

5th European Biosimilars Congress

June 27-29, 2016 Valencia, Spain

The emergence of orphan biosimilars

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There are \$33 billion worth of annual revenue for orphan biologics that have expired or are expiring in the next 10 years, yet no biosimilars for these products have surfaced or are in late stage development. With more clearly defined regulatory pathways for biosimilar approval recently, we address many critical questions facing originators and biosimilar makers:

- Will patient identification and clinical trial recruitment pose an insurmountable hurdle for orphan biosimilars?
- Will regulators entertain relaxing evidence requirements to enable biosimilar development?
- Are physician and patient services a highly proprietary and costly barrier to biosimilars?
- Are, or will there be, particular incentives for reimbursement of orphan biosimilars?
- Is there a market size threshold for biosimilars to achieve positive commercial returns?

To seek answers, we must appreciate the perspectives of four key stakeholders – regulators, payers, physicians and patients. Navigant's financial modeling shows that orphan biologics with more than \$250 million revenue will likely attract biosimilars from a profitability perspective. We are at the precipice of a new biosimilar era. Regulatory pathways have been paved; complex mAbs biosimilars like Remsima have been approved; a wave of patent expiries are sweeping across the product landscape; the first batch of biosimilars are establishing safety and credibility, providing comforting experience to physicians and patients. Investments made by major biologics companies and up starts alike will unmistakably accelerate and intensify the growth of biosimilar markets. In this context, while orphan disease presents a unique set of unknowns to biosimilar players such as the availability of clinical study subjects, KOL loyalty and payer activism, the law of pharmaceuticals will prevail in the end. Pricing strategy and payer effectiveness will be the most critical consideration in its commercial success, while a less strenuous clinical development program will make the path to market that much more favorable.

Biography

Triona holds a Ph.D from Kings College London and is a Senior Consultant in the Life Science Practice at Navigant Consulting with a strong interest in commercial strategy for both speciality and big pharma. She has over 4 years experience in life sciences, healthcare and consulting working in projects including stakeholder/payer mapping in an emerging market, market opportunity assessments, commercial opportunity assessment, pricing and product assessments, new product planning, market forecasting, commercial evaluation and brand planning. Triona previously worked with Alcimed, a boutique consulting firm specialising in innovative sectors: life sciences (food, biotech, health), energy, aerospace, ICT, chemicals, aerospace & defense. Additionally, Triona worked as a recruitment consultant with SRI Consulting, a specialist recruitment firm serving the Life Science, Consumer, Not for Profit, Climate Change and Academic sectors. Triona holds a Ph.D in Craniofacial Developmental Biology from Kings College London and a B.A.Sc in Biochemistry from Trinity College Dublin.

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