PRAHEALTHSCIENCES

Welcome

Welcome to the eighth edition of Biosimilars Newsletter, a quarterly publication dedicated to keeping you updated on current biosimilars news, including the global regulatory landscape, biosimilars articles and reports, and company news as reported by company press releases.

Highlights at a Glance

- Hot Topic – Formal FDA Meetings: Integral to Successful Biosimilar Marketing Approval
- Regulatory - EMA Consultation to Revision of Biosimilar G-CSF Guideline and the FDA Releases Draft Guidance on the Non-proprietary Naming of Biological Products
- Articles of Interest – US Senators Press FDA Director on Unresolved Biosimilar Policy Issues and the Patent Dance Continues
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HOT TOPIC

Formal FDA Meetings: Integral to Successful Biosimilar Marketing Approval

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Sponsors considering marketing approval from the Food and Drug Administration (FDA) in the US often ask how they can secure approval with limited rounds of FDA review (ie, first-cycle approval). The most important and valuable resources available to sponsors to ensure marketing success and first-cycle approval are FDA meetings. Successful planning and implementation of these meetings are crucial for keeping drug development on track and ensuring timely marketing approval. Early engagement with the FDA, before an Investigational New Drug (IND) application has been submitted, and frequent communication throughout the development process is an excellent way to: get to know the review team, learn about the FDA needs, and any concerns they have about the development program and application, and get the FDA excited to help co-champion a product through to approval.

Meetings at all stages of development can be valuable in advancing a product development and an application forward; data suggests that formal meetings are beneficial throughout development. These meetings allow regulators and sponsors to discuss various details about potential areas of concern. During financial years (FYs) 2008 to 2012, applications that included a pre-IND meeting had shorter clinical development times (n=49, median = 6.4 years) than applications that did not hold a pre-IND meeting (n=83, median = 8.3 years) (Vu & Pariser, 2015). End-of-phase 2 (EOP2) meetings are

reported to have had a positive impact on first-cycle approval rates; of products undertaking EOP2 meetings (n=46, FY 2002 to 2004) 52% received first-cycle approval. Whilst only 29% products submitted during this period (n=21) received first-cycle approval when an EOP2 meeting was not conducted (Booz Allen Hamilton Inc., 2008). Over 80% (55/64) of all Prescription Drug User Fee Act V (PDUFA) Program (new chemical entity) applications in FYs 2013 to 2014 held pre-submission meetings (PSMs). Compared to those that did not have PSMs or those that had PSMs but no documented agreements, product applications with PSMs and documented agreements had higher first-cycle approval rates (93.3% [n=15], 58.2% [n=12], p = 0.03) and faster first-cycle approvals (by 1.53 months [p = 0.093]) (Eastern Research Group, Inc., 2015).

FDA Meetings for Biosimilar Products

Overview of the Biosimilar User Fee Act of 2012

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act (BsUFA) of 2012, authorizes the FDA to assess and collect fees for biosimilar biological products from October 2012 through to September 2017. The FDA uses these fees to expedite the review process for biosimilar products. Biosimilar products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at a reduced cost to the patient. The biosimilar Biological Product Development (BPD) program was created as a part of the BsUFA, to provide a mechanism and structure for the collection of development-phase user fees, to support the FDA's biosimilar review program activities. When a sponsor joins the BPD program, and pays the associated user fee for a specific product development program, that program is managed by the FDA according to the BsUFA performance goals and procedures (Food & Drug Administration, US, 2012). When a sponsor submits a biosimilar product application, the fee for the application is reduced by the cumulative amount of previously paid BPD fees for the product.

Biosimilar BPD Fees

BPD fees include the initial fee, the annual fee, and the reactivation fee. The fee is an annual per-product fee, not a per-meeting, or per review activity fee. A sponsor must pay an initial fee for a product to participate in the FDA's BPD program. Once a sponsor has paid the initial fee for a product, beginning in the next fiscal year, the FDA will assess an annual fee for the product until the sponsor submits a biosimilar product application for that product that is accepted for filing, or discontinues participation in the BPD program for that product. If a sponsor has discontinued participation in the BPD program for a product, and wants to yet again engage with the FDA on development of the product as a biosimilar product, the sponsor must pay a reactivation fee to resume participation in the BPD program. BPD fees are not assessed for a product after the biosimilar product application is filed. The initial BPD fee is due within 5 calendar days after the FDA grants the first BPD meeting for the product or upon submission of the IND, whichever occurs first. If the fee is not paid, the FDA will cancel the BPD meeting, and will not consider the IND for the product to have been received. A sponsor of an IND on financial hold is prohibited from continuing the clinical investigation. The fee amount is 10% of the PDUFA fee for an application requiring clinical data. Payment can be made by completing a Biosimilar User Fee Cover Sheet, available on the FDA's website, and pay by electronic check, wire transfer, check, money order, bank draft, or US postal money order.

To discontinue participation after IND submission, the sponsor may withdraw the IND for the product in accordance with 21 CFR §312.38. Again, a reactivation fee is required to resume participation in the BPD program for a product that has discontinued participation following the IND submission. This reactivation fee amount is twice the amount of the initial BPD fee for that fiscal year. To make payment, the sponsor should complete a Biosimilar User Fee Cover Sheet, as described above.

Biosimilar BPD Meetings

Under the BsUFA program, there are 5 types of formal meetings that can occur between sponsors and FDA staff to discuss biosimilar development programs. Each type is subject to different procedures, described in Guidance for Industry Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants (2013).

The 5 types of BPD meetings are:

1. Biosimilar Initial Advisory Meeting: limited to general discussion whether licensure under section 351(k) of the Public Health Service (PHS) Act may be feasible for the product, and, if so, general advice on the expected content of the development program. *Scheduled within 90 calendar days of receipt of a request.*

2. BPD Type 1 Meeting: similar to a standard Type A meeting; used to help progress a stalled development program, or address an important safety issue. If sponsors are considering submission of a request for this meeting, they should contact the relevant Center for Biologics Evaluation and Research (CBER) or Center for Drug Evaluation and Research (CDER) division to discuss the request suitability. *Scheduled within 30 calendar days of a request.*

3. BPD Type 2 Meeting: used to discuss a specific issue (eg, study design or endpoints) or questions that will provide targeted advice. Usually includes substantive review of summary data, but does not include review of full study reports. *Scheduled within 75 calendar days of receipt of a request.*

4. BPD Type 3 Meeting: covers in-depth data review and advice meeting. Includes substantive review of full study reports, advice regarding the similarity between the biosimilar and reference product, need for additional studies including design and analysis. *Scheduled within 120 calendar days of receipt of a request.*

5. BPD Type 4 Meeting: is for discussing the format and content of a biosimilar application or supplement to be submitted under section 351(k) of the PHS Act. *Scheduled within 60 calendar days of receipt of a request.*

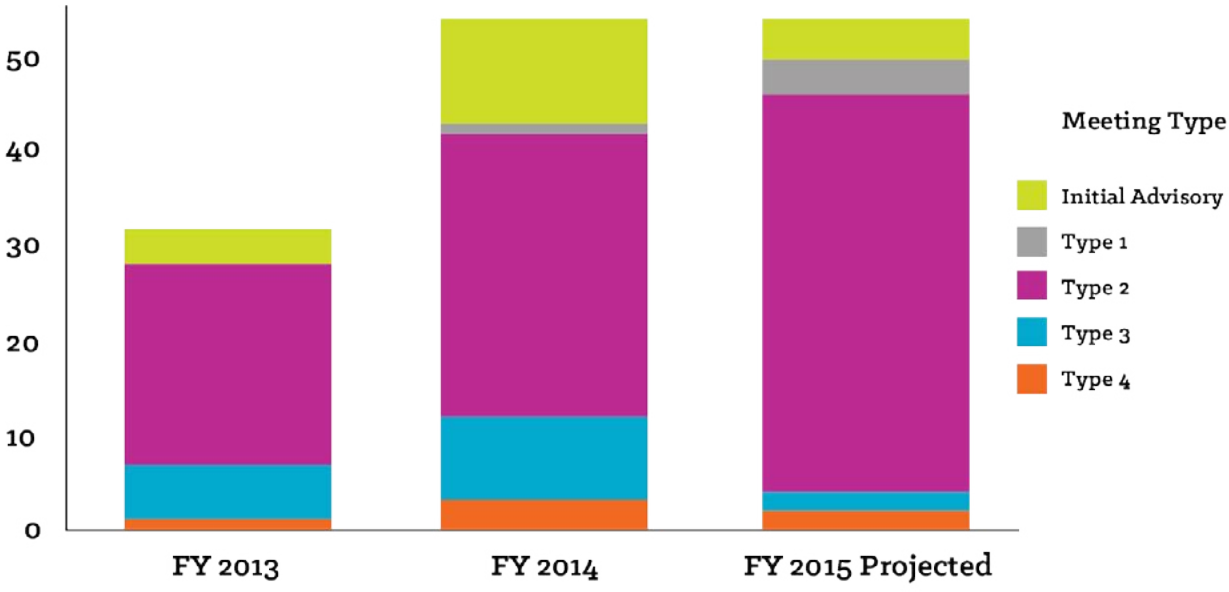
Implementation of the BPD meetings has been successful. As of 31 July 2015, 57 proposed biosimilar products to 16 different reference products were enrolled in the biosimilar BPD program. The number of sponsors in the BPD program is not reflective of the overall number of industry programs underway, as a sponsor may be in the early stages of interacting with the FDA, and not yet enrolled in the BPD program. Sponsors of an additional 27 proposed biosimilar products have had a Biosimilar Initial Advisory meeting with FDA, but have not joined the BPD program to pursue the development of these products.

The number of meeting requests and scheduled meetings has increased from FY 2013 to FY 2015, as can be seen in Figures 1 and 2, respectively (Woodcock, 2015).

Figure 1: Number of Scheduled Meetings by Fiscal Year

Total number of scheduled meetings continue to grow each Fiscal Year. FY 2015 projections calculated by doubling the total number of meetings scheduled through Q2 FY 2015 (March 31, 2015).

Figure 2: Number of Scheduled Meetings by Type and Fiscal Year



The types of scheduled meetings shift with each fiscal year, with BPD Type 1 and Type 2 meetings becoming a larger portion of scheduled meetings in FY 2015. FY 2015 projections calculated by doubling the number of meetings scheduled, by type, through the end of Q2 (March 31, 2015).

As biosimilar development programs mature, the type of interaction with the FDA is changing. There has been a shift in the types of meetings sponsors request and the FDA grants. As noted above, BsUFA established 5 meeting types specific to biosimilar development programs. Sponsors can choose the type of meeting or a combination of meetings to match development needs. Sponsors are increasingly requesting BPD Type 2 meetings to discuss specific aspects of their development programs. This approach facilitates biosimilar product development by providing a process for obtaining FDA advice throughout the development stage (Woodcock, 2015).

As the regulatory landscape of biosimilars continues to evolve, it is expected that the interactions with the FDA will evolve and change as well, providing the sponsor with more unique opportunities to interact with the FDA to ensure timely marketing approval.

In Conclusion

With rare exception, the benefits of an FDA meeting far outweigh the time, effort, resource, and costs. It is expected that the biological BDP meetings will greatly facilitate sponsors in their development program. Since the implementation of the BDP meetings, the first biosimilar, Zarxio®, was approved by the FDA in March 2015. To ensure meeting success, sponsors should clearly understand the issue, and then take steps to resolve that issue. The FDA may suggest ways to resolve the issue; the sponsor may follow their suggestion or can discuss an alternative to resolving the issue. Either way, following up with the FDA to ensure alignment on the issue will greatly increase chances of success. According to a 2010 report, 71% of applications with key issues identified during the pre-submission phase of development had not resolved the identified issues by the first NDA/BLA action date (Booz Allen Hamilton Inc., 2008). Compliance with the FDA requests is critical to ensuring timely development and marketing approval.

While the sponsor benefits greatly from meetings, the FDA also benefits from productive meetings. The FDA review teams that provided feedback on the different types of meetings stated that the FDA gains a better understanding of the sponsor's data being submitted, and is able to develop shared expectations with the sponsor and review team. The FDA also reported that these discussions enhance communication, predictability, and transparency, and permits better internal planning (Eastern Research Group, Inc., 2015).

For more information about BsUFA, please refer to the FDA's website at **http://www.fda.gov/bsufa**. The website includes links to the legislation, performance goals, and procedures, Federal Register notice of Biosimilar User Fee Rates for FY 2013, BsUFA contact information, and the link to the Biosimilar User Fee Cover Sheet.

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Regulatory Framework Updates

Europe

EMA Opens Consultation on Revision of Biosimilar G-CSF Buideline

The European Medicines Agency (EMA) has released a draft concept paper to discuss its planned revision of its specific guideline for biosimilars containing recombinant granulocyte colony-stimulating factor (G-CSF).

The biosimilar G-CSF guideline was one of the first specific biosimilarity guidelines, and came into effect on 22 February 2006, and includes recommendations for the development of biosimilar filgrastim and lenograstim. Pegylated rhG-CSF is not specifically addressed.

The EMA has proposed that the following aspects will need to be discussed and covered as appropriate by the revised guideline:

1. Considerations whether specific aspects with regard to the development of biosimilar pegylated.

2. rhG-CSF needs to be included in the guideline.

3. The focus of the non-clinical comparability exercise is on in vitro studies. It is suggested to adapt the guideline on biosimilar rhG-CSF containing products along these lines of thinking.

4. The current guideline puts much emphasis on confirmatory clinical trials to compare efficacy and safety of the biosimilar and reference rhG-CSF. However, the revised "overarching" guideline on similar biological medicinal products (CHMP/437/04 Rev. 1) states the possibility that, in specific circumstances, a confirmatory clinical trial may not be necessary.

The end of the consultation period is 31 October 2015.

Document released: 23 July 0215
http://www.ema.europa.eu

United States

FDA Releases Draft Guidance on the Non-proprietary Naming of Biological Products

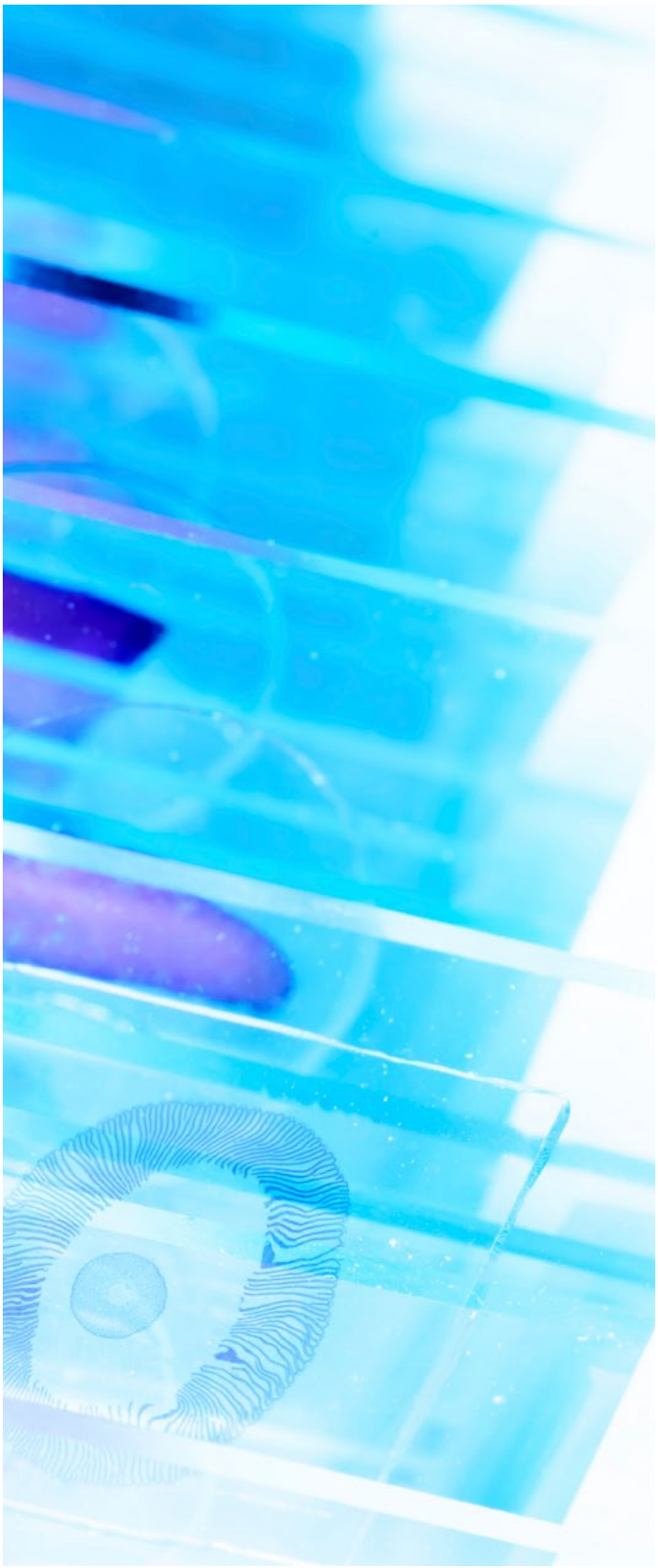
The FDA issued draft guidance on the non-proprietary naming of biological products but not everyone is happy with the proposals made by the agency.

The FDA is proposing that all biologicals and biosimilars have non-proprietary names and that a 4-letter suffix be added to the names to distinguish them from each other. Biosimilars makers, however, would prefer to use the same non-proprietary names as the brand-name biologicals without any suffix, while originator manufacturers would prefer completely different names.

Document released: 27 August 2015
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

Rest of World

None reported.



Biosimilars Applications Approved & Under Review

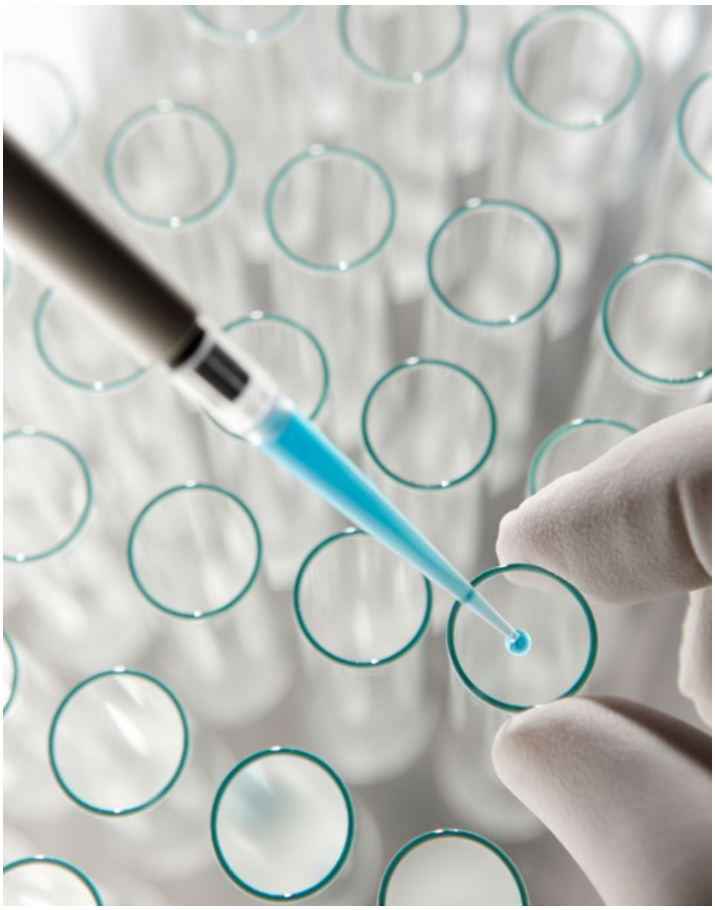
Europe

Applications For New Human Medicines Under Evaluation By The Committee For Medicinal Products For Human Use

According to EMA's list of applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use (CHMP) posted on 8 September 2015, the agency is reviewing 5 biosimilar applications.

Common Name	Therapeutic Area	Number of Applications	Originator Product	Originator Company
Enoxaparin sodium	Antithrombotic (blood-clot prevention)	2	Lovenox	Sanofi-Aventis
Etanercept	Immunosuppressant	1	Enbrel	Amgen
Human insulin	Diabetes	1	Insuman/Insulin Human Winthrop	Sanofi-Aventis
Infliximab	Immunosuppressant	1	Remicade	Johnson & Johnson

Link to applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use September 2015: 08 September 2015
http://www.ema.europa.eu



United States

None reported.

Rest of World

Australian Approval for Infliximab Biosimilar

Hospira have gained approval from Australia's drug regulator, the Therapeutic Goods Administration (TGA), for the infliximab biosimilar Inflectra.

Inflectra has been approved by the TGA for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, refractory fistulising Crohn's disease, adult and pediatric ulcerative colitis, and plaque psoriasis.

Australian Register of Therapeutic Goods:
https://www.tga.gov.au

Articles & Reports of Interest

US Senators Press FDA Director on Unresolved Biosimilar Policy Issues

During a hearing on biosimilar implementation before the Senate Subcommittee on Primary Health and Retirement Security's, the FDA Director, Dr Janet Woodcock, was asked why industry patients and physicians were still awaiting guidance on the following:

- transparent labeling for biosimilars;
- distinct names for biosimilars and biological reference products;
- rules of substitution for biosimilars deemed interchangeable with their reference biologic.

Dr Woodcock did not provide a specific timeframe for final FDA guidance on these issues, but acknowledged that it was forthcoming. She also noted that the FDA encourages feedback on its recent biosimilar naming guidance.

Senators pointed out that the FDA lags behind Europe in formulating such policies, to which Dr Woodcock responded that the US had been 6 years behind Europe in establishing a regulatory approval pathway for biosimilars.

Senate committee members stressed to Dr Woodcock one point in particular: A strong market for biosimilars requires physician and patient confidence in the products. As senators' questioning indicated, fostering confidence will require educating patients and clinicians about biological and biosimilar medications. It will also require clear, comprehensive, and timely FDA guidance on how these medications will be regulated.

Biosimilar Implementation: A Progress Report from FDA Subcommittee hearing: 17 September 2015:
http://www.help.senate.gov

US House to CMS: Don't Treat Biosimilars like Generics

A group of House Leaders are taking issue with the way the Centers for Medicare & Medicaid Services (CMS) has laid out plans to reimburse for biosimilars, according to a letter, 30 members of Congress sent to CMS' acting administrator last week.

Currently the CMS would assign "all biosimilars of a single reference product one Healthcare Common Procedure Coding System (HCPCS) code based on the weighted average of their average sales". The letter goes onto state the "CMS treats biosimilars as if they are generic drugs. As a primary matter, it is important to recognize that traditional small-molecules pharmaceuticals and biologics are fundamentally different…" and as such, each biosimilar should have its own unique payment rate and unique HCPCS code.

Letter dated: 04 August 2015
http://www.biosimilarsforum.org

Clarification of Stance on Biological & Biosimilar Medicines

The Dutch Medicines Evaluation Board (MEB) has further clarified its position on biosimilars since its last update in March 2015.

Following discussions with other professionals and patient groups, the Dutch agency has re-emphasized its stand that biosimilars have no relevant differences to originator biologicals in terms of quality, safety, and efficacy. However, it noted that several points remain in need of clarification regarding the substitution of biologicals and biosimilars.

Switching between biological medicines is possible, but only with adequate clinical monitoring and sufficient patient information. The MEB is in discussion with a number of patient organizations about developing educational material for patients about biosimilars.

Professional organizations have advised the MEB that questions surrounding the implementation of adequate monitoring and traceability of biologicals (including biosimilars) need to be addressed.

Link to MEB site: 17 August 2015
http://english.cbg-meb.nl

New Quantia Report Reveals Physician Attitudes Toward Biosimilars

Quantia announced key findings from its report, "Reading the Signs: A Roadmap for Increasing Physician Engagement in the Biosimilars Market." The report examines healthcare professionals' awareness of biosimilar drugs, potential barriers to adoption, and opportunities to provide education that may drive prescribing decisions.

Key findings from the report include:

- 94% of physician respondents believe biosimilars will provide value to healthcare.
- Top value cited is "lower costs to patients/the health system" (35%), followed by "greater patient access to therapies" (30%) and "increased choice among prescribing options" (27%).
- Only 17% of prescribing specialists (those who see patients with conditions commonly treated with biologics) report they would be "very likely" to prescribe biosimilars to eligible patients.
- Main concerns include safety/efficacy, drug substitution regulations, and accurate evaluation of when to prescribe a biosimilar vs. branded therapy.
- Specialty societies were prescribing specialists' most trusted source of information about biosimilars (25%), followed by peers (19%), and key opinion leaders (18%)
- 80% of prescribing specialists say they would want to learn about biosimilars through expert-led digital content.

The survey concluded that "even specialists who currently prescribe the biologics for emerging biosimilars generally lack the awareness and education to confidently express strong support of biosimilars". This highlights the need for targeting, engaging, educating, supporting, and ultimately influencing physician behaviours about biosimilars.

Link to the white paper:
http://info.quantia-inc.com

Articles & Reports of Interest

Continued

WHO Issues Draft Proposal for its Biological Qualifier

The World Health Organization (WHO) first introduced the concept of a biological qualifier (BQ) for naming biologicals back in 2014. Now the body has issued a draft proposal covering the issue of how to name biologicals, including biosimilars.

The proposal suggests that the BQ would be used in conjunction with the International Non-proprietary Name (INN) and would consist of a random alphabetic code, made up of 4 random consonants. The BQ code will be issued by an automated online system once a request is made by a BQ applicant.

The WHO reiterates that the established procedure for the selection of INNs will remain unchanged. Therefore, the BQ system would merely add a layer of naming to biologicals that is not used for small-molecule chemical drugs.

Link to Biological Qualifier, An INN proposal: June 1025 http://www.who.int

Biosimilars Patent Litigation in the EU and the US: A Comparative Strategic Overview

Brian J Malkan:
GaBI Volume 4 / Year 2015 / Issue 3

This manuscript takes a look at patent litigation strategies in a more developed biosimilars market (the EU), and compares them to a developing biosimilars market (the US), where the litigation strategies are still unfolding. This manuscript is a first in a two-part series, which will later include patent litigation strategies in Canada and Japan, as well as updates in the EU and the US.

Link to paper
http://gabi-journal.net

The Patent Dance Continues...

Federal Circuit Lifts Injunction Against Sandoz

(02 September 2015)

Sandoz has successfully overcome conventional wisdom, the plain language of the Biologics Price Competition and Innovation Act (BPCIA) (or, at least those provisions regarding patent litigation) and Amgen, in obtaining approval for its filgrastim biosimilar product, Zarxio™ in Amgen vs. Sandoz. The only thing standing between this biosimilar biologic drug and the marketplace, was an injunction imposed by the Federal Circuit during the pendency of the parties' cross appeals from the District Court's decision, favoring Sandoz with regard to the patent litigation provisions and Amgen with regard to the timing of the 180-day marketing notice provisions of the Act.

Sandoz Launches Zarxio™ (filgrastim-sndz), the First Biosimilar in the US

(03 September, 2015)

Sandoz announced that Zarxio™ (filgrastim-sndz) is now available in the US.

http://www.sandoz.com

Amgen Asks Federal Circuit to Stop Sandoz Launch of Zarxio™ Biosimilar

(04 September 2015)

Amgen made a last-ditch effort to block competition for its chemotherapy product Neupogen, asking the Federal Circuit to stop Sandoz's launch of its Zarxio™ biosimilar.

Amgen has asked the court to review its July 21 ruling — specifically a 3-judge panel's determination that biosimilars makers aren't obligated to share information in their aBLAs with the reference product maker. The Federal Circuit has yet to act on that request, and Amgen wants Zarxio's (filgrastim-sndz) launch to wait until a call is made.

In its emergency motion, Amgen argued that the panel erred when it held that manufacturers of reference biologicals and the courts can't compel biosimilars makers to disclose relevant patent information, and seeks a review of the decision that the proper remedy for non-compliance is litigation.

Sandoz filed a response arguing that no further injunction is warranted, and any "emergency" is entirely of Amgen's own making.

Meanwhile, Sandoz is waiting for the court to act on its request for en banc review of the panel's decision requiring biosimilars makers to give 180 days' notice before an expected product launch.

Company News

(The following information comes directly from company websites)

EPIRUS and Polpharma Enter Into Collaboration to Advance Biosimilar Portfolio Targeting

Epirus and Polpharma announced the signing of a multi-product, multi-region profit-sharing collaboration for select Epirus biosimilars, including BOW015 (infliximab, reference biologic Remicade®), BOW050 (adalimumab, reference biologic Humira®) and BOW070 (tocilizumab, reference biologic Actemra®), representing $6 billion in innovator sales in the specified territories.

Epirus will lead the global product development and clinical programs, both parties will jointly fund clinical development and collaborate on regulatory filings in the specified territories. Epirus will also be responsible for process development, scale-up and manufacturing, with Polpharma Group overseeing commercialization across the territories

Company press release: 14 July 0215: http://ir.epirusbiopharma.com

Pfizer Completes Acquisition of Hospira

Pfizer has announced that it has completed its acquisition of Hospira.

Pfizer's Global Established Pharmaceutical (GEP) business now has a leadership position in the large and growing sterile injectables category, with a robust portfolio of both generic and branded products. In addition, GEP has significantly advanced its biosimilars business with a broadened portfolio of marketed products and pipeline assets, which will benefit from Pfizer's best-in-class capabilities in monoclonal antibody development and manufacturing.

Company press release: 03 September 2015: http://www.pfizer.com

AstraZeneca and Fujifilm Kyowa Kirin Biologics to Collaborate on Bevacizumab Biosimilar

Fujifilm Kyowa Kirin Biologics have announced that it had entered into an agreement with AstraZeneca to establish a joint venture for the development and commercialization of its candidate biosimilar, FKB238 a biosimilar version of Roche's Avastin® (bevacizumab).

The 2 companies have agreed to set up a 50:50 joint venture for the development of the bevacizumab biosimilar. Under the terms of the agreement, Fujifilm Kyowa Kirin Biologics will transfer the rights to FKB238 to the new joint venture and will receive a lump sum payment of $45 million in return. The new company, which is yet to be named, will be located in the UK and is expected to start operations before the end of 2015.

Company press release: 24 July 2015: http://kyowa-kirin.com

Formycon AG Receives Favourable Scientific Advice from US FDA for its Partnered Biosimilar Candidate FYB201

Formycon, has received a scientific advice letter from the FDA regarding the pre-clinical and clinical development program for FYB201, the first biosimilar product candidate to emerge from its development pipeline, following the receipt of similarly favourable scientific advice from the EMA in December 2014. Formycon are now in a position to carry forward with a clinical study design for a global phase 3 trial which will enable them to apply simultaneously for regulatory approval in both the US and EU.

Company press release: 22 July 2015: http://www.formycon.com

Merck and Samsung Bioepis Announce Approval of BRENZYS™ (Etanercept), a Biosimilar of Enbrel, in Korea

Merck and Samsung Bioepis have announced the approval of Brenzys™ (etanercept), a biosimilar of Enbrel, by the Ministry of Food and Drug Safety (MFDS) in Korea.

The approval of Brenzys™ in Korea represents the first product approval under Merck's collaboration with Samsung Bioepis. Merck plans to launch Brenzys in South Korea by the end of this year or early next year.

Company press release: 08 September 2015: http://www.mercknewsroom.com

Mabion Begins Pre-Registration Scientific Advice With The EMA

Mabion has taken the first step to the registration of biosimilar drug MabionCD20 with the EMA. Mabion is receiving scientific advice from the EMA regarding the MabionCD20 drug, a biosimilar of MabThera, used in the treatment of blood cancers and rheumatoid arthritis.

Mabion SA intends to register MabionCD20 on all global markets. In regard to regions such as Africa or Asia, Mabion SA is planning both the implementation of sales and the entire registration procedure in cooperation with leading local pharmaceutical companies.

Company press release: 08 September 2015: http://mabion.eu

Amgen And Allergan Announce Positive Top-line Results From Phase 3 Study of Biosimilar Candidate ABP 215

Amgen and Allergan have announced a phase 3 study of biosimilar candidate ABP 215 met its primary and secondary endpoints. The study evaluated the efficacy and safety of ABP 215 compared with Avastin® (bevacizumab) in adult patients with advanced non-squamous non-small cell lung cancer (NSCLC).

The primary endpoint, an assessment of objective response rates (ORR), was within the prespecified margin for ABP 215 compared to bevacizumab, showing clinical equivalence. Safety and immunogenicity of ABP 215 were comparable to bevacizumab. Secondary endpoint results were consistent with the primary finding and included risk difference of ORR, duration of response and progression-free survival (PFS).

Company press release: 23 September 2015 https://www.amgen.com

Samsung Bioepis Announces Positive Top-Line Results from a Phase 3 Study of SB5

Samsung Bioepis have announced that its pivotal phase 3 clinical study of SB5, an investigational biosimilar of Humira (adalimumab), met its primary endpoint, demonstrating equivalence to the originator medicine in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. The primary endpoint was the American College of Rheumatology 20% response criteria (ACR20), at week 24. At week 24, the ACR20 improvement from baseline was within the prespecified equivalence margin for SB5 compared to adalimumab.

Company press release: 06 July 2015: http://www.samsungbioepis.com

Next Edition

Look out for the next edition of the Biosimilars Newsletter due out in January 2016.

Previous Editions

Please use the below link to find previous editions of PRA Health Sciences' Biosimilars Newsletters.

http://prahs.com

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