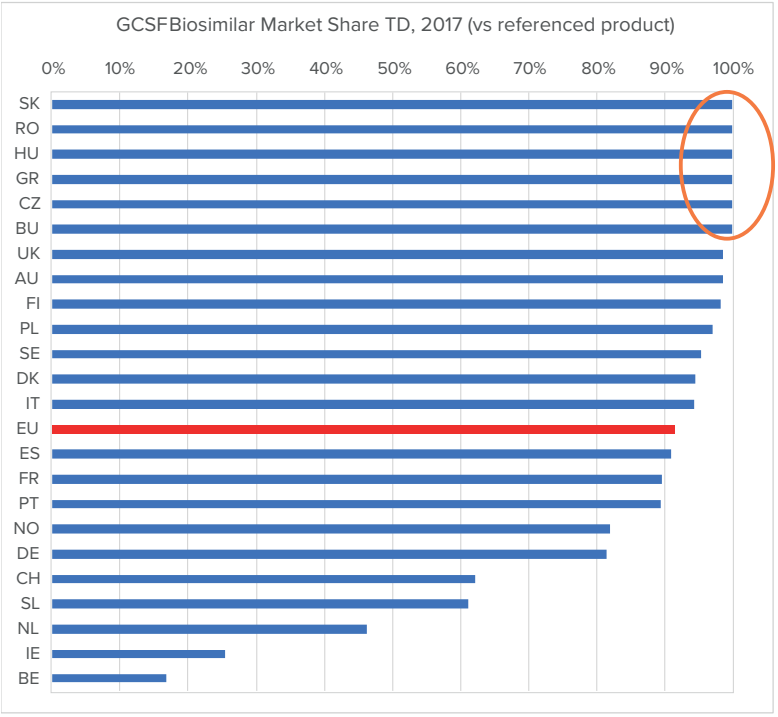


Exhibit 7: Biosimilar Market Share TD, 2017 (vs reference product)

4. In some therapeutic classes, lowering the price of the referenced product can limit the market penetration of the biosimilar

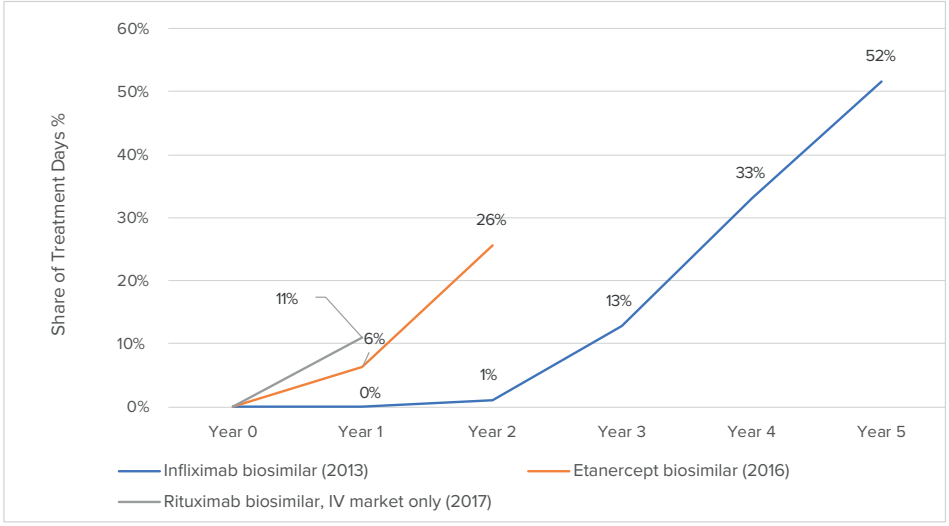
For some of the therapeutic classes, the same observation can be seen: there is a correlation between the price reduction of referenced products after biosimilar entry, and the biosimilar treatment day market share (vs referenced product). Therefore, the larger the originator's price cut on the referenced product, the less impact of biosimilars is seen, illustrating that originator competitive pricing strategies can influence the uptake of biosimilars in some areas. However, reducing originator prices (either because of regulations applied in a country or competitive originator pricing strategies), could result in biosimilars not entering the market at all, restricting competition in the market.

Exhibit 8. Change in price of the Referenced product(s) (2017/year before biosimilar entrance) vs Biosimilar treatment day market share in 2017

5. The speed of uptake has increased for some of the more recent biosimilar launches

The speed of uptake has increased for some of the more recent biosimilar launches, including those where there are multiple biosimilars in the same class. For example, in the anti-TNF class, the uptake of etanercept biosimilars (which had only one biosimilar approved in the first year) has been faster than infliximab biosimilars (which had two biosimilars approved in the first year) across Europe.

Exhibit 9. Share of treatment days of recent biosimilar launches, Europe (year of first launch)



Whilst there will be product specific differences partially driving this variation, it is also the case that over the years, stakeholders have gained more experience and familiarity with biosimilars. As prescribers become more receptive and willing to use biosimilars, this will continue to be an important lever in driving their uptake. In addition, the faster implementation of demand-side policies will also contribute to the faster uptake of newer biosimilars.

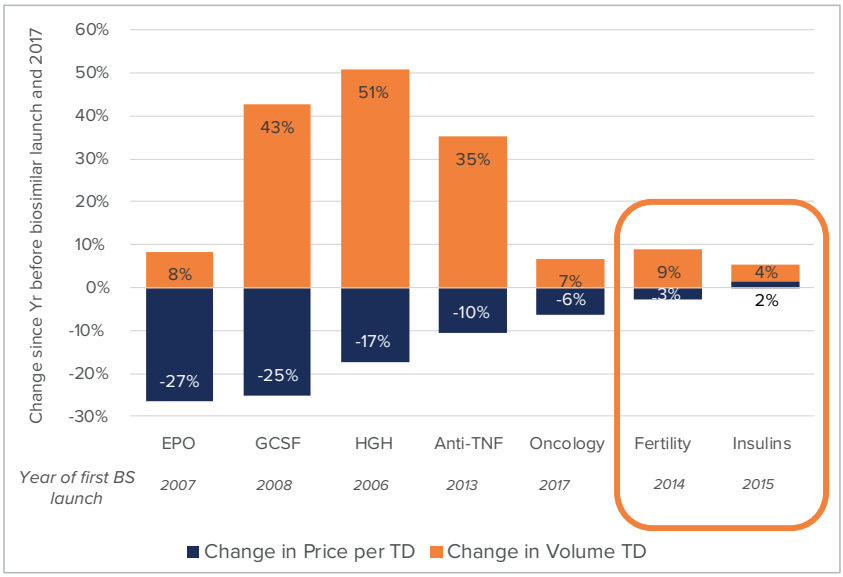
6. Not all classes have achieved high biosimilar uptake

There is a wide variation in the uptake of biosimilars across classes in Europe, and time on the market does not always determine success. For example, EPO biosimilars were launched before GCSF biosimilars but have a significantly lower change in volume treatment days since market entry.

In some classes, such as Insulins and Fertility, biosimilars have had a lower impact on price and volume in Europe. In these markets, prior to biosimilar entrance there was already a highly competitive market situation for established products. This provides less of an incentive for prescribers to switch to biosimilars, which can result in low biosimilar uptake.

There are also market specific characteristics which can influence uptake. For example, in most European markets, Insulin is a retail product, prescribed by primary care physicians, reimbursed from the retail budget. There are different barriers to launching retail biosimilars vs hospital biosimilars, such as the substantial company investment required to promote to a large population of primary care physicians, which can be a challenge. There are also often fewer incentives offered compared with hospital biosimilars, therefore collaboration with industry, physicians and payers is particularly critical for the success of biosimilars in the retail sector.

Exhibit 10. Change in price and volume treatment days of total market between year before biosimilar launch and 2017 (Europe)

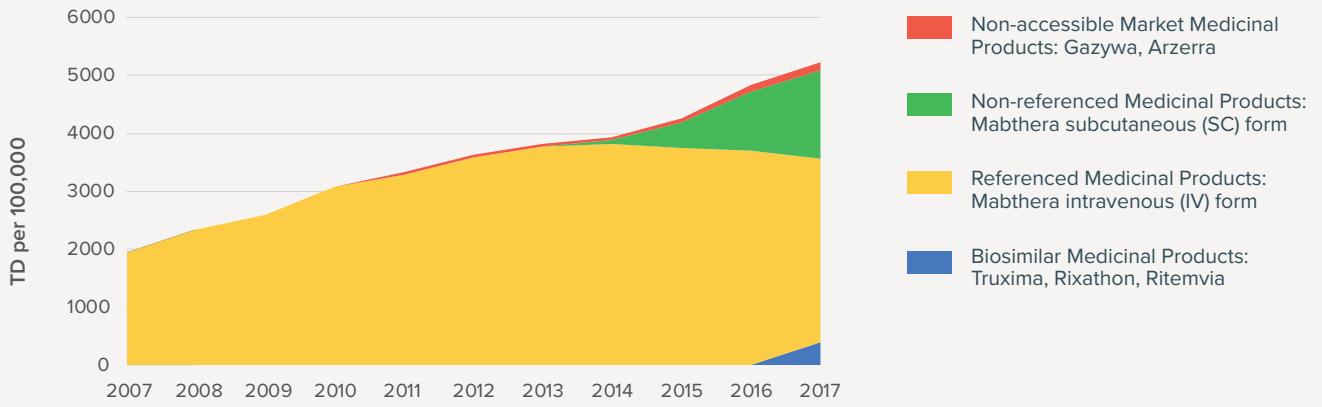


7. Originators can protect market share by developing new formulations

Case study: Mabthera defence strategy

Differences in formulation can influence prescribing. In the case of Mabthera, part of Roche's biosimilar defense strategy was to start switching patients from the intravenous (IV) version of Mabthera to the subcutaneous (SC) version prior to the biosimilar launch, which was available in IV only. In 2017, Biosimilars started eroding the European Mabthera IV market, whilst the Mabthera SC treatment day volume continues to grow, offering some protection.

Exhibit 11. Oncology market volume development, Europe

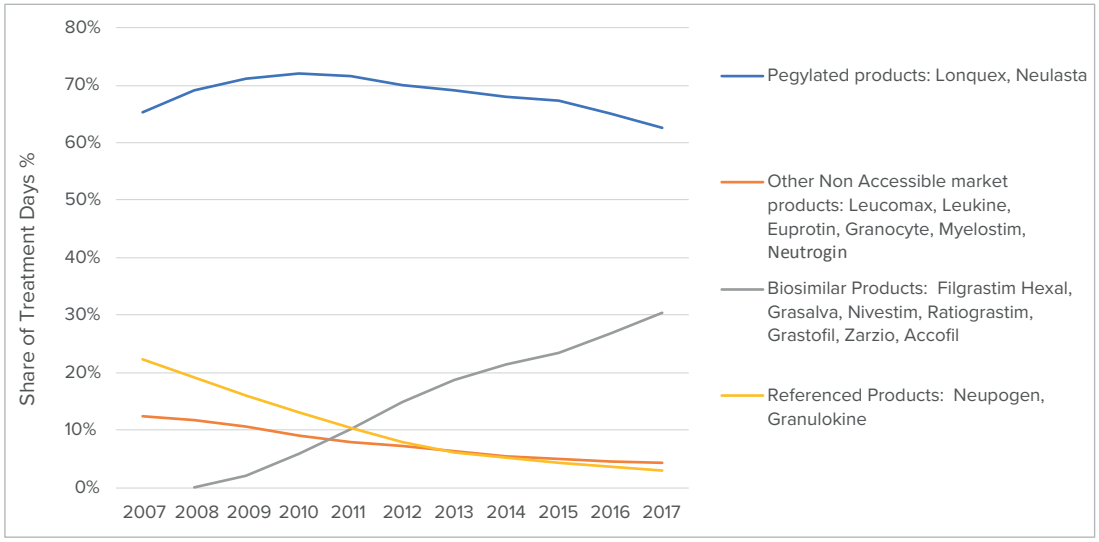


Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Case study: Pegylated filgrastim uptake

Longer acting versions of the originator can also change the treatment paradigm. Pegfilgrastim (Neulasta) and Lipegfilgrastim (Lonquex) are longer acting forms of filgrastim (single dose per treatment cycle vs once daily for a maximum of 14 days per treatment cycle). They have been able to maintain treatment day market share after the introduction of the filgrastim biosimilars in 2008, whilst the referenced products and other non-accessible market products share have dropped.

Exhibit 12. GCSF market share of treatment days

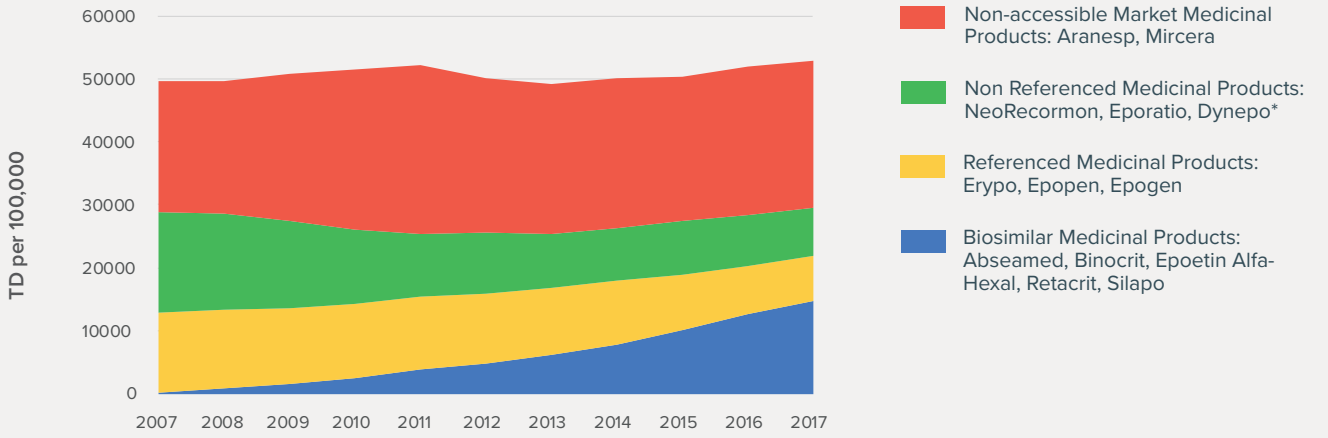


The experience so far with Biosimilars in Europe illustrates the heterogeneity between biosimilar products, therapy areas, and countries. There is not just one formula that will work to achieve the savings potential, but learnings can be taken from all areas.

The country and therapy areas KPIs
Epoetin (EPO)

Epo is a form of human erythropoietin produced by recombinant technology, with the same amino acid sequence and mechanism of action as endogenous erythropoietin. Its major functions are to promote the differentiation and development of red blood cells and to initiate the production of haemoglobin, the molecule within red blood cells that transports oxygen.

Epoetin volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

*Dynepo has been withdrawn by the EMA.

Summary of EMA information for approved indications for Epoetin products

Molecule	Product	Reference product	Biosimilar Product	Non-referenced Product	Non-accessible Product	Anaemia for Chemotherapy patients	Anaemia for patients with Chronic Kidney Disease	Preventing Anaemia in premature babies	Autologuos Blood Transfusion	Reduction of allogenic transfusion exposure in Orthopedic surgery	Patient type: Adult	Patient type: Paediatric	Frequency*	Route**: Subcutaneous	Route**: Intravenous
Epoetin alfa	Epopen	●				●	●		●	●	●	●	3x a week	●	●
	Erypo	●				●	●		●	●	●	●	3x a week	●	●
	Epogen	●				●	●		●	●	●	●	3x a week	●	●
	Abseamed		●			●	●		●	●	●	●	3x a week	●	●
	Epoetin Alfa Hexal		●			●	●		●	●	●	●	3x a week	●	●
	Binocrit		●			●	●		●	●	●	●	3x a week	●	●
Epoetin zeta	Retacrit		●			●	●		●		●	●	3x a week	●	●
	Silapo		●			●	●		●		●	●		●	●
Epoetin beta	NeoRecormon			●		●	●	●	●	●	●	●	3x a week	●	●
Epoetin theta	Eporatio			●		●	●				●		3x a week	●	●
Methoxy polyethlene glycol-epotein beta	Mircera				●		●				●		Every 2 weeks	●	●
Darbepoetin alfa	Aranesp				●	●	●				●		Weekly	●	●

*Anaemia for patients with Chronic kidney disease

** Subcutaneous injection is typically used for chemotherapy patients. Intravenous injection is typically used for patients with kidney problems and for patients who are going to donate their own blood.

Additional information about Epoetin

In June 2008 EMA recommended updating the product information for Epoetin-containing medicines with a new warning for their use in cancer patients stating that blood transfusion should be the preferred method of correcting anaemia. The Agency's Committee for Medicinal Products for Human Use (CHMP) had reviewed data from studies that showed an increased risk of tumour progression, venous thrombo-embolism and shorter overall survival in cancer patients who received Epoetins compared to patients who did not receive them. It also advised that prescribers take into account patients' individual circumstances and preferences when making the decision to use Epoetins. The Committee agreed that there is no consequence of the new information on the use of Epoetin-containing medicines for the treatment of anaemia in patients with chronic renal failure.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilar
AU	81%	33%	21%	-40%	-40%	-28%	-14%	-7%	-26%	0.93	0.69	2008
BE	10%	7%	2%	-2%	-2%	1%	-18%	-17%	1%	0.52	0.53	2014
BU	100%	76%	46%	-5%	-35%	-19%	51%	2%	28%	0.24	0.30	2011
CZ	99%	62%	38%	-47%	-39%	-34%	158%	12%	30%	0.09	0.12	2011
DK	14%	2%	0%	-9%	1%	-14%	-93%	-96%	-8%	0.49	0.45	2010
FI	100%	71%	12%	-44%	-40%	-24%	1371%	-49%	6%	0.34	0.36	2008
FR	54%	32%	12%	-34%	-33%	-32%	1%	-23%	4%	0.90	0.93	2009
DE	84%	71%	41%	-54%	-56%	-46%	48%	-16%	-11%	0.39	0.34	2007
GR	92%	91%	86%	-52%	-53%	-51%	387%	193%	103%	0.02	0.04	2008
HU	100%	55%	34%	-77%	-46%	-27%	46%	17%	-17%	0.36	0.30	2009
IE	98%	19%	7%	-32%	-32%	-20%	50%	-54%	-26%	0.51	0.37	2008
IT	70%	63%	50%	-15%	-13%	-8%	178%	74%	41%	0.82	1.16	2008
NL	32%	12%	3%	-48%	-43%	-35%	-67%	-54%	-23%	0.53	0.41	2009
NO	20%	1%	0%	23%	-11%	-4%	-85%	-58%	13%	0.21	0.23	2008
PL	100%	21%	10%	-62%	-61%	-37%	4028%	307%	418%	0.03	0.14	2009
PT	89%	30%	22%	-78%	-79%	-66%	252%	151%	13%	0.44	0.50	2010
RO	87%	63%	33%	-57%	-51%	-40%	67%	-74%	-56%	0.29	0.13	2009
SK	100%	72%	56%	-60%	-57%	-52%	313%	51%	3%	0.45	0.46	2010
SL	52%	25%	9%	-49%	-45%	-45%	-44%	-45%	6%	0.52	0.55	2009
ES	66%	52%	34%	-31%	-31%	-21%	77%	7%	-1%	0.70	0.69	2009
SE	93%	44%	27%	-15%	-31%	-22%	37%	-2%	-11%	0.47	0.42	2008
CH	25%	7%	1%	-46%	-45%	-42%	-52%	-54%	12%	0.34	0.38	2009
UK	6%	3%	1%	-7%	-13%	-10%	77%	-6%	32%	0.24	0.32	2009
EU	67%	50%	28%	-30%	-32%	-27%	76%	7%	8%	0.49	0.53	

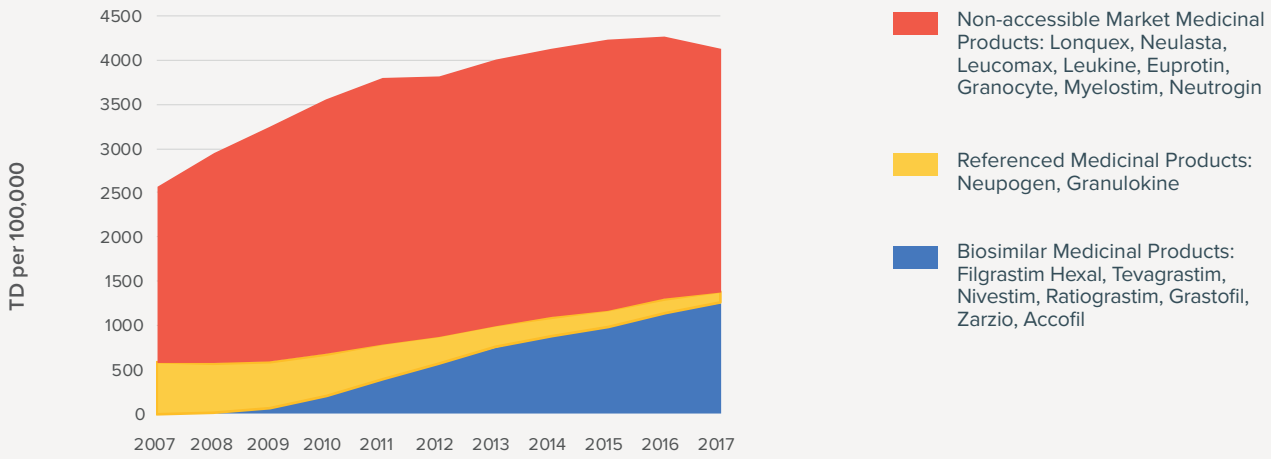
The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece

Prices per treatment day (total market) have been reduced in almost all markets but to a different degree from (-66%) to 1%, due to a combination of factors; the level of competition, to what extent non- accessible market products (largely differentiated by fewer injections) have been accepted, but also the price development of referenced and biosimilar medicinal products.

Granulocyte-colony stimulating factor (G-CSF)

G-CSF is a glycoprotein that stimulates the bone marrow to produce granulocytes and stem cells and release them into the bloodstream. G-CSF is used prophylactically with certain cancer patients accelerate recovery from neutropenia after chemotherapy, allowing higher-intensity treatment regimens.

G-CSF volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Summary of EMA information for approved indications for G-CSF products

		Classification				Indication					
Molecule	Product	Reference product	Biosimilar Product	Non-reference Product	Non-accessible Product	Cytotoxic Chemoterapy associated with Febrile induced Neutropenia	Neutropenia induced by Acute Myeloid Leukemia	Bone Marrow Transplantation for non myeloid malignancy induced Neutropenia	Mobilisation of Peripheral Blood Progenitor Cells (PBPCs)	Severe Chronic Neutropenia (SCN) with diagnois of congenital, cyclic, or idiopathic Neutropenia	Neutropenia prevention and treatment in patients with HIV
Filgrastim	Neupogen	●				●	●	●	●	●	●
	Granulokine	●				●	●	●	●	●	●
	Filgrastim Hexal		●			●	●	●	●	●	●
	Tevagrastim		●			●		●	●	●	●
	Grastofil		●			●		●	●	●	●
	Neukine		●			●	●	●	●	●	●
	Nivestim		●			●		●	●	●	●
	Ratiograstim		●			●		●	●	●	●
	Zarzio		●			●		●			●
Lenograstim	Euprotin				●	●		●	●		
	Granocyte				●	●		●	●		
	Myelostim				●	●		●	●		
	Neutrogin				●	●		●	●		
Lipegfilgrastim	Lonquex				●	●					
Pegfilgrastim	Neulasta				●	●					
Molgramostim	Leucomax				●	●	●	●	●		
Sargramostim	Leukine				●	●	●	●	●		

Additional information about G-CSF

Subcutaneous injection typically used to administer G-CSF daily for 5-7 days, starting 72hrs after completion of chemotherapy or bone marrow transplantation, with the exception of pegfilgrastim and lipegfilgrastim which are long acting G-CSF and therefore administered once only at least 24 hrs after completion of each chemotherapy cycle. GM-CSF (Granulocyte macrophage colony-stimulating factor) Sargramostim and Molgramostim are given daily, most often as a subcutaneous injection (under the skin), but can also be given directly into a vein (intravenous, IV).

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilar
AU	98%	98%	22%	-51%	-51%	-40%	90%	90%	77%	0.054	0.095	2009
BE	17%	17%	2%	-30%	-30%	-12%	8%	8%	18%	0.044	0.052	2011
BU	100%	100%	14%	-77%	-77%	-60%	354%	354%	1893%	0.002	0.035	2009
CZ	100%	100%	66%	-34%	-34%	-22%	290%	290%	122%	0.005	0.010	2010
DK	95%	95%	13%	-50%	-50%	-21%	-2%	-2%	17%	0.042	0.049	2009
FI	98%	98%	16%	-44%	-44%	-27%	70%	70%	51%	0.054	0.081	2009
FR	90%	90%	18%	-38%	-38%	-23%	225%	225%	40%	0.053	0.074	2009
DE	81%	81%	14%	-31%	-31%	-31%	57%	57%	108%	0.025	0.052	2008
GR	100%	100%	90%	-64%	-64%	-42%	1190%	1190%	-80%	0.020	0.004	2009
HU	100%	100%	80%	-67%	-67%	-49%	300%	300%	16%	0.035	0.041	2009
IE	25%	25%	3%	-29%	-29%	-16%	-1%	-1%	46%	0.055	0.080	2009
IT	94%	94%	39%	-26%	-26%	-17%	128%	128%	9%	0.032	0.034	2009
NL	46%	46%	5%	-34%	-34%	-27%	24%	24%	-14%	0.033	0.028	2009
NO	82%	82%	4%	-37%	-37%	-12%	28%	28%	152%	0.028	0.069	2009
PL	97%	97%	51%	-64%	-64%	-49%	173%	173%	118%	0.017	0.036	2009
PT	89%	89%	56%	-90%	-90%	-60%	98%	98%	-44%	0.038	0.021	2010
RO	100%	100%	71%	-70%	-70%	-63%	339%	339%	489%	0.003	0.019	2009
SK	100%	100%	35%	-83%	-83%	-65%	477%	477%	426%	0.009	0.045	2009
SL	61%	61%	10%	-69%	-69%	-56%	95%	95%	249%	0.018	0.063	2009
ES	91%	91%	74%	-39%	-39%	-24%	62%	62%	-33%	0.036	0.024	2009
SE	95%	95%	67%	-55%	-55%	-31%	270%	270%	33%	0.022	0.030	2009
CH	62%	62%	16%	-38%	-38%	-29%	39%	39%	54%	0.026	0.041	2009
UK	99%	99%	68%	8%	8%	15%	247%	247%	66%	0.014	0.024	2008
EU	91%	91%	30%	-39%	-39%	-25%	134%	134%	43%	0.029	0.041	

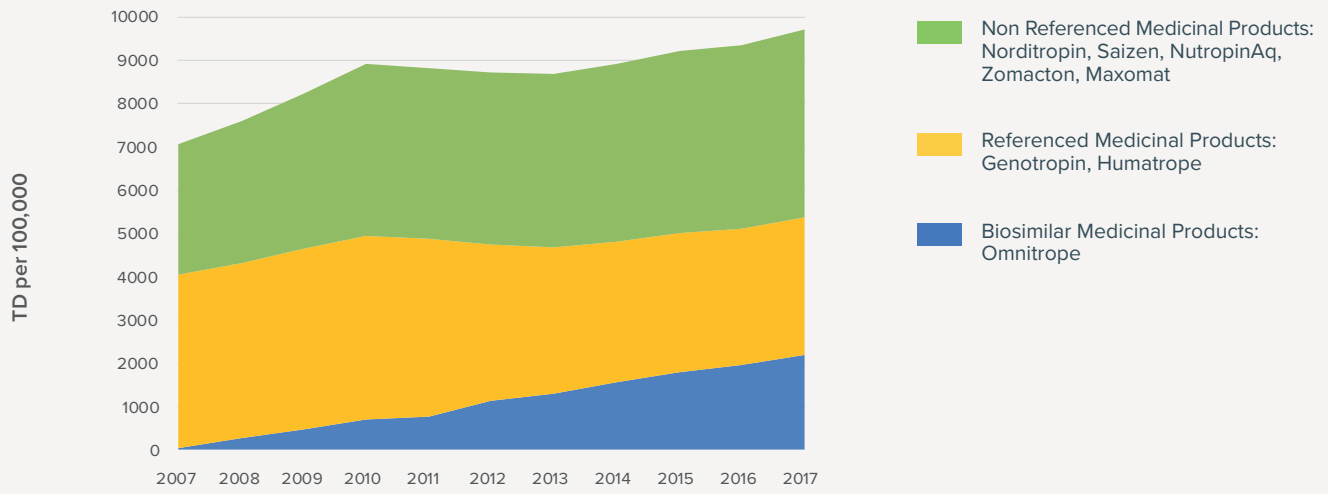
The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece

Price changes per treatment day (total market) vary considerably across the different European countries included in this study, ranging between (-65%) and 15%.

Human Growth Hormone (HGH)

HGH also known as somatropin, is a peptide hormone that stimulates growth, cell reproduction and regeneration in humans. It is used to treat growth disorders in children and growth hormone deficiency in adults.

HGH volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Summary of EMA information for approved indications for HGH products:

		Classification			Indications								
Molecule	Product	Referenced product	Biosimilar Product	Non-referenced Product	Pediatric Growth Hormone Deficiency	Adult Growth Hormone Deficiency	Turner Syndrome	Growth failure due to Chronic Renal Insufficiency (CRI)	SGA - Small for Gestational Age	PWS - Prader-Willi syndrome	Idiopathic Short Stature	SHOX - Short-Stature Homebox-Containing Gene Deficiency	Noonan Syndrome
Somatropin	Genotropin	●			●	●	●	●	●	●	●		
	Humatrope	●			●	●	●	●	●		●	●	
	Omnitrope		●		●	●	●	●	●	●			
	Norditropin			●	●	●	●	●	●				●
	Saizen			●	●	●	●	●	●				
	NutropinAq			●	●	●	●	●					
	Zomacton			●	●		●						

Additional information about HGH

Subcutaneous injection is typically used to administer Human Growth Hormone treatment. The dosage of administration should be individualised for each patient, with a weight-based regimen. The duration of treatment, usually a period of several years, will depend on maximum achievable therapeutic benefit.

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilars
AU	37%	12%	12%	-16%	-8%	-8%	-7%	64%	64%	0.04	0.06	2008
BE	26%	16%	16%	-16%	-16%	-16%	44%	39%	39%	0.09	0.13	2009
BU	51%	51%	51%	-27%	-28%	-28%	-2%	-4%	-4%	0.02	0.02	2012
CZ	20%	8%	8%	-28%	-31%	-31%	78%	85%	85%	0.08	0.15	2010
DK	97%	73%	73%	-14%	-15%	-15%	131%	-1%	-1%	0.15	0.15	2011
FI	50%	14%	14%	-35%	-49%	-49%	12%	71%	71%	0.06	0.10	2008
FR	37%	18%	18%	-14%	-11%	-11%	41%	51%	51%	0.10	0.15	2007
DE	37%	19%	19%	4%	7%	7%	14%	37%	37%	0.05	0.08	2006
GR	0%	0%	0%	-7%	-7%	-7%	31%	31%	31%	0.00	0.00	2015
HU	13%	7%	7%	-4%	-3%	-3%	-1%	14%	14%	0.05	0.06	2012
IE	0%	0%	0%	-10%	-10%	-10%	50%	75%	75%	0.04	0.08	2006
IT	36%	18%	18%	-21%	-21%	-21%	76%	63%	63%	0.06	0.10	2007
NL	31%	17%	17%	-38%	-34%	-34%	31%	33%	33%	0.09	0.12	2008
NO	4%	3%	3%	-17%	-14%	-14%	155%	43%	43%	0.13	0.19	2011
PL	99%	99%	99%	-40%	-41%	-41%	102%	102%	102%	0.04	0.08	2008
PT	18%	8%	8%	-46%	-30%	-30%	9%	7%	7%	0.04	0.05	2014
RO	57%	28%	28%	-18%	-31%	-31%	228%	145%	145%	0.02	0.05	2008
SK	0%	0%	0%	-11%	-10%	-10%	27%	39%	39%	0.06	0.09	2013
SL	10%	5%	5%	-40%	-37%	-37%	27%	20%	20%	0.06	0.07	2010
ES	28%	18%	18%	-19%	-19%	-19%	48%	45%	45%	0.10	0.14	2007
SE	36%	23%	23%	-36%	-35%	-35%	-17%	-9%	-9%	0.15	0.14	2007
CH	23%	5%	5%	-31%	-22%	-22%	-11%	49%	49%	0.07	0.10	2010
UK	27%	13%	13%	-25%	-16%	-16%	50%	94%	94%	0.04	0.07	2007
EU	41%	23%	23%	-22%	-17%	-17%	47%	51%	51%	0.06	0.10	

The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece.

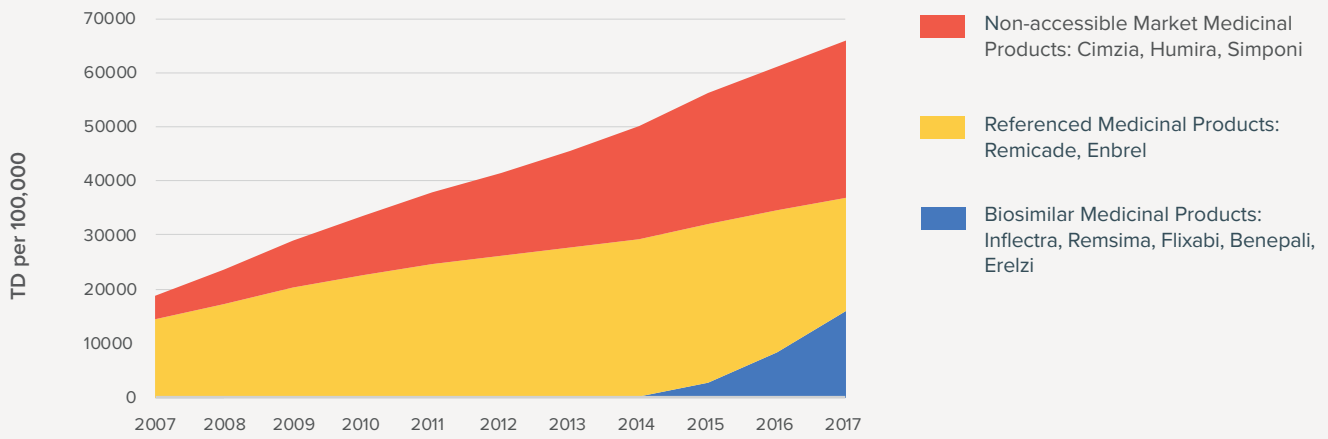
Prices per treatment day (total market) vary considerably across the different European countries studied, ranging between (-49%) to 7%.

Anti-Tumour Necrosis Factor (Anti-TNF)

Anti-TNF drugs are a class of drugs that are used to treat inflammatory conditions such as Rheumatoid Arthritis (RA), Ankylosing Spondylitis, Psoriatic Arthritis, Juvenile Arthritis, Crohn's Disease, Ulcerative Colitis, Psoriasis and Hidradinitis Suppurativa. These drugs are able to reduce inflammation and stop disease progression.

TNF is a chemical produced by the immune system that causes inflammation in the body. In healthy individuals, excess TNF in the blood is blocked naturally, but in those who have conditions like RA, higher levels of TNF in the blood lead to more inflammation, joint destruction and persistent symptoms. Anti-TNF agents can alter the disease's effect on the body by controlling inflammation in joints, gastrointestinal tract and skin.

Anti-TNF volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Additional information about Anti-TNF's

In this section we report insights from biosimilars on the market in Europe for two Anti-TNF molecules: infliximab and etanercept. The EMA approved the first infliximab biosimilars in September 2013, and the first etanercept biosimilar in January 2016. The EMA has also approved several rituximab biosimilars, however these have been considered separately in the Oncology section of the report.

The biosimilar share of molecule treatment days in the EU5 is reported below:

	Biosimilar treatment day share vs Referenced product (MAT December 2017)	
Country	**infliximab**	**etanercept**
UK	78.6% (34)	54.0% (22)
France	33.0% (34)	4.6% (15)
Germany	43.6% (35)	35.0% (22)
Italy	56.4% (34)	11.7% (15)
Spain	40.4% (35)	3.6% (15)

Source: IQVIA MAT December 2017, () number of months since biosimilar launch in the country

Summary of EMA information for approved indications for Anti-TNF products:

	Humira	Remicade	Remsima	Inflectra	Flixabi	Enbrel	Benepali	Erelzi	Simponi	Cimzia
Rheumatoid Arthritis	●	●	●	●	●	●	●	●	●	●
Juvenile Idiopathic Arthritis	●					●	●	●		
Psoriatic Arthritis	●	●	●	●	●	●	●	●	●	●
Axial Spondyloarthritis, comprising: Ankylosing Spondylitis (AS)	●	●	●	●	●	●	●	●	●	●
Axial Spondyloarthritis without radiographic evidence of AS	●					●	●	●	●	●
Crohn's Disease	●	●	●	●	●					
Paediatric Crohn's Disease	●	●	●	●	●					
Ulcerative Colitis	●	●	●	●	●				●	
Paediatric Ulcerative Colitis		●	●	●	●					
Plaque Psoriasis	●	●	●	●	●	●	●	●		
Hidradenitis Suppurativa	●									
Uveitis	●									

*Indications have been added over time expanding the potential patient population.

Summary of EMA information for administration frequency details for Anti-TNF products:

		Classification				Frequency of administration	Route of administartion	
Molecule	Product	Referenced product	Biosimilar Product	Non- referenced Product	Non-accessible Product		Subcutaneous	Intravenous
INFLIXIMAB	Remicade	●				every 8 weeks		●
	Remsima		●			every 8 weeks		●
	Inflectra		●			every 8 weeks		●
	Flixabi		●			every 8 weeks		●
ETANERCEPT	Enbrel	●				once or twice weekly	●	
	Benepali		●			once weekly	●	
	Erelzi		●			once or twice weekly	●	
ADALIMUMAB	Humira				●	every 2 weeks	●	
CERTOLIZUMAB PEGOL	Cimzia				●	every 4 weeks	●	
GOLIMUMAB	Simponi				●	monthly	●	

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilars
AU	25%	25%	10%	-6%	-6%	4%	162%	162%	407%	0.17	0.84	2015
BE	16%	16%	10%	-27%	-27%	-16%	29%	29%	26%	0.94	1.19	2015
BU	58%	58%	20%	-45%	-45%	-25%	215%	215%	242%	0.10	0.34	2014
CZ	40%	40%	27%	-13%	-13%	-12%	48%	48%	58%	0.24	0.38	2013
DK	94%	94%	65%	-32%	-32%	-25%	66%	66%	40%	0.90	1.27	2015
FI	70%	70%	43%	-30%	-30%	-23%	58%	58%	59%	0.64	1.02	2013
FR	26%	26%	15%	-22%	-22%	-18%	27%	27%	35%	0.62	0.83	2015
DE	40%	40%	21%	-13%	-13%	-7%	33%	33%	36%	0.50	0.68	2015
GR	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.01	0.01	
HU	26%	26%	14%	-7%	-7%	-3%	-2%	-2%	2%	0.32	0.33	2014
IE	9%	9%	5%	-24%	-24%	-13%	55%	55%	64%	0.98	1.60	2014
IT	35%	35%	18%	-9%	-9%	-5%	6%	6%	19%	0.36	0.43	2015
NL	55%	55%	35%	-16%	-16%	-12%	17%	17%	14%	0.99	1.13	2015
NO	93%	93%	64%	-12%	-12%	-1%	72%	72%	71%	1.07	1.82	2013
PL	62%	62%	32%	-44%	-44%	-30%	40%	40%	69%	0.04	0.07	2014
PT	29%	29%	18%	-26%	-26%	-19%	70%	70%	82%	0.26	0.48	2013
RO	18%	18%	9%	-14%	-14%	-11%	-12%	-12%	17%	0.20	0.24	2014
SK	12%	12%	6%	-33%	-33%	-15%	21%	21%	52%	0.49	0.75	2014
SL	45%	45%	22%	-36%	-36%	-22%	36%	36%	36%	0.47	0.64	2015
ES	29%	29%	16%	-22%	-22%	-9%	23%	23%	30%	0.49	0.64	2015
SE	66%	66%	41%	-23%	-23%	-16%	33%	33%	30%	0.93	1.21	2015
CH	7%	7%	4%	-4%	-4%	-4%	13%	13%	16%	0.83	0.96	2016
UK	69%	69%	35%	-9%	-9%	-3%	25%	25%	32%	0.61	0.81	2015
EU	43%	43%	24%	-17%	-17%	-10%	29%	29%	35%	0.49	0.66	

The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece.

Prices per treatment day (total market) vary across all markets but to a different degree, ranging between (-30) to 4.

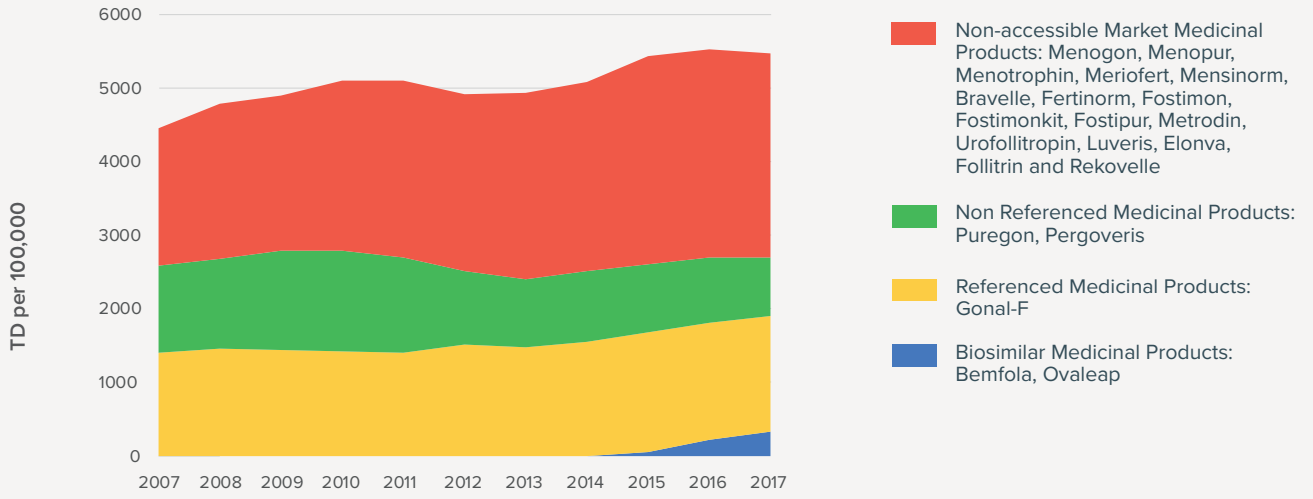
The Anti-TNF market is unique as it has two referenced products with different biosimilar molecules. The market shares and price/volume evolution figures refer to the total Anti-TNF market, therefore, include all products within each category. This means, for example, in markets where only infliximab biosimilars have launched, the "biosimilar versus referenced product" market share will still represent the biosimilar market share of all the biosimilars and referenced products on the market (including Enbrel).

Fertility (Follitropin alfa)

Gonadotropin preparations are drugs that mimic the physiological effects of gonadotropins, used therapeutically primarily as fertility medication for ovarian hyperstimulation and reversal of an ovulation.

For the purpose of this report, only Follicle-Stimulating Hormones (FSH) and Luteinizing Hormone (LH) preparations were considered.

Fertility volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Summary of EMA information for approved indications for Fertility products

		Classification				Indications					Frequency	Route		
Molecule	Product	Reference product	Biosimilar	Non-reference	Non-accessible	Infertility	Hypogonadism	Anovulation	Ovulation Induction	Reproductive Techniques, Assisted		Subcutaneous	Intravenous	Intramuscular
Follitropin alfa	Gonal-F	●				●		●			Daily	●	●	●
	Bemfola		●			●	●	●		●	Daily	●	●	●
	Ovaleap		●			●	●			●	Daily	●	●	●
Follitropin alfa / Lutropin alfa	Pergoveris			●		●					Daily	●	●	●
Follitropin beta	Puregon			●		●	●				Patient specific	●		
Follitropin Delta	Rekovelle			●		●			●	●	Daily	●		
	Follitrin			●		●			●	●	Daily	●		
Corifollitropin alfa	Elonva				●	●					Patient specific	●		
Lutropin alfa	Luveris				●	●			●		Daily	●	●	●
Follicle-stimulating hormone / Luteinising hormone	Menogon				●	●		●		●	Daily	●		●
	Menopur				●	●				●	Daily	●		
	Menotrophin				●	●				●	Daily	●		●
	Meriofert				●	●			●		Daily	●		
Follicle-stimulating hormone / Lutropin alfa	Mensinorm				●	●			●		Patient specific	●		●
Urofollitropin	Bravelle				●	●		●	●	●	Daily	●		●
	Fertinorm				●	●			●	●	Daily	●		●
	Fostimon				●	●			●		Daily			●
	Fostimonkit				●	●			●		Daily			●
	Fostipur				●	●			●		Daily	●		
	Metrodin				●	●			●	●	Daily	●		●

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilars
AU	0%	0%	0%	0%	-1%	-49%	1486%	368%	511%	0.005	0.029	2014
BE	35%	22%	9%	-6%	-3%	-9%	33%	21%	27%	0.040	0.050	2015
BU	49%	11%	6%	-13%	-9%	27%	115%	-15%	-47%	0.009	0.005	2016
CZ	8%	6%	3%	-20%	-18%	-14%	31%	37%	35%	0.052	0.070	2015
DK	12%	8%	4%	-28%	-25%	-21%	55%	31%	18%	0.101	0.120	2014
FI	25%	18%	8%	-23%	-21%	-15%	78%	0%	3%	0.045	0.046	2014
FR	18%	13%	7%	-4%	-3%	-5%	23%	2%	7%	0.089	0.095	2015
DE	30%	18%	11%	-7%	7%	11%	47%	18%	6%	0.038	0.040	2014
GR	24%	19%	7%	-12%	-10%	-4%	20%	6%	3%	0.022	0.023	2016
HU	11%	9%	6%	-2%	-2%	3%	79%	72%	57%	0.043	0.068	2015
IE	1%	1%	0%	-8%	-9%	-5%	16%	11%	8%	0.095	0.103	2016
IT	11%	8%	4%	-4%	-3%	-6%	-16%	-15%	-3%	0.074	0.071	2015
NL	2%	2%	1%	-4%	-3%	5%	26%	22%	11%	0.070	0.077	2016
NO	28%	21%	9%	-4%	-1%	-2%	91%	27%	31%	0.064	0.084	2014
PL	13%	5%	2%	35%	33%	16%	18%	66%	37%	0.018	0.025	2015
PT	23%	15%	7%	-14%	-9%	2%	51%	22%	21%	0.033	0.040	2015
RO	4%	3%	1%	-1%	3%	4%	-20%	-7%	-11%	0.015	0.013	2016
SK	14%	12%	4%	-9%	-8%	0%	67%	50%	24%	0.027	0.034	2016
SL	1%	0%	0%	0%	3%	6%	39%	26%	6%	0.061	0.064	2015
ES	25%	16%	7%	-26%	-16%	-11%	24%	4%	4%	0.078	0.081	2015
SE	23%	21%	8%	-17%	-17%	-9%	47%	12%	10%	0.085	0.093	2014
CH	0%	0%	0%								0.047	
UK	27%	26%	9%	-1%	0%	1%	25%	26%	17%	0.018	0.021	2015
EU	18%	12%	6%	-8%	-4%	-3%	23%	10%	9%	0.050	0.055	

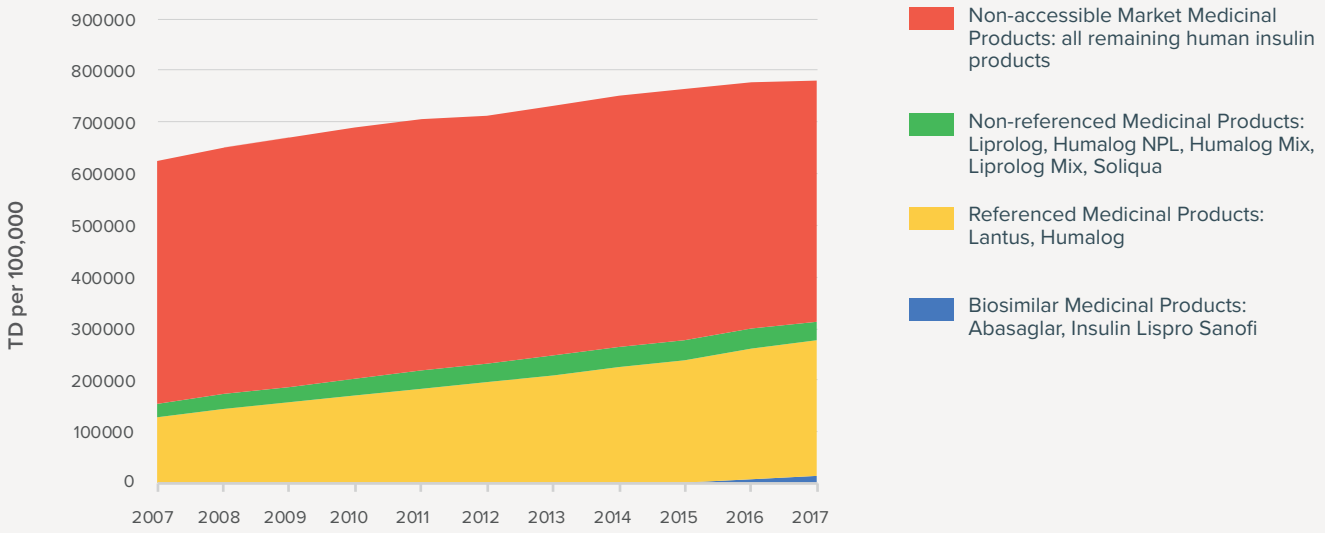
The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece

Prices per treatment day (total market) vary considerably across the European markets included in this study, ranging between (-49%) to 27%.

Insulins

Recombinant human insulin is a form of insulin made from recombinant DNA that is identical to human insulin; used to treat diabetics who are allergic to preparations made from beef or pork insulin.

Insulins volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Additional information about insulin medicines

Insulin preparations differ mainly by their kinetic/pharmacodynamic profiles. They are usually classified as rapid- (faster acting than soluble human insulin), short- (e.g. soluble human insulin), intermediate- (NPH /Neutral Protamine Hagedorn insulin, e.g. human isophane insulin), and long-acting preparations (insulins with action profiles significantly longer than NPH insulin). They are used alone or as free mixtures or premixed preparations of rapid/short-acting insulin and intermediate/long-acting (biphasic) insulin in various proportions.

Regular insulin is a short-acting insulin and is generally injected subcutaneously 2-5 times daily within 30-60 minutes before a meal. In conventional regimen the total daily insulin dose is administered as a mixture of rapid/short-acting and intermediate-acting insulins in 1-2 injections. In intensive regimen the total daily dose is administered as 3 or more injections or by continuous subcutaneous infusion to cover basal and pre-meal bolus insulin requirements.

Summary of EMA information for approved indications for Insulin products

		Classification				Indications	Frequency*	Mode of action	Route	
Molecule	Product	Reference product	Biosimilar	Non-reference	Non-accessible	Diabetes Mellitus			Subcutaneous	Intravenous
Insulin Glargine	Abasaglar		●			●	Daily	Long-acting	●	
	Lantus	●				●	Daily	Long-acting	●	
Insulin Glargine/ Lixisenatide	Soliqua			●		●	Daily	Long-acting	●	
Insulin Degludec	Tresiba				●	●	Daily	Long-acting	●	
Insulin Detemir	Levemir				●	●	Twice a day	Long-acting	●	
Insulin Degludec / Liraglutide	Xultophy				●	●	Daily	Long-acting	●	
Insulin Degludec / Insulin Aspart	Ryzodeg				●	●	Daily	Fast-acting	●	
Insulin Glulisine	Apidra				●	●	Before Every Meal	Fast-acting	●	
Insulin Human	Actraphane				●	●	Once / twice a day	Intermediate-acting	●	
	Actrapid				●	●	before every meal	Short-acting	●	
	Insuman				●	●	determined by a physician	Fast-acting	●	●
	Monotard				●	●	Once / twice a day	Intermediate-acting	●	
	Humalin				●	●	Once / twice a day	Short-acting	●	
	Protaphane				●	●	Once / twice a day	Intermediate-acting	●	
	Ultratard				●	●	Once / twice a day	Intermediate-acting	●	
Insulin Lispro	Liprolog			●		●	before every meal	Fast-acting	●	●
	Humalog	●				●	before every meal	Fast-acting	●	●
	Insulin Lispro Sanofi		●			●	determined by a physician	Fast-acting	●	●
Insulin Lispro/ Insulin Lispro Protamine	Humalog Mix			●		●	determined by a physician	Fast-acting	●	
Insulin Aspart	Novorapid				●	●	before every meal	Fast-acting	●	
Insulin Aspart / Insulin Aspart Protamine	Novomix						before every meal	Fast-acting	●	

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilars
AU	0%	0%	0%	1%	1%	1%	10%	7%	5%	5.5	5.8	2017
BE	1%	1%	0%	-14%	-13%	-3%	35%	31%	7%	6.6	7.1	2016
BU	4%	2%	1%	-14%	-7%	3%	44%	32%	11%	5.8	6.4	2015
CZ	8%	7%	2%	-2%	1%	15%	70%	54%	19%	7.7	9.1	2015
DK	5%	5%	1%	-5%	-5%	4%	45%	45%	9%	6.6	7.2	2015
FI	3%	3%	1%	-13%	-13%	-8%	14%	14%	0%	11.6	11.6	2015
FR	1%	1%	1%	-10%	-9%	-1%	11%	9%	4%	6.2	6.5	2016
DE	4%	4%	2%	0%	1%	4%	40%	38%	1%	11.5	11.7	2015
GR	7%	6%	3%	-8%	-5%	9%	20%	8%	6%	6.9	7.3	2016
HU	5%	5%	1%	1%	3%	19%	33%	25%	7%	9.2	9.8	2015
IE	0%	0%	0%	-18%	-17%	-7%	7%	7%	6%	4.7	5.0	2016
IT	8%	8%	4%	-5%	-4%	3%	8%	3%	0%	5.7	5.7	2016
NL	1%	1%	0%	-7%	-6%	5%	6%	6%	0%	9.1	9.1	2015
NO	2%	2%	0%	11%	11%	19%	25%	24%	8%	6.9	7.5	2015
PL	14%	10%	2%	-6%	-1%	1%	59%	29%	4%	6.7	6.9	2015
PT	5%	4%	2%	-10%	-7%	-1%	20%	17%	4%	5.6	5.9	2016
RO	4%	4%	2%	-3%	-1%	1%	40%	30%	11%	5.1	5.7	2016
SK	24%	20%	8%	-7%	-5%	2%	43%	34%	3%	6.5	6.7	2015
SL	4%	3%	1%	-15%	-10%	1%	13%	7%	2%	8.5	8.7	2016
ES	7%	6%	3%	-23%	-20%	-7%	27%	17%	4%	7.1	7.4	2015
SE	7%	6%	2%	-3%	-3%	4%	17%	14%	5%	9.8	10.3	2015
CH	1%	1%	0%	-7%	-7%	21%	-5%	-7%	2%	4.6	4.7	2015
UK	3%	2%	1%	-1%	-1%	0%	3%	2%	3%	7.4	7.7	2015
EU	5%	4%	2%	-6%	-5%	2%	22%	18%	4%	7.5	7.8	

The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece

Prices per treatment day (total market) have been reduced in some markets, the highest reduction being -8%. Conversely there has also been an increase in prices per treatment day in some countries, up to 21%.

Oncology (rituximab)

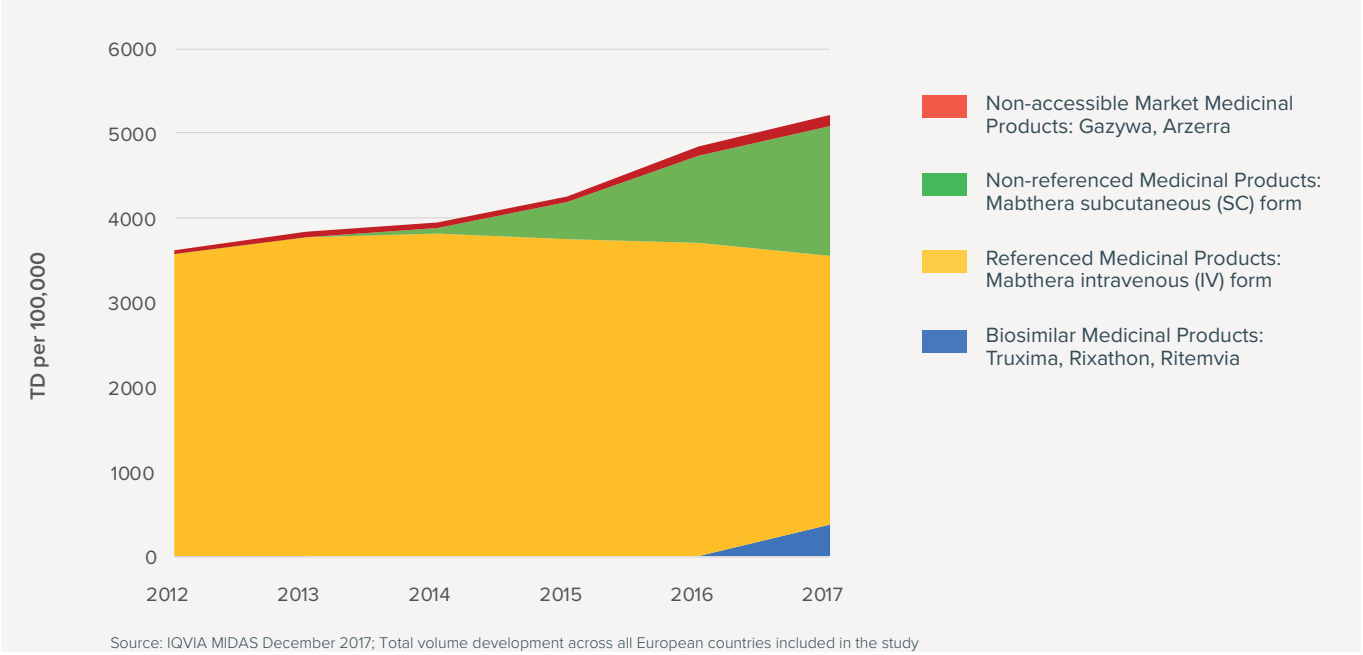
Monoclonal Antibody Antineoplastic agents use monoclonal antibodies (mAb) to bind monospecifically to certain cells or proteins to treat cancer. The objective is that this treatment will stimulate the patient's immune system to attack those cells.

Mabthera is a medicine used to treat several blood cancers and inflammatory conditions, including follicular lymphoma and diffuse large B cell non-Hodgkin's lymphoma (two types of non-Hodgkin's lymphoma) and chronic lymphocytic leukaemia (CLL). It is also used to treat severe RA and other inflammatory conditions. Considering that the primary indications used for Mabthera and rituximab biosimilars are in Oncology, and since IQVIA sales and treatment day volume cannot be split by indication, rituximab market dynamics are only considered in this separate Oncology section, within the Monoclonal Antibody Antineoplastic class.

In this market the non-accessible products are classified by identifying products which have a similar mechanism of action, and are used for similar indications to rituximab. There are both IV and SC forms of Mabthera available, but because the biosimilar is only available in IV form, Mabthera IV is classified as the referenced product, and Mabthera SC is classified as a non-referenced product.

WHO DDD's are not available for products in this class, so rituximab DDD's were calculated using IQVIA Oncology Dynamics data (MAT Dec 2017), accounting for the dosing and length of the treatment cycle in EU5. For other products in the class, the DDD's were calculated using EMA dosing information.

Oncology volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

Summary of EMA information for approved indications for Oncology products

		Classification				Indications					Route	
Molecule	Product	Reference product	Biosimilar	Non-reference	Non-accessible	Chronic Lymphocic Leukaemi a (CLL)	Follicular Lymphoma	Non-Hodgkin's Lymphoma	Rheumatold Arthritis	Granuloma-tosis with Polyangiitis	Subcutaneous	Intravenous
Rituxumab	MabThera (IV)	●				●	●	●	●			●
	MabThera (SC)			●		●	●	●	●		●	
	Truxima		●			●		●	●	●		●
	Rixathon		●			●	●	●	●	●		●
	Ritemvia		●				●	●		●		●
Obinutuzumab	Gazyva				●	●	●		●			●
Ofatumumab	Arzerra				●	●						●

Selected KPIs to illustrate volume share, price evolution, and volume evolution in selected European countries:

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilars
AU	1%	1%	1%	6%	5%	7%	-1%	-4%	-2%	0.09	0.08	2017
BE											0.05	
BU											0.03	
CZ											0.01	
DK	0%	0%	0%	-3%	-7%	-7%	-11%	2%	1%	0.08	0.08	2017
FI	0%	0%	0%	0%	0%	0%				0.09	0.09	
FR	2%	2%	2%	-10%	-15%	-15%	2%	15%	14%	0.06	0.07	2017
DE	16%	15%	14%	-5%	-5%	-5%	4%	4%	5%	0.06	0.06	2017
GR											0.00	
HU											0.04	
IE	2%	2%	1%	-7%	-7%	-7%	2%	3%	3%	0.06	0.06	2017
IT	3%	2%	2%	-1%	-5%	-5%	-5%	7%	8%	0.04	0.05	2017
NL	38%	33%	33%	-16%	-15%	-15%	16%	17%	17%	0.05	0.06	2017
NO	12%	7%	7%	13%	14%	14%	1%	2%	2%	0.08	0.08	2017
PL										0.02	0.02	
PT	2%	1%	1%	-4%	-3%	-3%	9%	10%	10%	0.04	0.05	2017
RO											0.01	
SK											0.03	
SL											0.06	
ES	5%	3%	3%	-1%	-11%	-9%	-16%	12%	13%	0.04	0.05	2017
SE											0.09	
CH											0.07	
UK	29%	18%	18%	-2%	-6%	-6%	-16%	6%	6%	0.06	0.06	2017
EU	11%	8%	7%	-3%	-7%	-6%	-2%	7%	7%	0.049	0.052	

The following data history is used: Portugal Hospital (2010-2017), only retail panel is available for Greece

Prices per treatment day (total market) vary over the European markets included in this study, ranging between (–15%) to 14%.

Low-molecular-weight heparin (LMWH)

Low-Molecular-Weight Heparin (LMWH) is a class of anticoagulant medications. They are used in the prevention of blood clots, treatment of venous thromboembolism (deep vein thrombosis and pulmonary embolism) and in the treatment of myocardial infarction. LMWH is obtained by fractionation of polymeric heparin. Many LMWH products are on the market, each similar in structure but created using different initial chemical procedures e.g. Enoxaparin is created using alkaline beta-eliminative cleavage of the benzyl ester of heparin.

Two Enoxaparin Sodium biosimilars (Inhixa and Thorinane) were authorised by the EMA in 09/2016. IQVIA MIDAS sales only started to be reported for these biosimilars in 2017 and in only three countries (Germany, UK and Italy), therefore, the KPI tables and charts are not included for this section.

Reading Guide

This example has been developed as a simplified guide to read the report that has a broad set of Key Performance Indicators for multiple countries. EPO in Austria is used as the example.

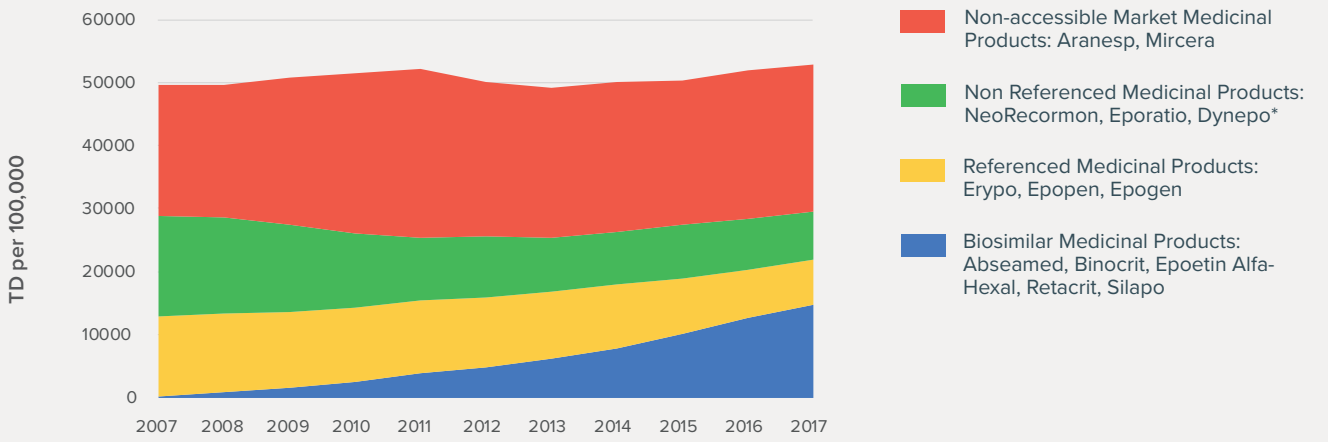
Volume development

The chart *Epoetin Volume Development* shows volume development over time across all the European countries included in the study. Volume is expressed in (WHO) DDDs as a proxy to be able to compare different products.

The blue part of the chart shows the volume share of Biosimilar Medicinal Products (listed) which is currently at 28%. The yellow part shows volume share of Referenced Medicinal Products to the approved Biosimilar products which is currently at 13%.

The Non-Referenced Competing Medicinal Products (green part of the chart) are other products with a largely similar profile to the Referenced Products, but have not been referenced. This category was affected by biosimilar entrance, which resulted in a loss of market share from 32% in 2007 to 15% in 2017. The Non-accessible market (red part of the chart) are the Pegylated (long-acting) products, with 44% market share.

Epoetin volume development



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

*Dynepo has been withdrawn by the EMA.

Approved indications

The table *Summary of EMA information for approved indications for Epoetin products* shows that the Biosimilar Medicinal Products receive the same indications as the Referenced Medicinal Products. It also shows that not all products are approved for all indications.

Summary of EMA information for approved indications for Epoetin products:

											Patient type		Frequency*	Route**	
Molecule	Product	Reference product	Biosimilar Product	Non-referenced Product	Non-accessible Product	Anaemia for Chemotherapy patients	Anaemia for patients with Chronic Kidney Disease	Preventing Anaemia in premature babies	Autologuos Blood Transfusion	Reduction of allogenic transfusion exposure in Orthopedic surgery	Adult	Paedriatic		Subcutaneous	Intravenous
Epoetin alfa	Epopen	●				●	●		●	●	●	●	3x a week	●	●
	Erypo	●				●	●		●	●	●	●	3x a week	●	●
	Epogen	●				●	●		●	●	●	●	3x a week	●	●
	Abseamed		●			●	●		●	●	●	●	3x a week	●	●
	Epoetin Alfa Hexal		●			●	●		●	●	●	●	3x a week	●	●
	Binocrit		●			●	●		●	●	●	●	3x a week	●	●
Epoetin zeta	Retacrit		●			●	●		●		●	●	3x a week	●	●
	Silapo		●			●	●		●		●	●		●	●
Epoetin beta	NeoRecormon			●		●	●	●	●	●	●	●	3x a week	●	●
Epoetin theta	Eporatio			●		●	●				●		3x a week	●	●
Methoxy polyethlene glycol-epotein beta	Mircera				●		●				●		Every 2 weeks	●	●
Darbepoetin alfa	Aranesp				●	●	●				●		Weekly	●	●

*Anaemia for patients with Chronic kidney disease

** Subcutaneous injection is typically used for chemotherapy patients. Intravenous injection is typically used for patients with kidney problems and for patients who are going to donate their own blood.

Selected KPIs

The first set of indicators is the *Market share TD 2017* calculated in treatments days. In Austria, Biosimilars represent 81% of Biosimilar + Referenced Products (which includes all the biosimilars and all the referenced products on the market for a therapy area). If the Non-Referenced Medicinal Product is also included (total accessible market), the share of Biosimilar Medicinal Product is 33%. Looking at the Biosimilar Medicinal Product versus total market, the market share is 21%.

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilar
AU	81%	33%	21%	-40%	-40%	-28%	-14%	-7%	-26%	0.93	0.69	2008

The second set of indicators, *Price per TD (2017/Year before biosimilar entrance)*, shows price development per treatment day (DDD) comparing 2017 price with prices in the year before the first Epoetin Biosimilar Medicinal Product was launched (which is 2008 in the case of Austria). The volume-weighted average price in 2017 vs. 2007 has fallen 40% for the Biosimilar Medicinal Product and Referenced Product, 40% for Biosimilar Accessible Market and 28% for the total market. This data illustrates that the competitive response, or the price regulators response is to lower prices on other products in the market, as competition intensifies.

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilar
AU	81%	33%	21%	-40%	-40%	-28%	-14%	-7%	-26%	0.93	0.69	2008

The third set of indicators, *Volume TD (2017/Year before biosimilar entrance)*, shows the volume development in treatment days (DDDs) comparing 2017 versus the year before the first Epoeitin Biosimilar Medicinal Product was launched (which is 2008 in the case of Austria). While the Biosimilar and the Referenced Product volume has decreased 14%; the full accessible market volume decreased 7% and the total market volume decreased 26%.

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilar
AU	81%	33%	21%	-40%	-40%	-28%	-14%	-7%	-26%	0.93	0.69	2008

The last set of indicators, TD per capita *(Year before biosimilar entrance)* and TD per capita 2017, show the usage per capita before the entrance of biosimilars (which is 0.93 in Austria), and the usage per capita of the total market in 2017 (which is 0.69 in Austria). The year with the First recorded sales of Biosimilar in Austria is 2008. In classes where there are multiple biosimilars, this will reflect the first recorded sales of the first biosimilar which entered the market.

	Market share TD (2017)			Price per TD (2017/Yr before BS entry)			Volume TD (2017/Yr before BS entry)					
	Biosimilar vs Referenced product	Biosimilar vs Accessible market	Biosimilar vs Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	Biosimilar and Referenced product	Biosimilar Accessible market	Total market	TD/capita (Yr before BS entrance)	TD per capita	First Recorded Sales of Biosimilar
AU	81%	33%	21%	-40%	-40%	-28%	-14%	-7%	-26%	0.93	0.69	2008

Appendices

1 EMA list of approved Biosimilars (May 2018)

Some of the biosimilars which have been authorised for use in Europe by the EMA are not yet captured in IQVIA MIDAS, either because they are not launched yet, or because there were no sales reported as of MAT Dec 2017. These products have not been included in the study.

Medicine Name	Active Substance	Atc code	Marketing Authorisation Holder	Authorisation date
Abasaglar (previously Abasria)	insulin glargine	A10AE04	Eli Lilly Nederland B.V.	09/09/2014
Abseamed	epoetin alfa	B03XA01	Medice Arzneimittel Pütter GmbH & Co. KG	28/08/2007
Accofil	filgrastim	L03AA02	Accord Healthcare Ltd	18/09/2014
Amgevita	adalimumab	L04AB04	Amgen Europe B.V.	22/03/2017
Bemfola	follitropin alfa	G03GA05	Gedeon Richter Plc.	27/03/2014
Benepali	etanercept	L04AB01	Samsung Bioepis UK Limited (SBUK)	14/01/2016
Binocrit	epoetin alfa	B03XA01	Sandoz GmbH	28/08/2007
Blitzima	rituximab	L01XC02	Celltrion Healthcare Hungary Kft	13/7/2017
Cyltezo	adalimimab	L04AB04	Boehringer Ingelheim International GmbH	10/11/2017
Epoetin Alfa Hexal	epotein alfa	B03XA01	Hexal AG	28/08/2007
Erelzi	etanercept	L04AB01	Sandoz GmbH	23/06/2017
Figrastim Hexal	filgrastim	L03AA02	Hexal AG	06/02/2009
Flixabi	infliximab	L04AB02	Samsung Bioepis UK Limited (SBUK)	26/05/2016
Grastofil	filgrastim	L03AA02	Apotex Europe BV	18/10/2013
Imraidi	adalimumab	L04AB04	Samsung Bioepis UK Limited (SBUK)	24/08/2017
Inflectra	infliximab	L04AB02	Hospira UK Limited	10/09/2013
Inhixa	enoxaparin sodium	B01AB05	Techdow Europe AB	15/09/2016
Insulin lispro Sanofi	insulin lispro	A10AB04	sanofi-aventis groupe	19/07/2017
Lusduna	insulin glargine	A10AE04	Merck Sharp & Dohme Limited	04/01/2017
Movymia	teriparatide	H05AA02	STADA Arzneimittel AG	11/01/2017
Mvasi	bevacizumab	L01XC07	Amgen Europe B.V.	15/01/2018
Nivestim	filgrastim	L03AA02	Hospira UK Ltd	08/06/2010
Omnitrope	somatropin	H01AC01	Sandoz GmbH	12/04/2006
Ontruzant	trastuzumab	L01XC03	Samsung Bioepis UK Limited (SBUK)	15/11/2017
Ovaleap	follitropin alfa	G03GA05	Teva Pharma B.V.	27/09/2013
Ratiograstim	filgrastim	L03AA02	Ratiopharm GmbH	15/09/2008
Remsima	infliximab	L04AB02	Celltrion Healthcare Hungary Kft.	10/09/2013
Retacrit	epoetin zeta	B03XA01	Hospira UK Limited	18/12/2007

Ritemvia	rituximab	L01XC02	Celltrion Healthcare Hungary Kft.	13/7/2017
Rituzena (previously tuxel)	rituximab	L01XC02	Celltrion Healthcare Hungary Kft.	13/07/2017
Rixathon	rituximab	L01XC02	Sandoz GmbH	15/06/2017
Riximyo	rituximab	L01XC02	Sandoz GmbH	15/06/2017
Silapo	epoetin zeta	B03XA01	Stada Arzneimittel AG	18/12/2007
Solymbic	adalimumab	L04AB04	Amgen Europe B.V.	22/03/2017
Terrosa	teriparatide	H05AA02	Gedeon Richter Plc.	04/01/2017
Tevagrastim	filgrastim	L03AA02	Teva GmbH	15/09/2008
Thorinane	enoxaparin sodium	B01AB05	Pharmathen S.A.	15/09/2016
Truxima	rituximab	L01XC02	Celltrion Healthcare Hungary Kft.	17/02/2017
Zarzio	filgrastim	L03AA02	Sandoz GmbH	06/02/2009

A list of Biosimilars under review by EMA (July 2018)

Common name	Therapeutic area	Number of applications	Originator product	Originator company
Adalimumab	Immunosuppressants	2	Humira	AbbVie Ltd
Bevacizumab	Antineoplastic medicines	1	Avastin	Roche
Etanercept	Immunosuppressants	1	Enbrel	Amgen
Pegfilgrastim	Immunostimulants	8	Neulasta	Amgen
Rituximab	Antineoplastic medicines	1	MabThera	Roche
Trastuzumab	Antineoplastic medicines	1	Herceptin	Roche

2 Methodology

- The volumes have been converted by IQVIA into daily doses using WHO DDDs. Consumption measures are therefore not adjusted for clinical practice guidelines, patient characteristics, indications for which the molecule is used, or other factors which may result in different volumes utilised on a per patient treatment day basis.
- Volume share is calculated as the volume in DDD versus the relevant market (reference market, accessible market, total market).
- Prices are calculated as a volume weighted ex-manufacturing price.
- Price evolution is calculated as the present price for the relevant market versus the price for the same relevant market before the introduction of biosimilars in the country.
- Volume evolution is calculated as the present total volume versus the total volume before the introduction of biosimilars in the country.

		Methodology
Market share TD	Biosimilar vs Reference product	TD Biosimilars as % of TD Reference products in 2017
	Biosimilar vs Accessible market	TD Biosimilars as % of TD Accessible market in 2017
	Biosimilar vs Total market	TD Biosimilars as % of TD Total market in 2017
Price per TD	Biosimilar Reference product	Δ in Price per TD for Biosimilar Reference products 2017/the year before biosimilar entrance
	Biosimilar Accessible market	Δ in Price per TD for Biosimilar Accessible market 2017/the year before biosimilar entrance
	Total market	Δ in Price per TD for Total market 2017/the year before biosimilar entrance
Volume TD	Biosimilar and Reference product	Δ in TD for Biosimilars and Reference products 2017/the year before biosimilar entrance
	Biosimilar Accessible market	Δ in TD for Biosimilar Accessible market 2017/the year before biosimilar entrance
	Total market	Δ in TD for Total market 2017/the year before biosimilar entrance
TD per capita 2017		No. Of Treatment Days per capita in 2017
TD per capita year before biosimilar entrance		No. Of Treatment Days per capita the year before biosimilars entered the market
First recorded sales		The year first sales of biosimilar were recorded

3 IQVIA source of volume data

Volume information is based on channel audits for retail and non-retail channels, covering the majority of volume consumed in a country market, though may exclude some direct sales made from the manufacturer to dispensing locations. IQVIA source of volume data collection route and sample varies by country; data can be collected at various points within the pharmaceutical supply chain.

Note: Points of collection
Sell-in data represents the supply of products from wholesalers to pharmacies.
Sell-out data represents the demand for products from the pharmacies to patients.
Hospital consumption data measures dispensing of products by hospital pharmacies within the hospital wards.

The table below is a matrix to identify these points of collection by country.

	AU	BE	BU	CZ	DK	FI	FR	DE	GR	HU	IE	IT	NL	NO	PL	PT	RO	SK	SL	ES	SE	CH	UK
Retail	In	In	In	In	In	In	Out	Out	Out	In	In	In	In	In	In	In	In	In		In	Out	In	Out
Hospital	C	C	In	In	In	In	C	C		In	In	C	In	In	In	C	In	In		C	In	In	C
Combined																			In				

4 IQVIA source of price data

Sales data is collected in terms of the number of Pack Units sold and are then multiplied by the Pack Price to produce the sales values. Pricing information is based on a variety of sources including list price, wholesaler transactions, government price list and industry publications, but does not reflect rebates and discounts which in some countries and channels may be significant. Country volumes may also be impacted by unknown parallel exports or imports which cannot be identified or adjusted for. Inclusion of VAT and taxes varies per country.

In March 2017, IQVIA implemented changes to price calculations resulting in improved accuracy of sales data reporting in the Norwegian market. All Hospital tender (LIS) products are now reported in maximum list prices (MAX AIP) instead of the previous re-calculation methodology. This change will impact most of the therapeutic classes and there may discrepancies with previous years analyses.

The table below shows the price source reference within each country included in the study:

EU Geography			
Country		**Sector (Data Type)**	**Price Source**
Austria	**AU**	HOSPITAL (CONSUMPTION),RETAIL (SELL-IN)	Hospital & Retail - List price - Arzneimittelverzeichnis or Taxe (Apotheker-Verlag)
Belgium	**BE**	HOSPITAL (CONSUMPTION),RETAIL (SELL-IN)	Hospital - List price - Association Général de l'Industrie du Médicament (AGIM), Retail - List price - Association Pharmaceutique Belge (APB)
Bulgaria	**BU**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Czech Rep.	**CZ**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Denmark	**DK**	RETAIL (SELL-IN),HOSPITAL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Finland	**FI**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - List Price - Wholesalers, based on official published prices of Finnish Pharmacy Association
France	**FR**	HOSPITAL (CONSUMPTION),RETAIL (SELL-OUT)	Hospital - List price - Journal Officiel, manufacturer hospital price lists, Retail - List price - Journal Officiel, wholesaler catalogues, average transaction prices
Germany	**DE**	HOSPITAL (CONSUMPTION),RETAIL (SELL-OUT)	Hospital - Estimated transaction price reflecting the average level of rebates and discounts, Pharmascope - List price - ABDATA (Pharmacist Association), sourced from IFA (German Health Institute)
Greece	**GR**	RETAIL (SELL-OUT)	Retail - List price - Ministry of Development
Hungary	**HU**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - List price - National Health Fund, National Institute of Pharmacy
Ireland	**IE**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - List price - Irish prescription drug databases
Italy	**IT**	DPC (CONSUMPTION),HOSPITAL (CONSUMPTION), RETAIL (SELL-IN)	DPC & Retail - List price - CFO - Farmadati, Gazzetta Ufficiale della Repubblica Italiana, Hospital - List price - 45% public level retail list price
Netherlands	**NL**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - List price - Wholesaler price list
Norway	**NO**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Poland	**PL**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Portugal	**PT**	HOSPITAL (CONSUMPTION),RETAIL (SELL-IN)	Hospital - Average invoiced pack price, Retail - List price - Manufacturer published price list
Romania	**RO**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Slovakia	**SK**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - Average invoiced pack price
Slovenia	**SL**	COMBINED (SELL-IN)	Hospital & Retail - Average invoiced pack price
Spain	**ES**	HOSPITAL (CONSUMPTION), RETAIL (SELL-IN)	Hospital & Retail - List price - Manufacturer price list, Base de Datos del Medicamento (BOT)
Sweden	**SE**	RETAIL (SELL-OUT),HOSPITAL (SELL-IN)	Hospital & Retail - List price - Apoteket AB, The Dental and Pharmaceutical Benefits Agency, The Drug Benefit Board, The LFN
Switzerland	**CH**	HOSPITAL (SELL-IN),RETAIL (SELL-IN)	Hospital & Retail - List price - Wholesalers, manufacturers
UK	**UK**	HOSPITAL (CONSUMPTION),RETAIL (SELL-OUT)	Hospital & Retail - List price - Chemist and Druggist, Drug Tariff

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About IQVIA

IQVIA is a leading global information and technology services company providing clients in the healthcare industry with comprehensive solutions to measure and improve their performance. End-to-end proprietary applications and configurable solutions connect 10+ petabytes of complex healthcare data through the IMS OneTM cloud-based master data management platform, providing comprehensive insights into diseases, treatments, costs and outcomes. The company's 15,000 employees blend global consistency and local market knowledge across 100 countries to help clients run their operations more efficiently. Customers include pharmaceutical, consumer health and medical device manufacturers and distributors, providers, payers, government agencies, policymakers, researchers and the financial community.

As a global leader in protecting individual patient privacy, IQVIA uses anonymous healthcare data to deliver critical, real-world disease and treatment insights. These insights help biotech and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders to identify unmet treatment needs and understand the effectiveness and value of pharmaceutical products in improving overall health outcomes. Additional information is available at www.iqvia.com.

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