ROVI Enoxaparin Biosimilar

An opportunity worldwide

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Introduction

- ROVI’s history has been linked to heparins since it was founded.
- Bemiparin, a second generation Low Molecular Weight Heparin (LMWH): ROVI’s first major R&D milestone.
  - ✓ Present in more than 55 countries.
  - ✓ Second market position in Spain with a market share of 28%.
- Development of a biosimilar of enoxaparin: logical evolution of our business.
  - ✓ Marketing authorisation requested in 2014 in Europe.
  - ✓ Validation and starting of the assessment process in Feb 2015.
  - ✓ Decentralised procedure (DCP) used with Germany as Reference State Member.
- DCP of ROVI's biosimilar of Enoxaparin completed with a positive outcome in Feb 2017.
- Starting of the National Phase in 26 countries in the EU (Lithuania not included), which is expected to be completed with the granting by the competent local authorities of the marketing authorization.
  - ✓ This National Phase could last from three to ten months.
- With the biosimilar of enoxaparin, ROVI:
  - ✓ Is aiming to become one of the European top players in a €1Bn* market where no biosimilars have been launched yet.
  - ✓ Could increase its footprint in emerging markets, with a potential market of €0.5Bn*.
  - ✓ Has a significant competitive advantage thanks to vertical integration.

*Source: Sanofi 2016

European Market: a clear opportunity

Enoxaparin: the market

- Enoxaparin was launched by Sanofi-Aventis and marketed under the trade names of Lovenox (USA) and Clexane (Europe).

  ✓ In Europe, Clexane is the leading anti-thrombotic and no biosimilars have been launched yet (although patent expired). The market achieved €1.0Bn* sales in 2016.

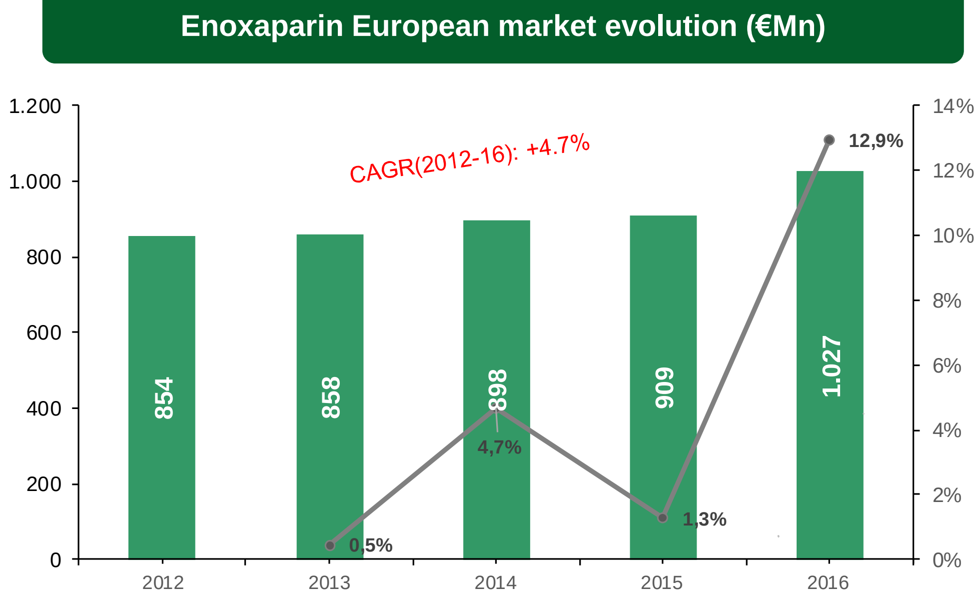
  ✓ In Spain, Clexane has a market share of 63% vs. 28% of Hibor.

  ✓ In Europe: Other Enoxaparin biosimilars (Techdow and Pharmathen) were approved. Limited number of additional competitors is expected.

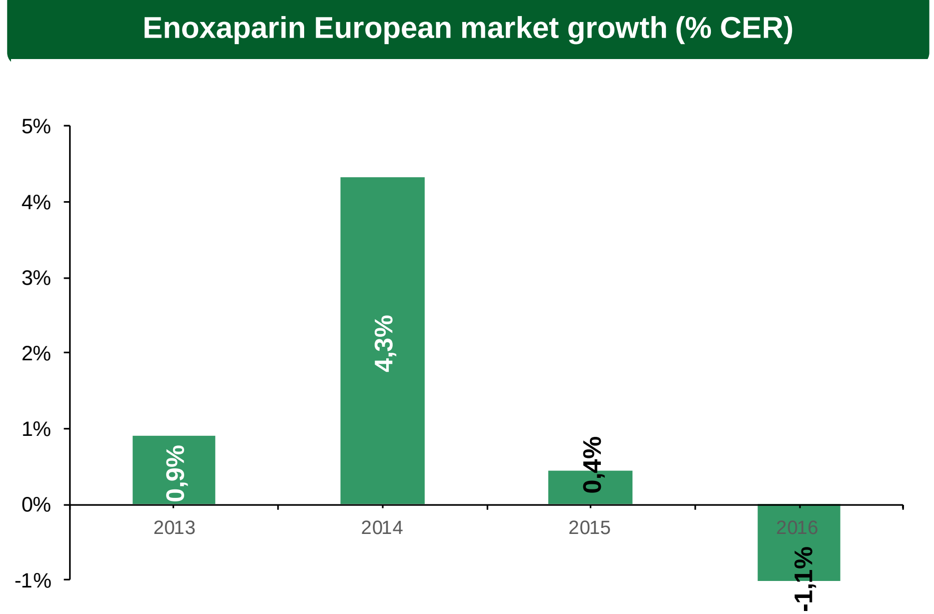
Market	Generics on the market
Europe	No biosimilars on the market Other biosimilars approved in Europe (Techdow and Pharmathen) ROVI's biosimilar started the National Phase after DCP completed with a positive outcome
USA	Momenta/Sandoz (Novartis) since 2010 Amphastar, Actavis (acquired by TEVA) since 2012 New launches in 2015: TEVA and Fresenius (Sanofi's license)

*Source: Sanofi annual results

Enoxaparin market in Europe



Note: Sanofi reported sale figures in Europe in 2016 compared to sale figures in Western Europe the previous years



CER: Constant Exchange Rates or constant currencies: eliminate the impact of exchange rate fluctuations when calculating sale annual variations.

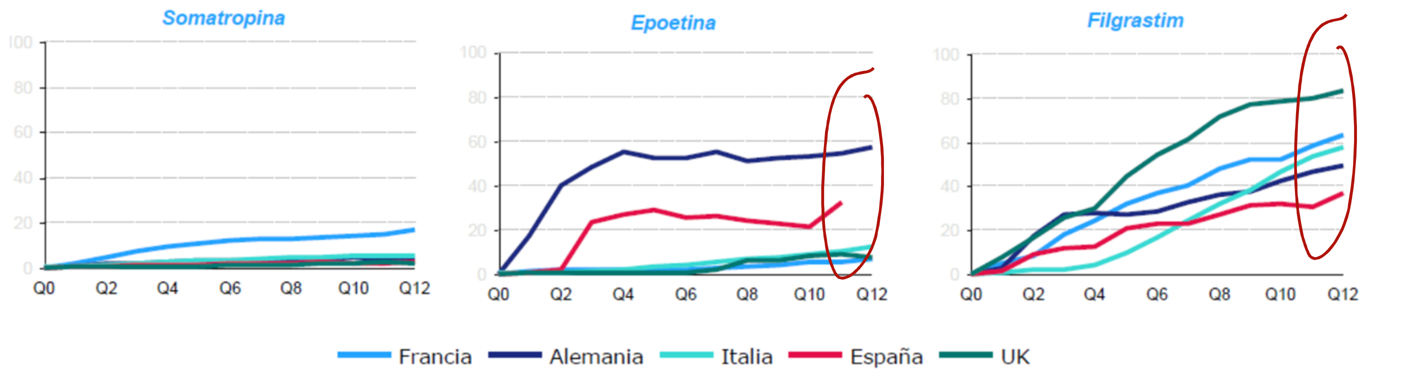
- Europe is the largest Enoxaparin market worldwide with **€1,027Mn** and **396Mn*** units (2015 figure).
- In 2016, Europe represented 63% (in value) of total Enoxaparin sales.
- The Enoxaparin European market increased +4.7% (CAGR 2012-2016) in terms of value. Eliminating the effect of exchange rate fluctuations, the European Enoxaparin market decreased by 1.1% in 2016.
- Top 5 largest markets in Europe (France, Germany, Italy, Spain and UK) represent 73%* in units.

Source: Sanofi annual results
*** QuintilesIMS, 2015**
Note: units (U) are related to pre-filled syringes.

Biosimilar market in Europe (1/2)

- Penetration of biosimilars varies depending on acute and chronic diseases, and the active principle.
- Epoetin (acute) reached a market share of 60% and 30% the first year, after the launch of the product, in Germany and Spain respectively.
- Penetration of Filgrastim (acute), the first year, was of 40% in Spain and 80% in UK.

Biosimilars' market share evolution per country (U)



	First biosimilar entrance	Nº compet.
	2007	*1*
	2006	*1*
	2007	*1*
	2007	*1*
	2007	*1*

	First biosimilar entrance	Nº compet.
	2009	*1*
	2007	*3*
	2009	*2*
	2009	*1*
	2009	*2*

	First biosimilar entrance	Nº compet.
	2009	*5*
	2008	*3*
	2009	*4*
	2009	*4*
	2008	*6*

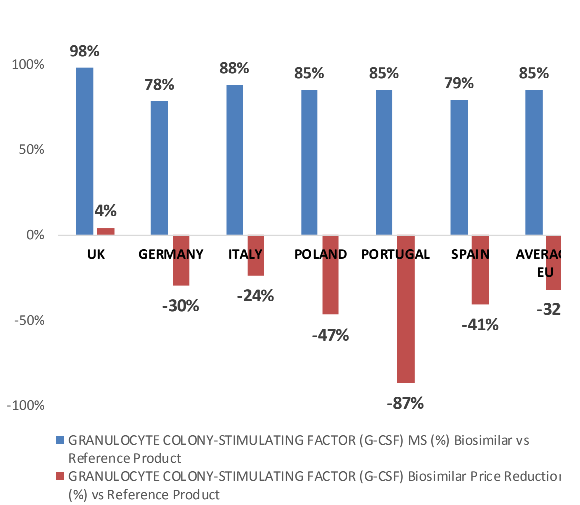
Source: QuintilesIMS
Note: units (U) are related to pre-filled siringes
Somatropin, Epoetin, Filgrastim and Infliximab are hospital biosimilars.

Biosimilar market in Europe (2/2)

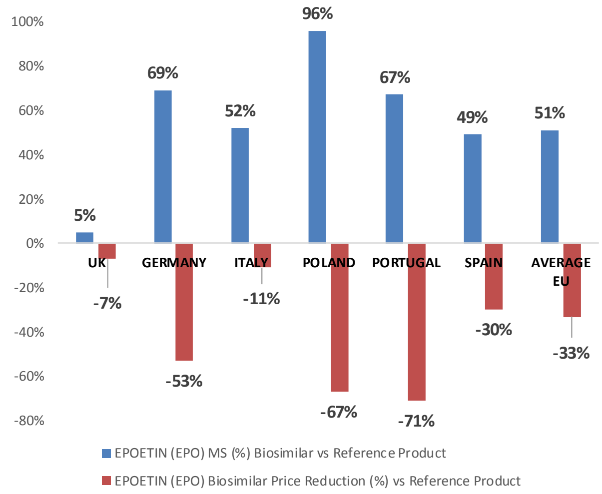
Acute Diseases

High potential market.

G-CSF (Filgrastim) (U)



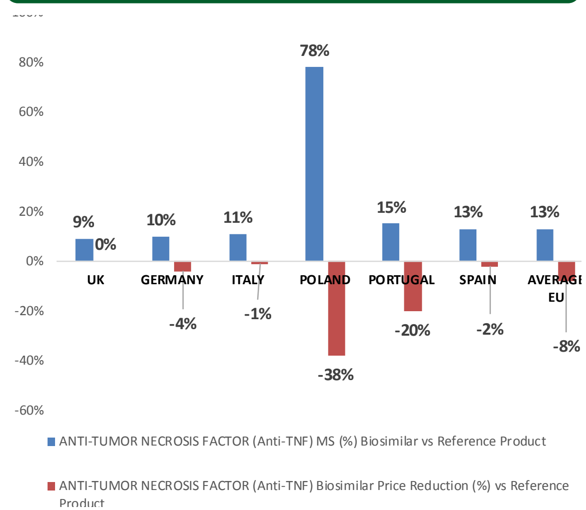
Epoetin (U)



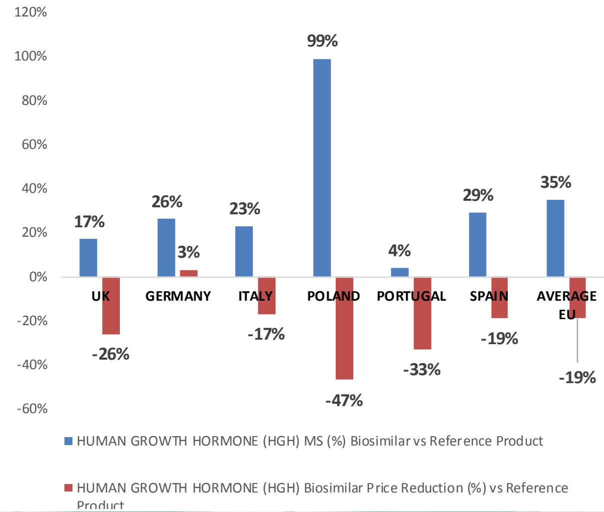
Chronic Diseases

Limited potential market as chronic diseases have higher resistance to changing medicines.

Anti TNF (Infliximab) (U)



HGH (Somatropin) (U)



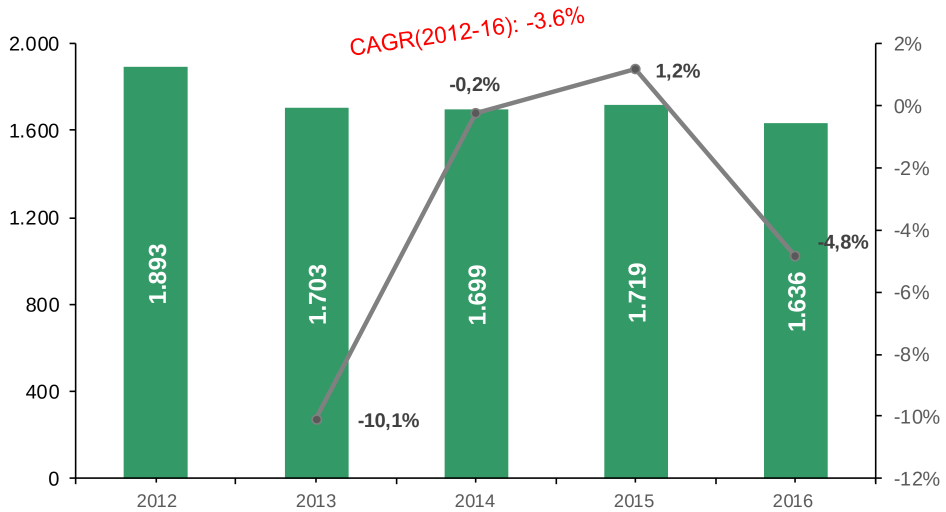
Source: QuintilesIMS, June 2016
Note: units (U) are related to pre-filled syringes
Somatropin, Epoetin, Filgrastim and Infliximab are hospital biosimilars.

Enoxaparin worldwide market

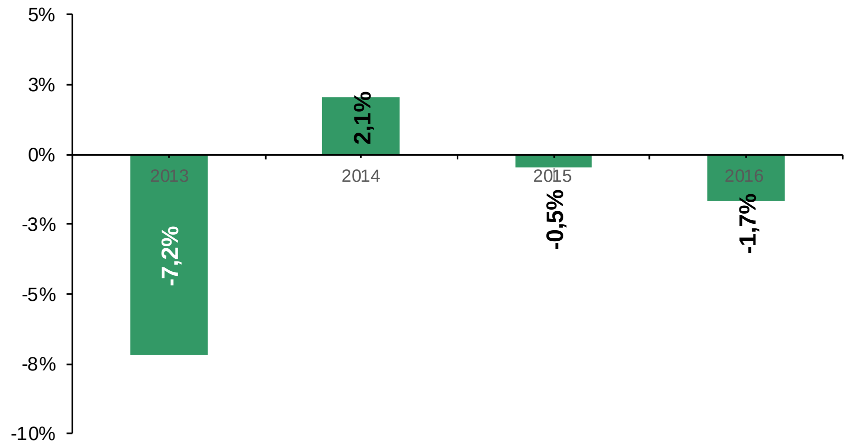
- Enoxaparin is the LMWH worldwide market leader.
- In 2016, the sales of Enoxaparin reached €1.6Bn, with 612*Mn units (2015 figure).
- The Enoxaparin worldwide market decreased -3.6% (CAGR 2012-2016) in terms of value. Eliminating the effect of exchange rate fluctuations, the Enoxaparin worldwide market decreased by 1.7% in 2016.
- Europe is the biggest market with a market share (in value) of 63%.

	2016	
	€ Mn	% over total sales
Europe	1.027	63%
USA	54	3%
Emerging markets	462	28%
Rest of the world	93	6%
Total worldwide sales	**1.636**	**100%**

Enoxaparin worldwide market evolution (€Mn)



Enoxaparin worldwide market growth (% CER)



CER: Constant Exchange Rates or constant currencies: eliminate the impact of exchange rate fluctuations when calculating sale annual variations.

Source: Sanofi annual results
*** QuintilesIMS, 2015**
Note: units (U) are related to pre-filled syringes.

ROVI in the Enoxaparin market

ROVI's competitive advantages

- ROVI has competitive advantages within the LMWHs market:
  - ✓ Heparin has been the main focus of the company since its foundation: deep knowledge of LMWH products.
  - ✓ Present in > 55 countries: excellent knowledge of the LMWH market.
  - ✓ Owner of the dossier and the know-how.
  - ✓ Important player with a market share of 28% in Spain.
  - ✓ Vertically integrated manufacturing process:

✓ IP/ registration	➡	Owner of the dossier
✓ API		
✓ Filling & Packaging		
✓ Distribution	➡	ROVI sales force/International & domestic partners

- ROVI aims to be a key player of the LMWH market in the long term.

Vertical integration

- ROVI will manufacture the active principle and will fill and package its biosimilar of Enoxaparin.

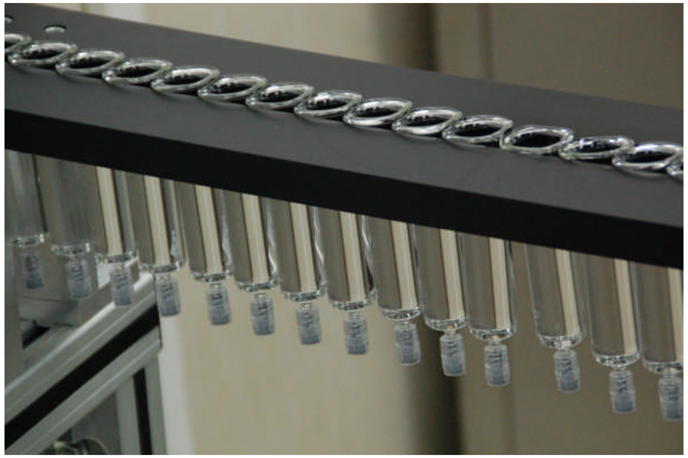
- San Sebastián de los Reyes plant approved by authorities from Europe.

- Julián Camarillo plant approved by authorities from Europe, USA, Korea, Brazil and Gulf countries.

- €17.2Mn invested in the last 3 years to increase capacity in the plants.

- Limited initial capacity subject to regulatory variations for the first 18/20 months.

- Potential additional investments in the future to increase capacity.



Commercial strategy

- ROVI obtained the approval for two registrations in Europe. Depending on the market evolution, ROVI may use one registration to grant licenses to third parties.

- ROVI expects to follow a double strategy in distributing the biosimilar of enoxaparin, based on:

✓ Direct presence in some countries

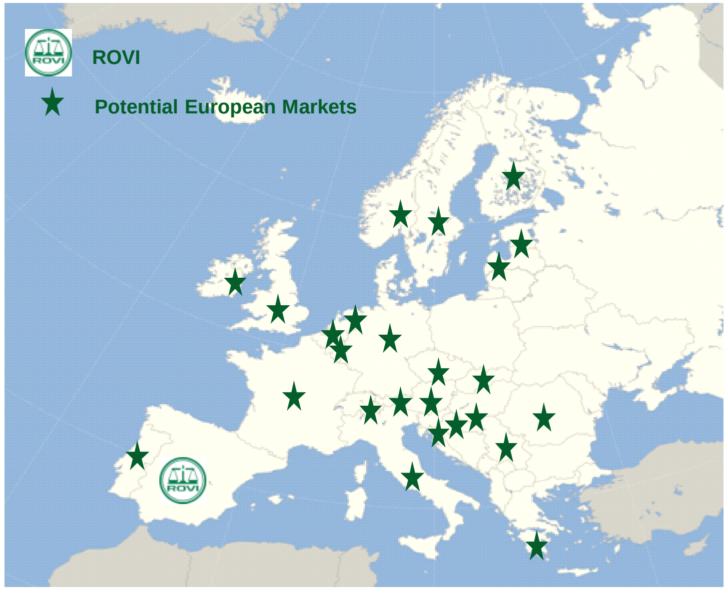
✓ ROVI will have its own sales force in some countries.

✓ Decision of countries where ROVI would have direct presence yet to be taken.

✓ Partnership with domestic and/or international players

✓ Distribution through domestic and/or international players.

✓ Potential agreements based on up-front fees, royalties and milestones.



- ROVI is in advanced negotiations with a partner in USA. Once the agreement is reached,

  ✓ It will specify dates for the resubmission of the dossier.

  ✓ It will use the European information for the resubmission.

- Distribution agreements (subject to marketing authorization to be granted by local authorities in each country) already signed to commercialize the product in 26 countries (outside EU and USA).

Decentralised procedure in Europe – National phase

- End of the Decentralised procedure with positive outcome.
- Germany acted as Reference Member State.
- ROVI obtained the approval for two registrations in Europe.
- Starting of the national phase of the registration process.
  - ✓ 26 countries of the European Union (Lithuania is not included).
  - ✓ National translation of:
    - Summary of Product Characteristics (SmPC)
    - Package Leaflet (PL)
    - Labelling
  - ✓ Presumably granting of national Marketing Authorisations.
- Pricing and reimbursement in each country*.
- Length of the process: 3 to 10 months.

*** Only for countries where prices are regulated. In some countries such as UK and Germany prices are free.**