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Successful commercialization of biosimilars in Europe-1 market authorization, 27 markets

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Biological therapeutics have been enourmously successful over the past decades, both from a clinical perspective-meeting sometimes desperate medical needs-and from a commercial perspective, with aggregated revenues of well over $ 160 billion in 2012. Prominent among these biologics are 4 monoclonal antibodies with a collective sale of €Mn 6, 5 (IMS MAT) Q3 2012 in Europe, all of which will shortly lose or have already lost patent protection: Inliximab, Etanercept, Adalimimab and Rituximab. On June 28 this year, EMA's CHMP published its recommendation for the granting of market authorization of Remsima (Celltrion) and Inflectra (Hospira), two medicinal products that contain identical biosimilars of Infliximab. Infliximab itself has been authorised in the EU since 1999, covering a wide range of autoimmune diseases. Remsima and Inflectra have been recommended for the same indications as its comparator product by the CHMP.

Since 2006, 12 biosimilars of 3 biological products have been approved by the EMA. Their market uptake throughout Europe, however, has been slow and generally disappointing, ranging from 10% (somatropin, competitive and device driven) to 37% (GCSF, market switching to long-acting).

This presentation will address the challenges faced regarding effective commercialization of biosimilars in Europe, with specific focus on Germany-one of the big 5 markets in the EU-as an example country.

Biography

Marguerite Mensonides-Harsema drives the portfolio development of medac's autoimmune diseases division, involving life cycle management of small molecules, in licensing of generics/biosimilars and co-development of NCEs. She holds M.Sc. degree in Pharmacy (University of Groningen, Netherlands, 1994) and in Clinical Research Management (University of Lahr/Freiburg, Germany, 2012) and received her Ph.D. degree in natural sciences from the University of Groningen in 2001. Her experience ranges from R&D at big pharma to small CRO to a mid-size, privately owned pharmaceutical company. She is the (co)author of several publications, patents and reports and has been a speaker at biosimilar events both in Europe and in the Middle East.

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