

For immediate release 24 April 2006

Western Biotech not threatened by Generic East – according to a new survey by Eden Biodesign

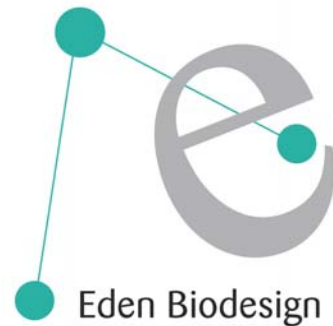
Overview

- Possible approvals of Biogenerics are viewed as an opportunity and not a threat by European biotechs
- Western biotechs are far more skeptical about the market potential of biosimilars than Asian counterparts
- USA lags behind Europe in facing up to reality of biosimilars

Following the first full market approval of a biosimilar within the last few days^[1] and imminence of their European market debut, a recent survey (of biotech companies worldwide) shows that remarkably, the majority of established Western biotech companies now view this as an opportunity, and do not feel threatened by emerging Asian competition.^[2] This represents a marked shift in opinion from previously published articles and surveys.^[3]

The survey, commissioned by Eden Biodesign, revealed divided opinions across the continents on how the approval of European and American regulatory pathways for biogeneric products will affect the \$60 billion biologics industry as a whole.

Within Europe, where the European Medicines Agency (EMA)^[4] has led the way in issuing guidelines to help manufacturers of biogenerics to gain regulatory approval, 83.8% of those surveyed thought that the opening up of the biosimilar market represented an opportunity. UK figures were very similar with 81.8% of the same opinion.

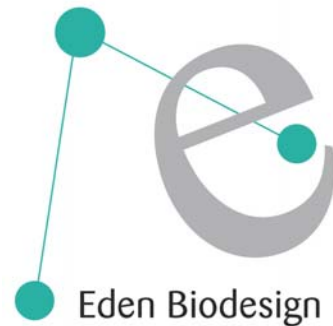


Unsurprisingly, 85.0% of biotech companies in Asia, which - excluding Japan - has a small market share and limited original drug development, viewed the possibilities of producing biogeneric drugs to compete with the established branded counterparts as an opportunity. This figure is comparable to the European figure; however, it would appear that elsewhere, striking differences between European and Asian attitudes remain. Only 37.8% of European biotechs (36.4% in the UK) felt that the approval of a regulatory pathway for biogenerics would 'open the floodgates' to biosimilar products compared with 75% of Asian biotechs. (Correspondingly 59.5% of European biotech's felt that it actually would not, compared with just 20% in Asia).

In America, which accounts for 59.6% of the global biotech market, the established biotech companies seem intent on delaying the US Food and Drug Administration (FDA) from introducing simplified regulatory pathways for biosimilars. Across the States attitudes remain less welcoming to increased competition from generic biopharmaceutical producers. Only 69.4% felt that the expiry of patents and the possibility of manufacturing biogenerics would be an opportunity, and twice as many felt it was a threat compared with Europe.^[5] 80.1% of US biotechs believe the FDA will take between three and five years to follow the EMEA and introduce guidelines, and early indications are that protracted legal battles may be involved.^[6] The global biogenerics market is not expected to mature until 2010.^[7]

Dr Derek Ellison of Eden Biodesign commented on the results: "*The biogenerics market is bound to be big business. Globally, the biologics field is worth \$60 billion, so it's very competitive.*^[8] *The results show businesses in the UK and Europe being really positive about generics. Across Europe, established companies have the practical and development expertise needed for the manufacture of biopharmaceuticals.*

"Generic biopharmaceuticals are very different from traditional generic pharmaceuticals. Unlike generic NCE (small molecule) drugs, the sheer complexity of biological molecules



and processes required to make them make it much harder to say with any certainty that a biogeneric product is actually a bioequivalent. Even very small changes to a protein can result in dramatic changes in the efficacy and effect of a drug.

“The manufacturing process is much more expensive, and with the EMEA rules only just introduced, and the FDA still to take action, there remains a lot of uncertainty in the field.. This could well have a knock on effect on the way generics are tested and approved. The safety concerns with new biogenerics are much greater than traditional generics. I think it could be very hard for inexperienced companies to make a real impact on the market.”

The survey shows a predictable division of opinion between the developers of new medicines and Contract Manufacturing Organisations (CMOs) which actually often manufacture generics. CMOs generally welcome the possibilities afforded by them, where an increasing number of companies marketing generic drugs will result in cheaper prices, greater availability of contracts and therefore increased demand for manufacturing expertise around the globe. The division is far less pronounced, however, than many would have predicted.

^[1] April 18, 2006 – Sandoz announced that the European Commission has granted marketing authorization for the company’s recombinant human growth hormone Omnitrope - approved under the biosimilar pathway of the European Commission, it will be the first biosimilar to be marketed within the European Union.

^[2] The survey asked over 20,000 developers and manufacturers of biopharmaceuticals world wide what the impact of biosimilars would be to their businesses

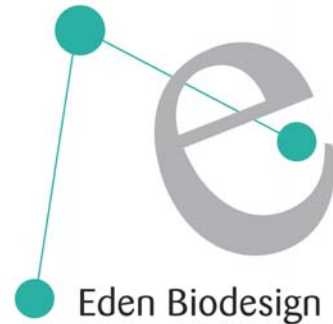
^[3] Visiongain's World Biotech Market Report 2005

^[4] Previously known as the European Medicines Evaluation Agency, but retaining the same acronym

^[5] In the US 19.6% of those surveyed felt that biosimilars posed a threat, compared with 10.8% in continental Europe

^[6] Sandoz Inc v Michael Leavitt, Secretary of Health and Human Services, 05-1810, US District Court of the District of Columbia

^[7] Datamonitor, 2006



^[8] Ernst & Young's Global Biotechnology Report 2006, recording a growth of European Biotech of more than 20% for the tenth consecutive year

Ends

For further details regarding the survey or Eden Biodesign and the National Biomanufacturing Centre contact: Charmaine Colvin or Alex Denny on 0870 240 5536 or e-mail:

charmaine@redheadpr.co.uk

alex@redheadpr.co.uk

Notes to editor

Eden Biodesign

Eden Biodesign is a successful international biopharmaceutical development and manufacturing services business that provides 'state of the art' services to biotech clients across Europe, the USA and Asia. Eden Biodesign operates the UK National Biomanufacturing Centre, recently opened in Liverpool.

Eden Biodesign promises all clients a committed service plus the strategic thinking to guide clients through process development, manufacturing, regulatory and technology transfer challenges.

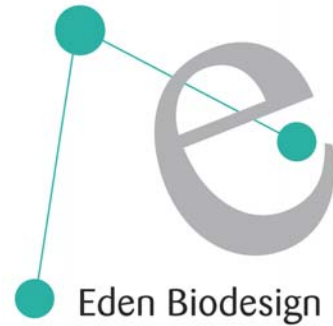
The company uses the principles of 'Good Science' at every step of biopharmaceutical development to design programmes and processes that deliver clinically and commercially valuable products, with an accomplished and attentive level of project management that clients need.

This month, Eden announced a new deal to supply Onyvax Limited, the biotechnology company developing novel cancer therapies with cGMP clinical manufacturing services for its Cell Vaccine program in ovarian cancer.

The National Biomanufacturing Centre

The £34.25 million National Biomanufacturing Centre, which opened in February 2006, is a Government-funded initiative led by the Northwest Regional Development Agency (NWDA) and is additionally funded through the European Regional Development Fund and the Department of Trade and Industry. It aims to establish England's Northwest as one of the foremost biomanufacturing centres in Europe.

The centre will provide the expertise and facilities to support new and existing biotechnology companies, offering product development services designed to fill in the skill and resource gaps that exist within these organisations. It will also provide training



in biomanufacturing and analytical sciences, delivering the skilled workforce required to expand the UK biopharmaceutical sector.

There is also an Access Fund of nearly £3 million which is available to qualifying small to medium companies and academic groups in the biotechnology sector to assist them in purchasing development and clinical manufacturing services from the Centre.

Derek Ellison BSc, PhD: Business Development Director

Derek leads commercial activities at Eden Biodesign - the operator of the UK National Biomanufacturing Centre. Derek was a co-founder of Eden Biodesign's sister company, Eden Biopharm, the international biopharmaceutical development consultancy. Derek's technical area of expertise is in protein characterisation and analytical development: he still provides training and strategic consultancy in these areas.

Prior to Eden, Derek led the biochemistry development group at Celltech-Medeva during the successful pan European approval of a recombinant vaccine product. Derek has a PhD in protein biochemistry from Liverpool University and performed post doctoral research for the British Heart Foundation at Manchester University.