

Biosimilar Pricing in Europe:

A look at Infliximab



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ABSTRACT

Biosimilar uptake has been swift in Europe, increasing rapidly since Europe approved its first biosimilar, Sandoz's Omnitrope (somatropin), in 2006. Member States of the European Union enacted differing regulatory policies and pricing schemes to ensure price discounts with the advent of biosimilars; nonetheless, each Member State seeks cheaper biologic products to lessen the onerous cost of biologic products on their national health systems. When a biosimilar enters the market, the reference drug tends to drop in price in the face of competition, whether through internal or external

reference pricing or health technology assessment. Janssen's Remicade (infliximab) serves as the vessel for this exploration into the ways in which European Union Member States, particularly the EU5, have managed the pricing of biosimilars. Germany and the United Kingdom allow free pricing of biosimilars, albeit discounts are expected, whereas France is keen on mandated price cuts and Italy utilizes reference pricing; these procedures serve as a microcosmic representation of biosimilar pricing schemes among Member States.

Introduction

Europe, biosimilar stalwart

The European Medicines Agency (EMA) is the health technology assessment (HTA) gatekeeper for manufacturers to receive marketing authorization of not just biosimilars, but of all drugs in Europe—at least, for within the European Union. EMA conducts its own HTA procedures with help from its Committee for Medicinal Products for Human Use (CHMP) before authorizing a drug. Afterwards, each member state of the EU conducts HTA for new drugs before granting national-level marketing authorization. Being that biosimilars are “copycat” drugs, yet still innately complex due to the organic variability and vulnerability of these medicines, EMA and its constituent member states have had to draft and adopt new guidance to approve biosimilars.

Since the EMA published official guidelines for biosimilar approval in 2005, biosimilar uptake within the EU has been on the rise. Europe’s first biosimilar, Sandoz’s Omnitrope (somatropin) was approved in 2006, and since then, the European Union has authorized marketing of over 40 biosimilars (as of June 2018), based on active substances ranging from filgrastim to adalimumab and trastuzumab.

The EU5 (i.e. France, Germany, Italy, Spain, and, for now, the United Kingdom) tend to be trend-setters for the rest of the EU. Examining the biosimilar guidelines and regulatory practices of the EU5, including their utilization of reference pricing (internal and/or external) or lack thereof, serves as a microcosmic demonstration of how uptake has occurred across Europe.

Janssen’s Remicade (infliximab) has seen the authorization of four biosimilars in Europe; the advent of its biosimilars demonstrates how the EU5, in light of their own guidelines and procedures, managed the pricing of these cheaper drugs, whether through internal reference pricing (IRP) and external reference pricing (ERP), or separately, by conducting HTA. Within the European Union, additional Member States have established pricing schemes and guidelines representative of the EU5, and even Norway, which is separate from EU but a part of the European Economic Area (EEA), has been keen on biosimilar uptake, enacting stringent legislation to ensure price cuts.

The EU5 and Biosimilar Guidelines

In Europe, biosimilar uptake has seen a swift upward trend in the last few years, although biosimilar regulatory rules have existed since 2003, but were finalized in 2005.

Whereas generic drugs are identical copycats of small-molecule chemical products, biosimilars are only similar to biologic products. Innately more complex than chemical products, biologics are large-molecule, organic drugs, subject to natural variability and vulnerability during the manufacturing process, so it is nearly impossible to produce an exact replica of a biologic—hence the use of the nomenclature “biosimilar.”

To clarify the difference between generics and biosimilars, Alliance Life Sciences Senior Consultant Max Klietmann offered an analogy. “Generics,” he explained, “are an identical copy of a race car based on published blueprints,” while on the other hand, “biosimilars are more like copying a racehorse based on its published family tree—you can get close, but it will never be the same.”

Nonetheless, biosimilar uptake has been strong in Europe, mainly because their arrival

has meant, for lack of better words, cheaper drugs. With the same safety and efficacy profile as the reference drug, biosimilars have been seen as crucial to the sustainability of many European healthcare systems, which are public, and thus have budget constraints.

Upon the introduction of biosimilars, there was uncertainty as to how competition and uptake would play out due to the varied regulatory processes, etc. across the EU. EMA serves as the gatekeeper, but each country must grant marketing authorization and approval. Additionally, drug procurement varies throughout Europe.

Regardless of initial reservations, biosimilar uptake has grown and is continuing to grow. The EU5 are microcosmic of European biosimilar legislation, regulation, and pricing mechanisms, including mandated price discounts, IRP, and ERP. Overall, the UK conducts HTA and utilizes a type of IRP based predominantly on cost-effectiveness, while its EU5 counterparts rely on mandated discounts, IRP, and ERP—especially Italy—to establish a price.



THE UK

Like Germany, the UK permits manufacturers to set prices, even for biosimilars—albeit a discount of 10-25% usually applies. Prescription budgets can be found in the UK for general practitioners. Upon the commercialization of biosimilars to Janssen’s Remicade (infliximab), Local Clinical Commissioning Groups (CCGs), which set prescription budgets, and the University Hospital Southampton National Health Service (NHS) Foundation Trust entered a gain-sharing agreement to incentivize the use of biosimilars to save money. The UK is less concerned with IRP and ERP; rather, the UK employs its Medicines and Healthcare Regulatory Agency (MHRA) and National Institute for Health and Care Excellence (NICE) to conduct HTA to negotiate the best pricing. Additionally, the UK utilizes volume-based pricing schemes, as biosimilars are predominantly used within the hospital setting.

FRANCE

In France, biosimilars must first and foremost demonstrate bioequivalence. September 2017 witnessed the publication of “Similar Biologic Groups” by the National Agency for Medicines and Health Products Safety (ANSM), which permitted substitution between a biologic product and its biosimilar. France’s Economic Committee on Health Care Products (CEPS) mandated that before a biosimilar launches in France, the reference drug must take a 15% minimum discount. Through the use of IRP and ERP focused on Germany, Italy, Spain and the UK, biosimilars receive an ASMR V rating, meaning the drug (i.e. the biosimilar) offers no improvement because technically, it already exists, although it is still recommended because it’s equally as safe and effective, but cheaper. Once approved, the biosimilar can cost less than the originator, but due to the price cut taken by the reference drug, prices tend to be equal; however, hospitals will see an automatic price cut of 10%.



GERMANY

Biosimilars are allowed free pricing, but there are certain restrictions, as Germany utilizes IRP for biosimilars. On a regional level, sickness funds negotiate the supply of and discounts for biosimilars via tenders. Germany is considered one of the most biosimilar-friendly countries, and ambulatory care in the country has been subjected to prescription budgets and biosimilar quotas. As biosimilars have grown to dominate market shares, Germany has seen discounts upwards of 20-25% not only for biosimilar products, but for the reference drugs, too. These price cuts are largely attested to price linkage and price re-evaluation, as Germany's higher and lower HTA bodies, the Federal Joint Committee (G-BA) and the Institute for Quality and Efficiency in Health Care (IQWiG) respectively, actively re-examine a drug's pricing and efficacy and safety to ensure fairness.

ITALY

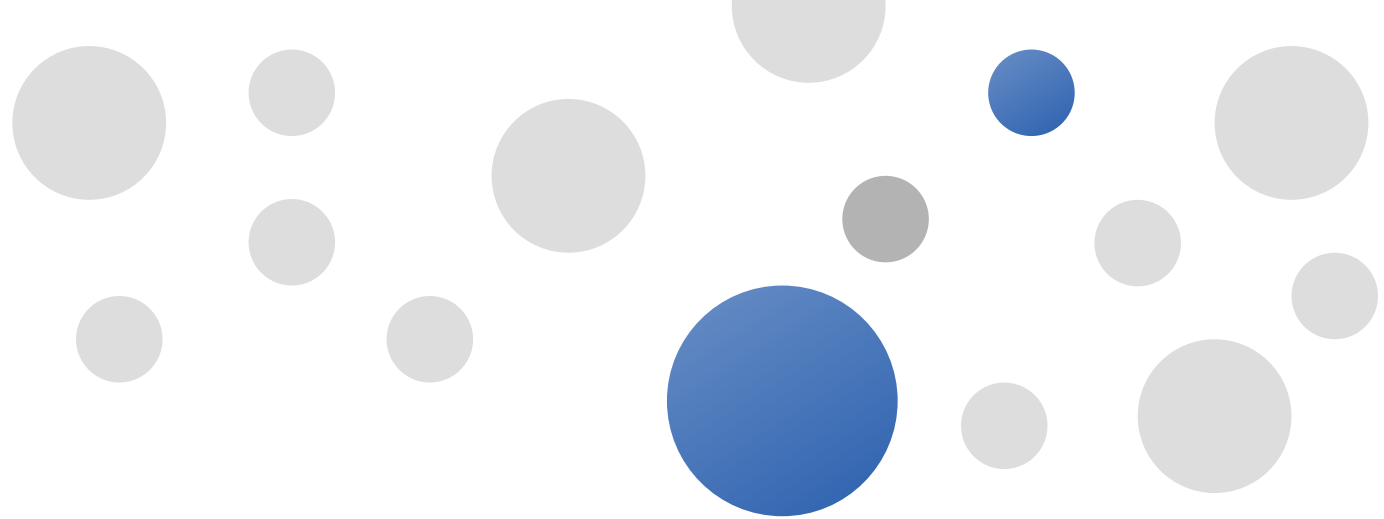
Though muddled, biosimilar use and legislation has been increasing in Italy, and the country's Ministry of Health pledged fealty to biosimilars. To be used, a biosimilar must be certified by EMA and/or Italy's national HTA body, the Italian Medicines Agency (AIFA). AIFA favorably recommended interchangeability, and while drug switching is common, country-wide availability of drugs varies due to Regional discrepancies. Italy utilizes price-linkage, meaning there is a mandatory reduction to the price of biologics and biosimilars upon the commercialization of competition (i.e. biosimilars). On average, a biosimilar will cost 20+% less than the reference drug. Moreover, Italy is a proponent of ERP, looking at its reference basket countries to rationalize pricing rather than actively participating in IRP, save for mandating discounts.

SPAIN

Biosimilars are hospital only medicines in Spain and must intend an action equivalent to the reference drug. Internally, the reference price group for a biosimilar consists of all formulations of reimbursed medicines with the same active ingredient and mode of administration. The reference group must include 1 generic and/or biosimilar (if available), along with 2 other similar products. Overall, biosimilars have brought

about discounts upwards of 30% below the reference biological medicine price, due to an agreement with the Interministerial Commission for pricing; however, this practice is not mandatory. While no true regulation on switching exist, there is a 15% margin for generics and biosimilars once approved by EMA, and these drugs can be purchased via tenders for naïve patients.





Once Remicade was granted EMA approval, the following MNF rates were established within the EU5:

Starting MNF for Remicade Infusion 1 Lyophilized Powder Vial 10 ML 100 MG

Country	MNF (€)
France	561.00
Germany	730.47
Italy	570.68
Spain	536.28
UK	510.78

EMA APPROVAL DATES:

Remicade - AUG. 30, 1999
 Remsima - SEP. 10, 2013
 Inflectra - SEP. 10, 2013
 Flixabi - MAY 26, 2016

Infliximab Branded to Biosimilar

While Sandoz’s recombinant human growth factor Omnitrope was the first biosimilar to be granted EMA approval, Janssen’s Remicade (infliximab) was the first large-molecule to have more than one biosimilar greenlighted by EMA (biosimilar uptake has only recently increased).

Granted EU-wide marketing authorization on August 13, 1999, Janssen’s (or in the UK, Merck’s) Remicade is an intravenously-administered, chimeric monoclonal antibody that targets the tumor necrosis factor alpha (TNF-α) to treat autoimmune diseases. As approved by the EMA, Remicade is currently indicated in the treatment of chronic inflammatory diseases, including ankylosing spondylitis, rheumatoid arthritis, ulcerative colitis, psoriatic arthritis, Crohn’s disease, and psoriasis.

On September 9, 2013, both Celltrion’s Remsima (infliximab) and Pfizer/Hospira’s Inflectra (infliximab) were granted EU authorization as biosimilars to Remicade. Remsima and Inflectra were followed by Biogen/Samsung Bioepis’ Flixabi (infliximab) on May 26, 2016. The fourth and most recent biosimilar to Remicade, Sandoz’s Zessly (infliximab), was granted EU authorization May 18, 2018.

With the introduction of competition (i.e the biosimilars Remsima, Inflectra, and Flixabi), prices for Remicade among the EU5 changed, except in Spain. Even the price of the biosimilars have undergone change. Below, the prices of each pack presentation of Remicade and its biosimilars are listed by country, along with the dates and price changes to each drug.

Pricing

FRANCE

Remicade

- MAY 2005—561.00
- ▼ SEP 2009—536.28
- ▼ OCT 2010—509.47
- ▼ JUN 2011—482.67
- ▼ NOV 2014—434.40
- ▼ JAN 2016—382.27
- ▼ MAR 2018—290.53

Remsima

- MAR 2015—434.40
- ▼ JAN 2016—382.27
- ▼ MAR 2018—290.53

Inflectra

- DEC 2014—434.40
- ▼ SEP 2016—382.27
- ▼ MAR 2018—290.53

Flixabi

- OCT 2016—382.27
- ▼ MAR 2018—290.53

***All pack presentations are “_____”
 Infusion 1 Lyophilized Powder Vial 10 ML
 100 MG and are listed as MNF (€) for cross-
 country consistency

- ▼ indicates a price reduction
- ▲ indicates a price increase

The price for Remicade has dwindled consistently since May 2005, dropping from €561 to €434.40 in November 2014. In December 2014, Inflectra entered the market, followed by Remsima in March 2015, and both biosimilars were set at the same price as Remicade (€434.40) at the time. In January 2016, the prices of all three drugs were lowered to equal that of Flixabi, the most recent biosimilar to enter the French market. Finally, and most recently, in March 2018, the prices of all 4 drugs were cut again, this time quite significantly to €290.53.

While France does not mandate that biosimilars are cheaper, it is evident that these drugs have entered the market at priced lower than the reference product. Moreover, in November 2014, Remicade was discounted from its previous rate of €482.67, which had been noted since June 2011, to €434.40, thus representing CEP’s mandate for the originator drug to be discounted; albeit not 15%, the discount was significant to establish a threshold for the biosimilars.

Pricing

GERMANY

Remicade

- AUG 2013—730.47
- ▼ JUL 2016—728.19
- ▼ APR 2018—578.52
- ▼ JUN 2018—578.12

Remsima

- FEB 2015—670.00
- ▼ MAR 2015—603.00
- ▼ APR 2018—578.52

Inflectra

- FEB 2015—626.40
- ▼ MAR 2015—559.40

Flixabi

- AUG 2016—669.00
- ▼ JAN 2018—448.33

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- ▲ indicates a price increase

While the price of Remicade remained consistent in Germany for almost five years, the drug saw a price drop in 2018, along with Remsima. Previously, its first two biosimilars Remsima and Inflectra, which were both approved in September 2013, witnessed price cuts after one month, over a year after finding EMA approval. Concurrently, Flixabi, the most recent biosimilar to be marketed in Germany (save for what will most assuredly be Zessly), saw a price cut at the start of 2018, placing its per pack rate at the lowest, over €200 cheaper than when it entered the market. However, the costs of Remicade, Remsima, and Inflectra remain competitively

comparable nowadays, except for minor discrepancies.

From the data, it can be observed that the biosimilars were allowed free pricing upon their adoption, although the price of Inflectra dropped significantly a month after its arrival on the market. Remsima changed slightly from February 2015 to March 2015, but more noticeably in April 2018. As noted, the adoption of biosimilars saw discounts for the reference product; from August 2013 through June 2018, Remicade experienced an overall discount of 20+%.

Pricing ITALY

Remicade

- APR 2000—570.68
- ▼ OCT 2014—515.03
- ▲ NOV 2014—570.68

Remsima

- FEB 2015—406.61

Inflectra

- FEB 2015—428.01

Flixabi

- AUG 2017—428.01

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- ▲ indicates a price increase

As seen in Italy, when the biosimilars to Remicade entered the market, their prices were much lower than that of the reference product. On average, the infliximab biosimilars cost an MNF rate of 25+% less than that of Remicade, thus representing Italy’s utilization of price-linkage; however, the reference product has remained at a consistent rate.

Since Italy employs ERP, with a reference basket focused on the EU5, it is evident that the individual prices for Remsima, Inflectra, and Flixabi reflect prices noticed in France,

Germany, Spain, and the UK. For example, Inflectra Infusion 1 Lyophilized Powder Vial 10 ML 100 MG costs an MNF of €428.01 in Italy, whereas in Germany, the MNF cost at the time of the drug’s release was €626.40, in France, the MNF cost was €434.40, in Spain, the MNF cost was €439.75, and in the UK, the MNF cost was €427.53. The MNF cost in Italy is on the lower end of the spectrum, only cents more than the cost of Inflectra in the UK.

Pricing SPAIN

Remicade

- DEC 1999—536.28

Remsima

- FEB 2015—439.75

Inflectra

- FEB 2015—439.75

Flixabi

- JUL 2017—482.65

In Spain, Remsima and Inflectra cost almost 20% less than the reference product, Remicade. When establishing the price of Remsima and Inflectra, Spain had only the reference product to serve as a measure for IRP, thus the agreement with the Interministerial Commission for pricing was used. Nonetheless, Flixabi entered the market at a higher rate. This can be attested to the fact that discounts are not mandated, but rather desired.

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Pricing

UNITED KINGDOM

Remicade

- AUG 1999—510.78
- ▼ SEP 2013—475.03

Remsima

- FEB 2015—427.53

Inflectra

- FEB 2015—427.53

Flixabi

- SEP 2016—426.78

Although the UK does not truly reference the drug prices of its EU neighbors, the price for Remicade and its biosimilars are comparable to the prices found in the remaining EU5 countries, save for France. The UK permits manufacturers to set drug prices, akin to Germany, but as seen with the price of the infliximab biosimilars, a 10-25% discount was applied. Consequently, in September 2013, when Remicade and Inflectra were granted approval by EMA, the price of Remicade dropped, although its price is still higher than that of its biosimilars.

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- ▲ indicates a price increase

What about the rest of Europe?

The EU5 best exemplify European biosimilar guidelines, as fellow Member States tend to reiterate the policies and guidelines within these 5 countries. Or more often, the Member States refer to the EU5 when establishing price ceilings.

AUSTRIA

Pricing

- After the 3rd biosimilar is approved, the reference product's price must match that of the cheapest biosimilar available
- 3 months after biosimilar uptake, the reference product must be discounted by 30%

IRP

Utilizes IRP: 1st biosimilar sees a 38% discount on the reference product; the 2nd sees a 15% discount on the 1st; and the 3rd sees a 10% on the 2nd

Substitution

Substitution is not allowed

Incentives

Incentives for prescribing biosimilars

BELGIUM

Pricing

- Pricing is negotiated on a case-by-case basis, by utilizing HTA procedures for price evaluation; however, the maximum price cannot exceed the reference product (i.e. Class 2 Reimbursement)
- Once biosimilars are available, there a mandatory discount to the reference product

IRP

No true IRP

Substitution

Substitution is not allowed

Incentives

Incentives for prescribing biosimilars
July 2015: Ministry of Social Affairs and Public Health signed the "Future Pact," pledging 20% of new patients will be given biosimilars

BULGARIA

Pricing

A biosimilar cannot be priced higher than the cost of the same product within Bulgaria's hefty basket of reference countries

IRP

IRP is utilized, as there are 3-level margin scales and ceiling prices

Substitution

Substitution is not allowed

Incentives

There is no incentive for prescribing biosimilars

CROATIA

IRP

IRP, as the 1st biosimilar sees a 15% discount on the reference product and the next sees a 10% discount on the previous biosimilar

ERP

ERP is used, and the basket of reference countries includes Italy, Slovenia, the Czech Republic, Spain, and France

Substitution

Substitution is not allowed

Incentives

There is no incentive for prescribing biosimilars

CZECH REPUBLIC

Pricing

Due to the Amendment to Act No. 48/1997 (April 1, 2017), the price and reimbursement of the 1st biosimilar is 30% of the reference product

ERP

ERP is used, with a basket of multiple, lower-priced reference countries—but Germany is included—to determine the maximum price for a biosimilar

ESTONIA

Pricing

For hospital use, there are no fixed percentages for discounts

IRP

IRP is utilized, although a biosimilar price is negotiated, the cost is expected to be at least 15% less than that of the reference product

Substitution

Substitution is allowed

Incentives

Incentives for prescribing biosimilars

FINLAND

Pricing

- The price of the biosimilar will be set below the reference price (the wholesale price of the first biosimilar will be 30% less than the wholesale price of the reference product), so IRP is used
- Once a biosimilar has launched, the reference drug price will be re-examined

Substitution

Substitution is allowed

Incentives

Incentive for prescribing biosimilars

GREECE

Pricing

Greece constantly re-evaluates the price of biosimilars and reference drugs

ERP

Greece takes the average of the 3 lowest prices in its ERP basket, which includes nearly every EU country

Incentives

Greece caps physician and pharmacy prescription budgets

HUNGARY

Pricing

- Hungary re-evaluates drug pricing
- The Preferred Reference Pricing System: if there are 2 or more biologics, the cheapest option will find reimbursement

IRP

IRP is used: the 1st biosimilar sees a 30% discount on the reference product, and each subsequent biosimilar sees a 10% discount

Procurement

Outpatient tenders

Substitution

Switching only in clinically-justified cases

Incentives

Quotas and targets are set, seeking cheapest medicines possible

IRELAND

Pricing

Biosimilar prices are negotiated, and are typically 10-20% below the price of the reference product

ERP

No IRP

Substitution

Substitution is not allowed

Incentives

No incentives for prescribing biosimilars

LATVIA

IRP

IRP is used: 1st biosimilar sees a 30% discount on reference product; 2nd and 3rd biosimilars see a 10% on 1st and 2nd respectively; and the next biosimilars see a 5% discount

ERP

ERP is also used: the price of the biosimilar must be lower than the 3rd lowest of the Czech Republic, Romania, Slovakia, and Denmark, but cannot be higher than prices in Estonia and Lithuania

Substitution

Substitution is allowed

Incentives

No incentives for prescribing biosimilars

LITHUANIA

Pricing

Pricing negotiation procedures, meaning a full HTA dossier is required for biosimilars

IRP

IRP is used: 1st biosimilar sees a 10% discount and the 2nd and subsequent biosimilars see a 15% discount

Substitution

Substitution is not allowed

MALTA

PRICING

Since procurement is by the INN, biosimilars and reference products can compete in the same procurement procedure

IRP

IRP is not used

ERP

The maximum price is set through utilizing ERP

Substitution

Substitution is not allowed

Incentives

No incentives for prescribing biosimilars

THE NETHERLANDS

IRP

The biosimilar should cost the same as the reference drug; thus, the Netherlands uses IRP

Substitution

Substitution is not allowed

Incentives

No incentives for prescribing biosimilars

POLAND

Pricing

- A limit group establishes that the cheapest is the limit for the group
- EU data is necessary when seeking approval for a biosimilar; if there is no equivalent data, then national HTA is used

IRP

IRP is used: 1st biosimilar sees a 25% discount on the reference product and the 2nd must be cheaper than the first (i.e. mandatory price cuts)

ERP

ERP is used as supportive information

Substitution

- Treatment naïve patients are given biosimilars
- Outpatient and hospital tenders are mandatory for purchases greater than 30,000 EUR, which often leads to switching of treatments

Incentives

No incentives for prescribing biosimilars

PORTUGAL

IRP

IRP is not used

ERP

Portugal has a basket of ERP countries that changes annually, which the country uses to establish a maximum price. The biosimilar price is 20% lower than the maximum.

Substitution

Substitution is not allowed

Incentives

Incentives for prescribing biosimilars in the hospital

ROMANIA

Pricing

- There are no pricing negotiation procedures in place, but a 20% discount is mandatory
- Romania conducts HTA based on therapeutic value, and looks at other EU countries for reimbursement status

SLOVAKIA

Pricing

There are no pricing negotiation procedures in place, but a 20% discount is mandatory

Procurement

Price criteria for tendering

Substitution

Under healthcare professional supervision, interchangeability is allowed

Incentives

Proponent of drug competition, as it drives pricing down

SLOVENIA

Pricing

- If the price is not available, then the price will be 68% of the reference price
- Prices are established by individual hospitals and through public procurement
- JAZMP established the maximum allowed price, so there are no negotiations

ERP

If the biosimilar is available in the basket of ERP countries, or EU or EEA, the price of biosimilar will be 92% of the lowest, or 92% of the median

Procurement

Public

SWEDEN

Pricing

The biosimilar must cost less than or equal to the reference product, but Sweden also conducts its own HTA and cost-effectiveness analysis, which is the true basis for biosimilar pricing

IRP

IRP is not truly used

Substitution

Substitution is not allowed

Incentives

Incentives for prescribing exist on a regional level

The EU5 best exemplify European biosimilar guidelines, as fellow Member States tend to reiterate the policies and guidelines within these 5 countries. Or more often, the Member States refer to the EU5 when establishing price ceilings.

Pricing

NORWAY

Remicade (Parallel Import: Orifarm)

- JAN 2011—422.60
- ▼ DEC 2012—408.01
- ▼ JAN 2013—402.03
- ▲ FEB 2014—410.14
- ▲ JAN 2017—463.15
- ▼ DEC 2015—431.89
- ▼ JAN 2017—424.01
- ▼ DEC 2017—412.80

Remsima

- SEP 2013—372.02
- ▼ DEC 2015—291.16
- ▲ JAN 2017—301.31
- ▼ DEC 2017—298.05

Inflectra

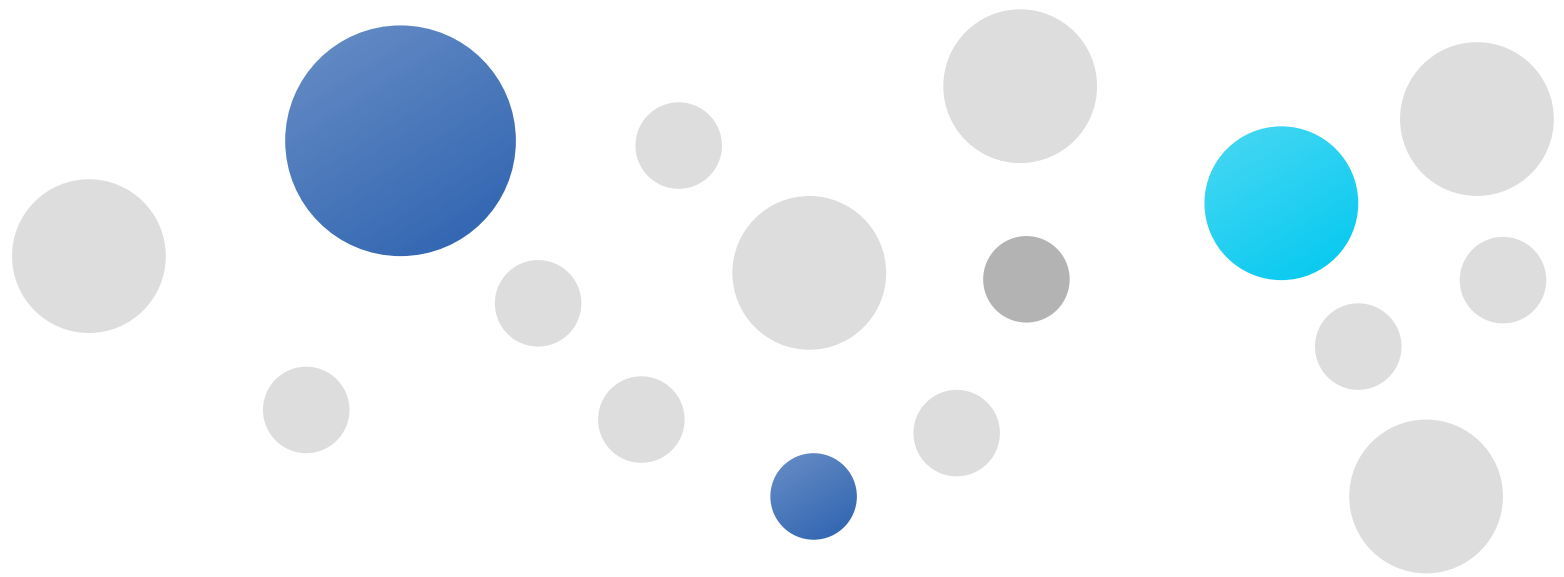
- OCT 2013—372.02
- ▼ DEC 2015—291.16
- ▲ JAN 2017—301.31
- ▼ DEC 2017—298.05

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Norway is an interesting case. Although not a member of the EU but a part of the European Economic Area (EEA), Norway has been a vocal proponent of biosimilars since their advent. The Scandinavian country has seen huge discounts and consequently, recommends that its constituents, along with other countries, switch to biosimilars. Overall, Norway requests that biosimilars are 40% cheaper than the reference product. Biosimilar uptake also gained momentum due to tendering at the hospital-level. Once executives saw the price tag for branded drugs, they jumped on board the biosimilar train.

Evidently, the biosimilars to Remicade are much cheaper, and although the pricing varied mildly, the MNF per-pack costs for Remsima and Inflectra are over €100 less than Remicade. In fact, the price of the reference product rose throughout the years, only dropping recently along with the current price drops of Remsima and Inflectra. Thus, Norway is a loyal implementor of IRP to win the best pricing from pharma.



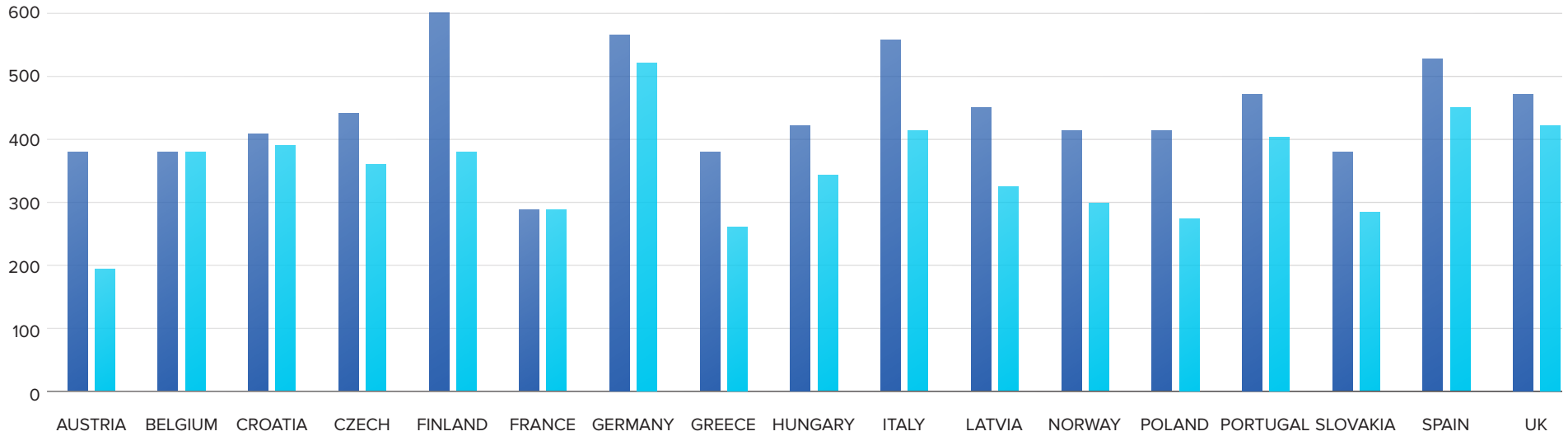
Observations of what is to come

Since Remicade was first to see the most biosimilars, infliximab is a well-established biosimilar to observe, as prices have become distinguished and trends are easily observed. Biosimilar approval in Europe picked up rapidly in 2017; therefore, countries within the EU and their neighbors are in the midst of establishing pricing through negotiations, IRP, and ERP.

Of notice is the approval of Sandoz's Zessly, the most recent infliximab biosimilar to be greenlighted by EMA. On May 18, 2018, EMA authorized Zessly, so pricing should soon be published for at least Germany and the UK, as these countries tend to allow commercialization of a drug soon after EMA approval.

This year alone, biosimilars to Remicade have already dominated 60% of the market share in Germany, 53% in France, and 65% in Italy, and across Europe, most countries have seen individual savings in the millions with the uptake of additional biosimilar products.

MNF (EUR) Remedicade and Average Biosimilar Cost Per Pack Across Europe



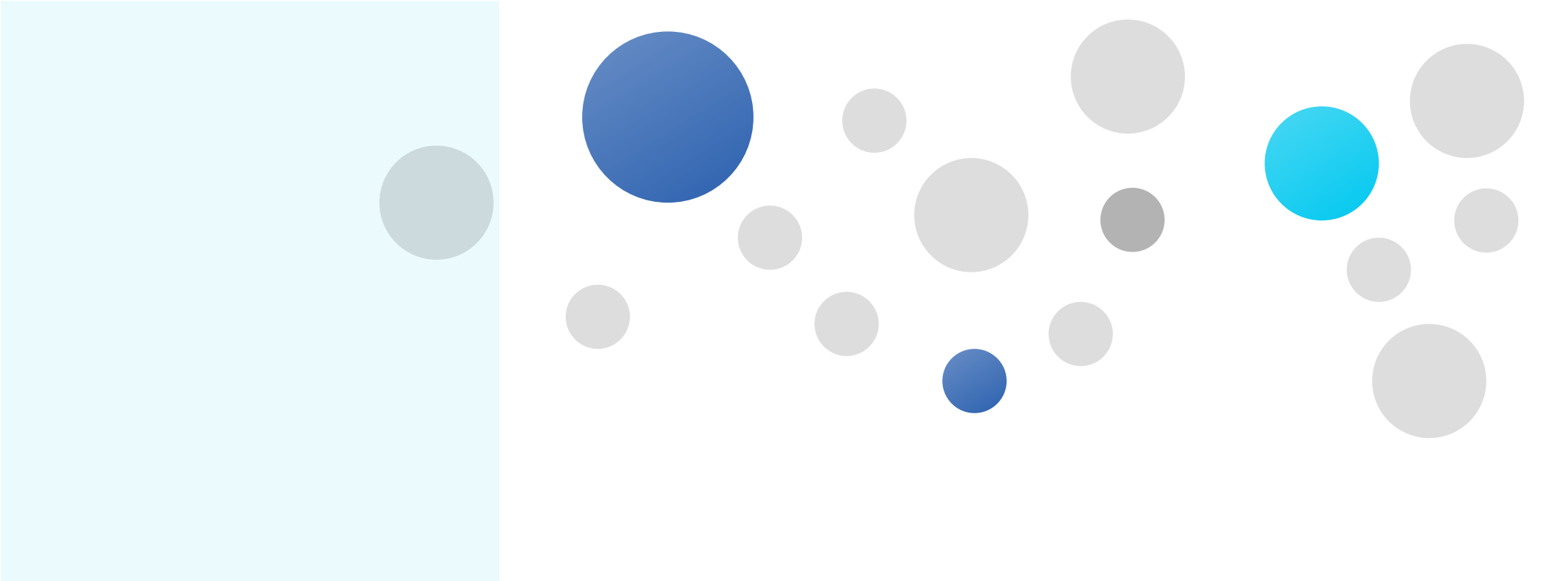
■ Reference Drug Price
 ■ Average Biosimilar Price

All data, including pricing and approval dates, is courteous of Pricentric and was last validated 1 July 2018.

In the above graph, it can be observed, quite evidently, that across Europe, biosimilars have helped save quite a bit of money.

Moreover, for example, filgrastim (based on Amgen’s Neupogen) has witnessed EMA approval of 7 biosimilars. A study of biosimilar uptake in Europe conducted by the Andalusian School of Public Health found that among a slew of European countries, the difference in price between the reference product, Amgen’s Neupogen (filgrastim), and its biosimilars was noticeably high; in some instances, such as in France and Slovenia, there were discounts upwards of 30% and 50+% respectively.

The EU5 have their own approaches to figuring a price for biosimilars, but overall, each country has found ways to save money by mandating some sort of discount, either through IRP or ERP. Germany and France have been fruitful breeding grounds for biosimilar uptake, and more recently, Italy’s HTA authority AIFA has asserted its fealty towards biosimilars. Norway, although not a member of the EU, exists within the EEA and has been a vocal supporter of biosimilars, ensuring discounts and cheaper medicines to its citizens.



AUTHOR BIO

Sean Skulski is a Health Technology Research Associate at Alliance Life Sciences Consulting Group. Focused primarily on Europe, he tracks HTA approvals along with policy and regulatory changes to manage ALSCG's Pricentric newsfeed. He is interested in relaying accurate and up-to-date policy and regulatory information, as well as market trends, to clients to ensure the optimal launch of a new drug.

Conclusion

EU Member States have their own approaches to figuring a price for biosimilars, but overall, each country has found ways to save money by ascertaining some sort of discount, either through IRP or ERP or HTA. Germany and France have been fruitful breeding grounds for biosimilar uptake, and more recently, Italy's HTA authority AIFA has asserted its fealty towards biosimilars. Norway, although not a member of the EU, exists within the EEA and has been a vocal supporter of biosimilars, ensuring discounts and cheaper medicines to its citizens. Manufacturers of biosimilars should not only heed these observances to ensure an optimal launch but should also be aware of pricing expectations held by each country.

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