RHYTHM

Clinical biosimilar data should be accessible to all

Calls are growing for biosimilar manufacturers to publish their data in the public domain, particularly when developing versions of monoclonal antibodies that are associated with potential survival benefits. One of GaBI Online's readers totally agrees with this message. However, few others wonder why biosimilar producers must handle safety and efficacy data with transparency while the originator will have its data protected through temporary periods of exclusivity. Leaving aside economic reasons, are there any public health or access to information arguments that justify meaningful differences of treatment between both sets of data?

http://gabionline.net/Reports/Clinical-biosimilar-data-should-be-accessible-to-all

FDA Form 483: punishment or learning opportunity?

Based on one GaBI Online reader's comments, 2010 represents an all-time high for the number of FDA 483s issued by FDA. And there is no reason for 2011 not to be another record-breaking year. You are not required to respond to 483s, but you'd be foolish not to. You should respond as comprehensively, swiftly, and logically as possible. And make sure you respond to every single observation individually. Good luck!

http://gabionline.net/Guidelines/FDA-Form-483-punishment-or-learning-opportunity

Biosimilars: challenges getting into the US

The fact is, if the Americans are hell-bent on fooling themselves by trying to block competition from biosimilars, there really is nothing that the rest of the world can or will want to do. Let's see how long the originator companies are able to price their drugs atrociously, even in the US. Finally somebody has to pay for it and something will give way.

http://gabionline.net/Biosimilars/News/TNF-biosimilar-approved-in-China

Biosimilar regulatory issues

Regulatory issues may be the driving factor determining whether manufacturers go down the biobetter or biosimilar route. Both biosimilars and biobetters have lower early-stage R & D costs compared to originator drugs. Biobetters, however, also have an advantage over biosimilars in that they may be patentable – reducing competition. A table giving more information regarding regulatory issues related to biobetters and biosimilars in China, Europe, India and the US, has sparked much interest amongst readers. If you would like to receive a copy of the table, please contact *GaBI Journal*.

http://gabionline.net/Biosimilars/Research/Biosimilars-or-biobetters-what-does-the-future-hold

New Amgen '182' Enbrel patent

The news that Amgen had gained approval in the US for a new patent covering its blockbuster Enbrel (etanercept) has sparked debate. How will this affect Europe? How will this affect biosimilars manufacturers who were expecting to launch biosimilar competitors to Enbrel in the US as of October 2012? The patent covers the fusion protein that is etanercept and not the autopen delivery system, however, some believe the '182' substance patent can be invalidated in the US. Another question raised was why a new patent covering the claims of an existing one was approved? Maybe this is one for the US patent office? One thing is for sure: if Amgen manage to delay access to a cheaper biosimilar version until 22 November 2028 this can only be bad news for patients in the US.

http://gabionline.net/Biosimilars/News/New-Amgen-Enbrel-patent-could-block-biosimilars-until-2028

Interchangeability or substitution of biosimilars

The interchangeability or substitution of biosimilars is a subject that differs somewhat between Europe and the US. In the EU, the EMA does not have the authority to designate biosimilars as being interchangeable with the reference product.

In the US, however, the Biologics Price Competition and Innovation Act gives FDA the authority to designate a biosimilar as interchangeable with its reference product. This means that the biosimilar may be substituted for the originator product by the pharmacist without reference to the prescribing physician.

http://gabionline.net/Biosimilars/Research/Interchangeability-or-substitution-of-biosimilars

Is anyone developing biosimilars of darbepoetin alfa in Europe?

Dr Reddy's Laboratories launched Cresp, the first biosimilar darbepoetin alfa in the world, and the only darbepoetin alfa in India, in August 2010. Avesthagen, another Indian biosimilar manufacturer, also announced that it had started clinical trials for its biosimilar darbepoetin alfa, Avdesp, in March 2011. However, the question is, what is happening in Europe? The patent on Amgen's originator drug Aranesp expires in Europe in 2016. Maybe Sandoz will soon be in on the act? The German company has already been studying quality attributes of Aranesp, surely with a view to making a biosimilar version. If anyone has any information regarding clinical trials planned for Europe we would love to spread the word. Please contact *GaBI Journal*.

http://gabionline.net/Biosimilars/News/Dr-Reddy-s-launches-biosimilar-Aranesp
http://gabionline.net/Biosimilars/Research/Changes-in-the-quality-attributes-of-darbepoetin-alfa
http://gabionline.net/Biosimilars/Research/US-54-billion-worth-of-biosimilar-patents-expiring-before-2020

Biosimilar patents expiring before 2020

Interest in when patents on originator biological molecules will expire has been high among readers. By 2020, biological products with sales of around US$23 billion in the EU and US$29 billion in the US are expected to be exposed to biosimilar competition, so it is not surprising that the sector is generating so much interest. If you would like to see a table of biological patents expiring before 2020, visit the GaBI Online website: www.gabionline.net.

http://gabionline.net/Biosimilars/Research/US-54-billion-worth-of-biosimilar-patents-expiring-before-2020