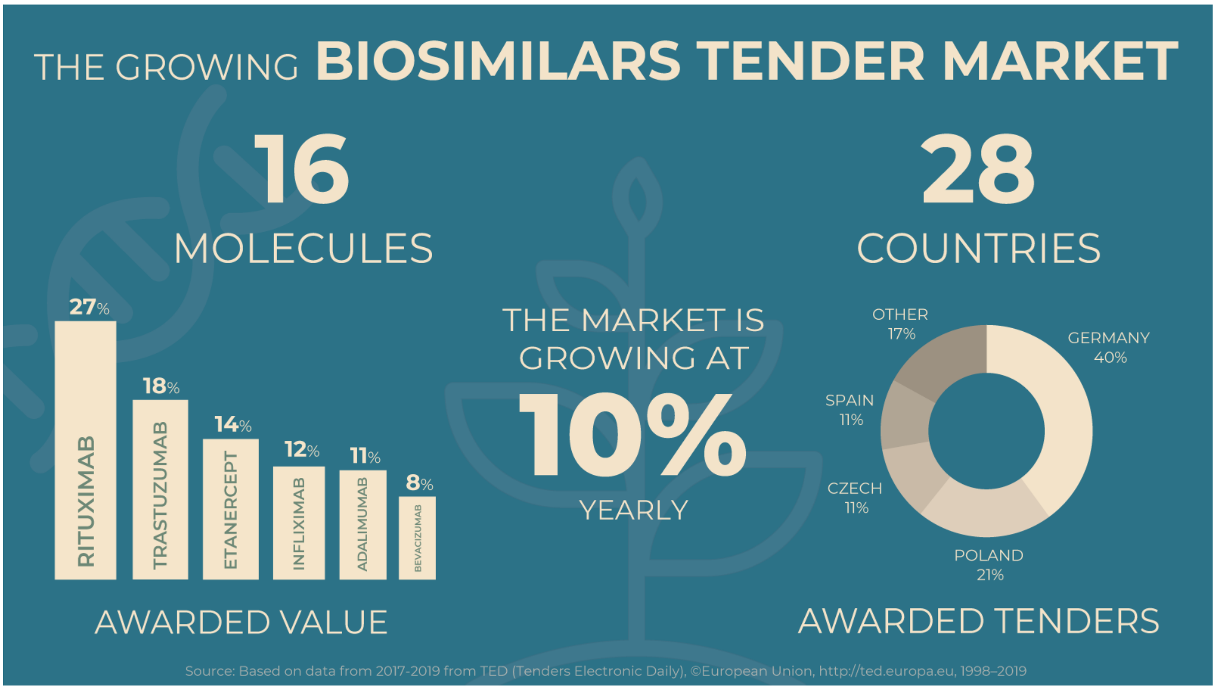


Insights & Trends regarding Tendering of Biosimilars in Europe

Oct 2019

The topic of Biosimilars has gained a lot of attention and increased importance during the past few years. With some of the world's largest biologic medicines being at the brink of losing patent protection it can be assumed that the biosimilars market will continue to grow over the coming years despite downward price pressure.

Whilst there are many reports out there on Biosimilars, only very little information seems to be available on Tendering of Biosimilars. Since the main procurement approach to purchasing Biosimilars in Europe is and will continue to be tendering, we thought it could be interesting to bring both topics together into one report.

Tendering excellence, coupled with a solid understanding of the Biosimilars market, will most definitely be a key capability for almost any pharmaceutical company and a prerequisite for success.

As shown in Fig.1, Tender activity on Biosimilars in Europe, measured by numbers of awarded tenders, has been and will most probably continue to grow steadily, in par with the overall pharmaceutical market.

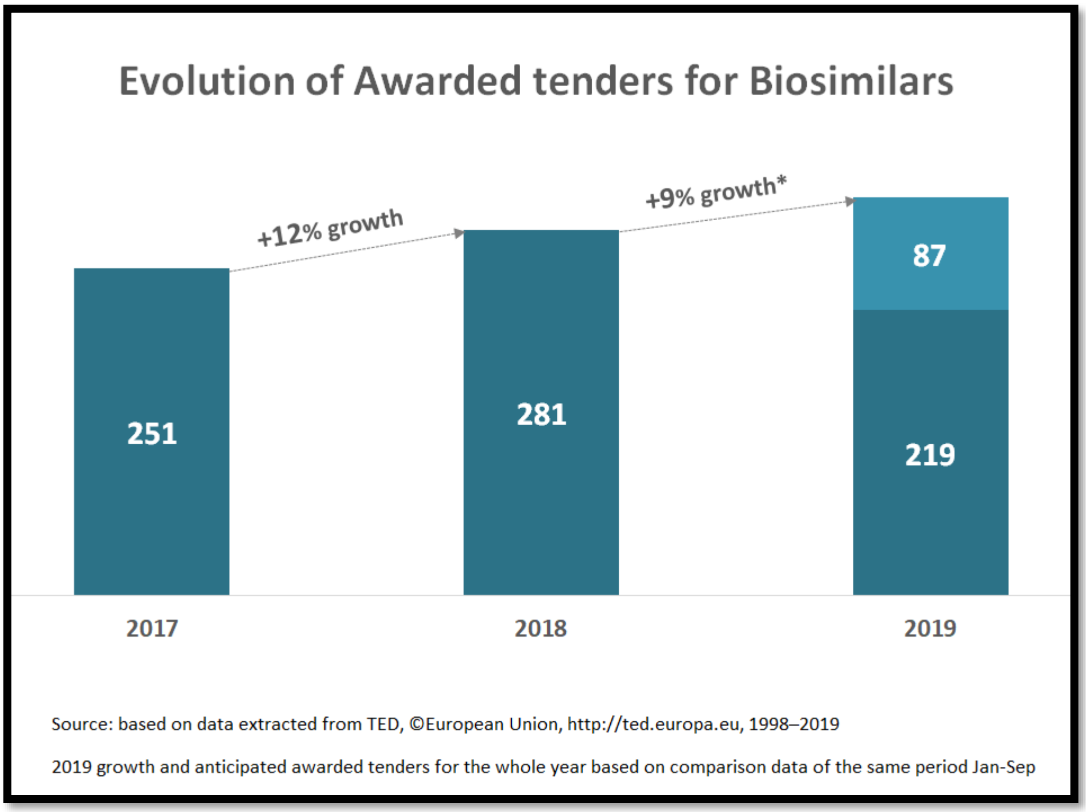


Fig. 1. Evolution of awarded tenders for Biosimilars in the EU unveils a steady growing trend

We have examined TED data from 2017-2019 for all countries of the European Union and 16 biologics that either already have a Biosimilar approved in the EU or where a Biosimilar will be approved soon (see Table 1). From our analysis and experience, we see that data-quality in TED has improved significantly over the last years, however, there can still be deviations in specific countries or on specific molecules as well as slight variations due to the different handling of tenders and data in the individual countries.

adalimumab	epoetin zeta	infliximab	rituximab
bevacizumab	etanercept	insulin glargine	somatropin
enoxaparin sodium	filgrastim	insulin lispro	teriparatide
epoetin alfa	follitropin alfa	pegfilgrastim	trastuzumab

Table 1. List of biologics that have a Biosimilar already approved in the EU or pending approval

As you can see in Fig.2, Germany and Poland were the main drivers in terms of tendering activity in the EU between 2017 and 2019. Over 50% of all tenders were published and awarded in these two countries only.

Italy is the biggest Biosimilars market in the EU in terms of net awarded value followed by other big healthcare markets like France, Spain, and the UK. Surprisingly for us, in this 3-year snapshot, Hungary also ranks quite high in terms of awarded tender value for Biosimilars. All the awarded tender value is coming from the National Health Insurance Fund of Hungary (Nemzeti Egészségbiztosítási Alapkezelő) and all of it from 2018, mainly driven by Adalimumab, Bevacizumab, and Etanercept. In 2019, no significant Biosimilars tenders have been awarded so far in Hungary, which could mean that the big volumes in the 2018 tenders will last for a while.

The other country that stands out is Germany. As one of the top five European healthcare markets, according to TED, it is not ranking high in terms of awarded tender values. The German tender market is managed by big Insurance companies such as AOK, IKK, Techniker-Krankenkasse, or Barmer, which work through tenders and a lot of Rebate-agreements (Rabatt-Verträge) with multiple companies. Some of the biggest Insurance companies have switched from one-winner to multiple-winner tenders for molecules that are prescribed often. This, on one hand, prevents patients with chronic diseases from having to change their medication too often. On the other hand, it also aims to improve supply reliability and prevention of out-of-stock situations for important medicines by splitting volumes across multiple suppliers.

Also, in German tenders in TED, a near zero-Euro placeholder can be found quite frequently under the awarded value. This is unique to German Tenders in TED, as more than 97% of all tenders in Europe with 0-1 Euro placeholder values are found in Germany. This means the awarded value is clearly understated due to these placeholder numbers. It can be assumed that the real net award values in Germany, despite high discounts negotiated by the insurance companies, are amongst the other top European healthcare markets Italy, Spain, France, and the UK.

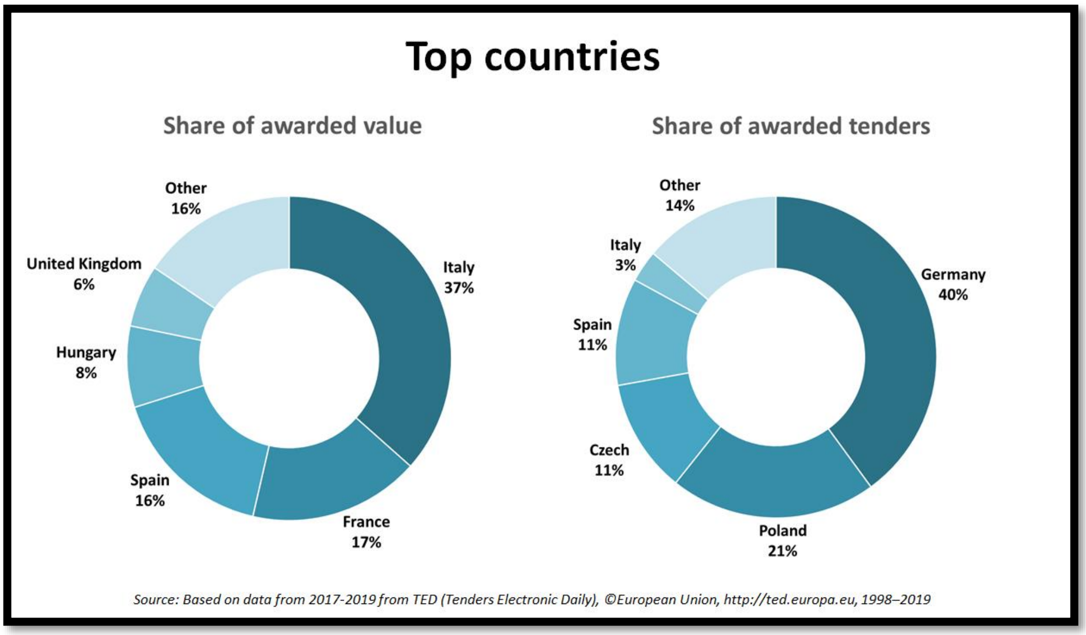


Fig. 2 Top countries for biosimilars tenders 2017-2019

Using Cube RM's Natural Language Processing (NLP) technology, we were able to identify the specific pharmaceutical substances mentioned in awarded tenders on TED over the last three years. Based on this analysis, it turns out that most of the biosimilar substances that have been approved in the EU are actively tendered in most markets. Unsurprisingly, topping the list are the Biosimilars of some of the globally largest pharmaceutical biological products of the last years such as Rituximab, Trastuzumab, Etanercept, Infliximab, Adalimumab, and Bevacizumab. These top 6 biologics molecules (out of 16) together have captured 90% of the value in Europe for Biosimilar/Biologics tenders over the last 3 years (see Fig.3).

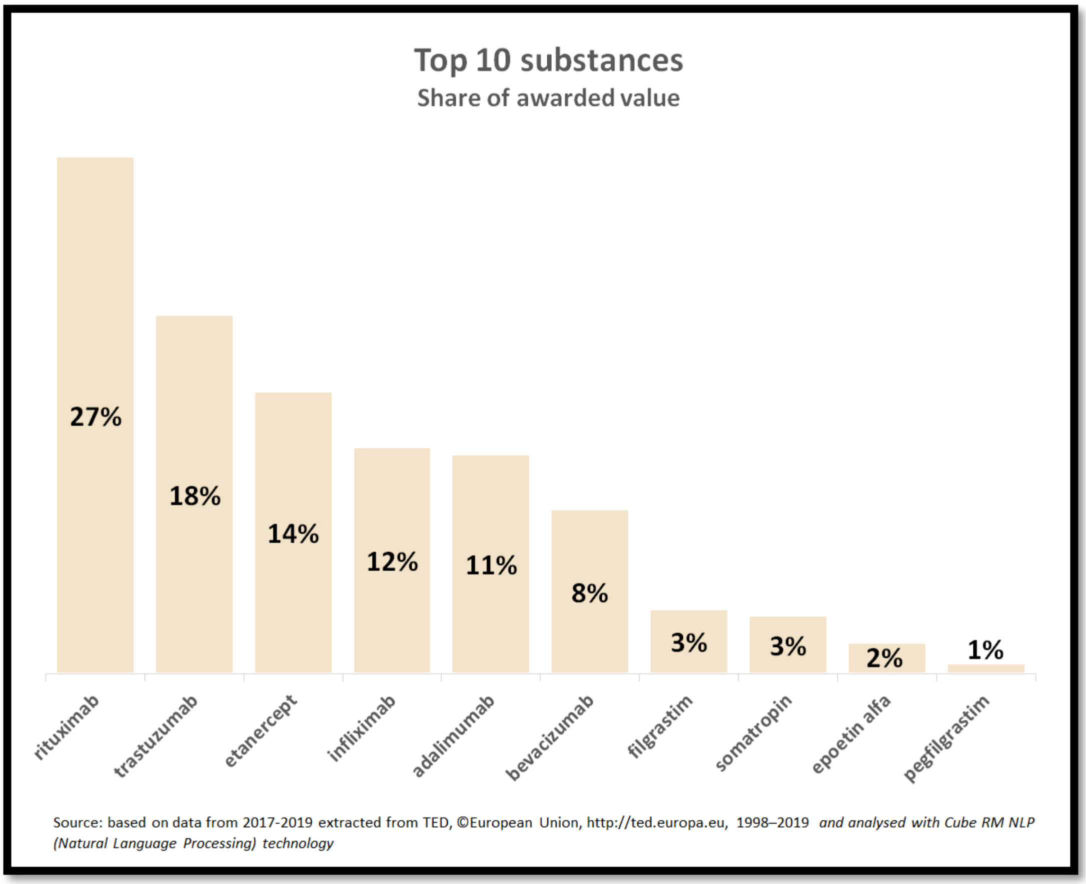
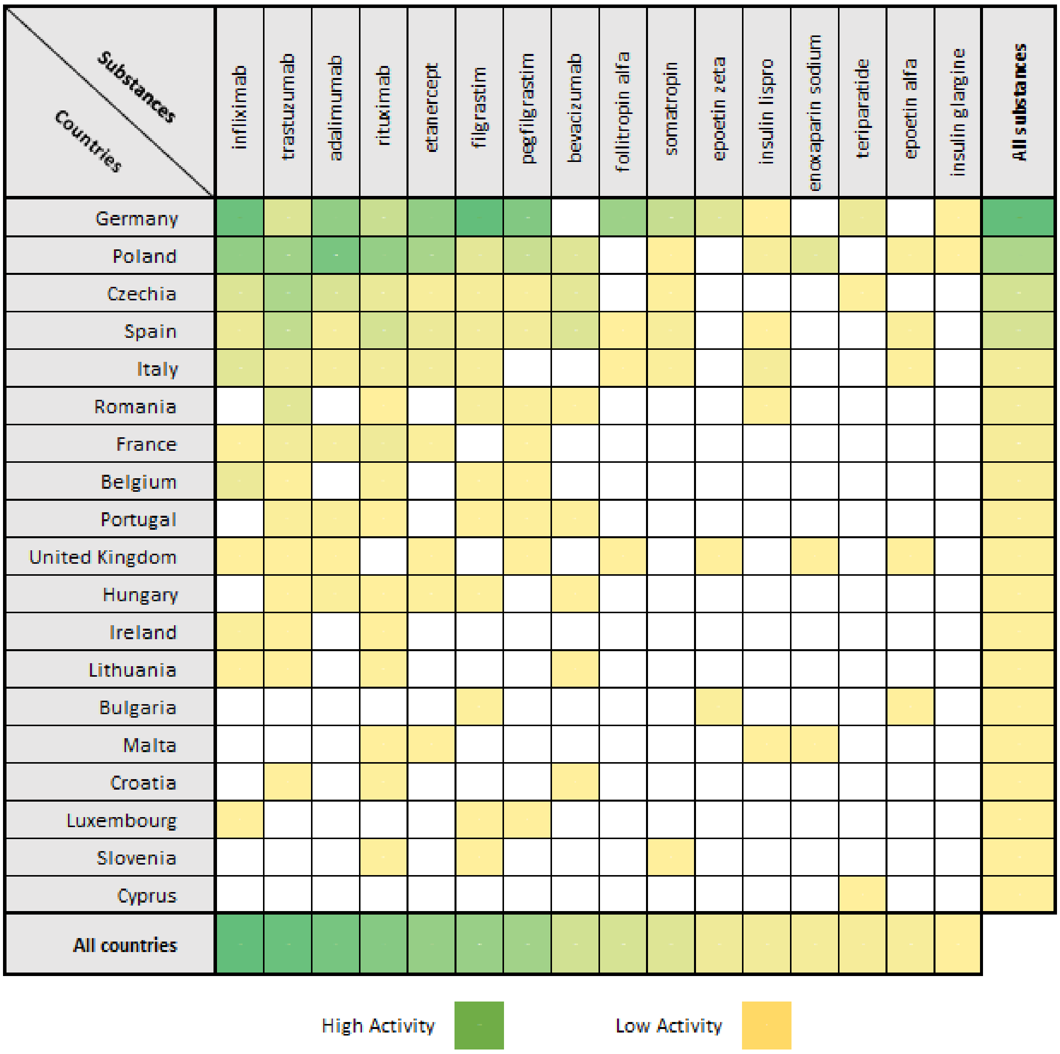


Fig. 3. Detailed analysis with NLP unveils the top 10 substances for tenders 2017-2019 in terms of awarded value

Table 2 shows the combined view in regard to tender activity per country and per Biosimilars molecule from 2017-2019. In terms of molecules, we see again the big 6 with Rituximab, Trastuzumab, Etanercept, Infliximab, Adalimumab, and Bevacizumab, but also a very high activity on Filgrastim and Pegfilgrastim. Filgrastim and Pegfilgrastim tenders are mainly present in Germany and Poland.

What seems to be missing from the table below are the big Nordics tenders such as Amgros in Denmark, LIS (Drug procurement Cooperation) in Norway, the regional tenders of Sweden as well as the four University hospital districts (Helsinki, Tampere, Turku, and Oulu) in Finland. The above table only shows tenders that have been officially awarded and closed in TED between 2017 and September 2019, but, of course, we know the above countries and institutions have been publishing Biosimilars tenders on a national and/or regional level during the last 3 years. All these countries would range at the lower end in terms of numbers of tenders, but as we will see later on, on the higher end in terms of Biosimilars adoption due to their very efficient way of managing big tenders and high effectiveness in implementing the outcomes.



Source: based on data from 2017-2019 extracted from TED, ©European Union, http://ted.europa.eu, 1998–2019 *and analysed with Cube RM NLP (Natural Language Processing) technology*

Table 2. Countries vs Substances activity for awarded biosimilars tenders from 2017-2019

Taking the above heat map but replacing the numbers of tenders with the awarded budget values in Euros, would show a very similar picture in terms of molecules, but a very different one in terms of countries. In terms of molecules, the big 6 molecules would remain at the top of the list also in regard to value. Regarding countries, the bigger European Healthcare markets mentioned in Fig.2 would top the list.

The distribution of numbers of biosimilars tenders over Europe is obviously affected by the different health-care systems and tender archetypes in each country. Some have few but bigger tenders, others have many but smaller tenders. Some tenders are price-only and winner-takes-all, others are MEAT-tenders (Most Economically Advantageous Tenders), where qualitative criteria are important as well. As briefly mentioned in the example of Germany, over the last years, some countries have moved away from winner-takes-all tenders to multiple winner tenders in order to split the supply across several companies with the objective to address the rising challenges of supply disruptions.

In Table 3 you can see some of EU's main tender markets, sorted geographically from north to south. What stands out is that all northern countries in this list manage their drug procurement very efficiently through a very limited number of tenders. There also seems to be a positive correlation between low numbers of tenders and the Biosimilars adoption in these markets. The middle-European countries are a 'mixed-bag' of tender archetypes, whereas it is safe to say that in almost all these countries the hospital channel plays an important role. As we move forward to the south of Europe, there seems to be a tendency towards more fragmented tender markets, with generally a medium to high number of tenders. The different market archetypes can require a different organisational set-up for pharma-companies, as well as a different set of capabilities and tools in order to be most successful in the respective countries.

Market	Geography	Tender Type	Number of Tenders	Biosimilar Penetration
Finland	North	National Tender	low	high
Norway	North	Regional Tender	low	high
Sweden	North	Regional Tender	low	high
Denmark	North	Regional Tender	low	high
United Kingdom	North	Regional Tender	low	high
Ireland	North	Hospital Tender	low	low
Netherlands	Middle	Hospital Tender	low	medium
Poland	Middle	Hospital Tender	high	high
Germany	Middle	Insurance Tender	high	medium
Belgium	Middle	Hospital Tender	medium	low
Czech Republik	Middle	Hospital Tender	high	medium
Austria	Middle	Hospital Tender	low	medium
France	Middle	Regional Tender	medium	medium
Spain	South	Hospital Tender	high	medium
Italy	South	Regional Tender	medium	medium
Portugal	South	Hospital Tender	medium	medium

Table 3. Tender archetypes per country

Of course, the tender archetype is not the only driver of biosimilars' adoption. There are further important factors such as the level of education and trust in Biosimilars from the hospitals, the physicians but also the patients. Also, the switching policies that regulate how and when patients can be switched from the original biologic to the biosimilar play an important factor. In addition, the pressure or ambition for healthcare cost savings will also impact how the regulations and policies around Biosimilars are created and implemented within a country.

Looking at the biggest single tender issuers in the EU (Table 4), in terms of awarded value between 2017-2019, it is not a surprise that all the top countries (see Fig.2) are present. For Italy as well as Spain, some of the major health-regions can be found on the list, as well as two of the main Hospitals in France in Marseille and Paris. The NHS as the main buyer from the United Kingdom is amongst the biggest buyers of Biosimilars as well as the already discussed National Health Insurance Fund of Hungary.

Tender issuer	Country
The Common Services Agency (more commonly known as NHS National Services Scotland)	United Kingdom
Consip S.p.A. a socio unico (Italian Public Procurement Central Authority)	Italy
InnovaPuglia S.p.A.	Italy
Società regionale per la sanità (So.Re.Sa. S.p.A.) - Regional Society for Health Campagnia	Italy
Stazione Unica Appaltante della Regione Marche (SUAM)	Italy
Centre hospitalier régional de Marseille (Central Regional Hospital of Marseille)	France
Publique Hôpitaux de Paris (Public Hospital of Paris)	France
Osakidetza (Healthcare system in the autonomous community of the Basque County)	Spain
Dirección General de Recursos Humanos y Económicos de la Consellería de Sanidad y Salud Pública	Spain
Nemzeti Egészségbiztosítási Alapkezelő (National Heath Insurance Fund of Hungary)	Hungary

Source: based on data from 2017-2019 extracted from TED, ©European Union, http://ted.europa.eu, 1998–2019

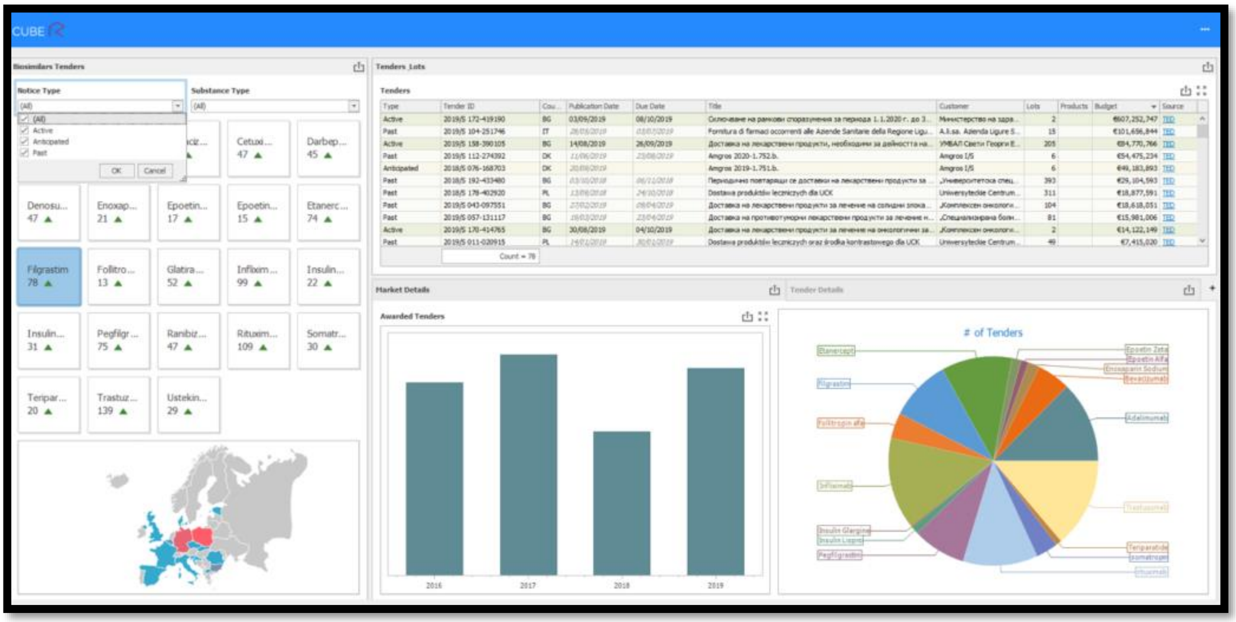
Table 4. Biggest Contracting authorities in the EU in terms of awarded value

As mentioned in our previous Cube RM insight, the Pharmaceutical Industry is one of the most active in the tendering market and Biosimilars is certainly a driver for this.

It's only natural that the growth of Biosimilars combined with the increasing use of tendering will lead pharma companies to try and optimize their tender-driven business in order to capitalize on this attractive market.

The first steps for a successful tender business involve visibility of all upcoming opportunities, as well as early planning. These two capabilities are the basis of moving from an emergency and ad-hoc type of tender management, into a more pro-active and strategic tender management.

*In our next post, we will present the **Cube RM European Biosimilars Tender Discovery calendar**: The first customizable, fully automated daily update on your upcoming tender opportunities for Biosimilars. Stay tuned. If you want to know more, please fill in the contact form below.*



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