Last year, the global market for biological products exceeded $125 billion, accounting for 17% of the total market for pharma/biopharma products; however, its portion of the global market is expected to rise markedly in the next few years.

In fact, by 2015, we estimate that the top three products in terms of global sales will be biotech medicines), collectively accounting for $25.4 billion, with today’s small molecule brand leaders being relegated to commodity generics.

However, in spite of this potential, last year biosimilars only generated around $89 million in sales, with omnitrope accounting for the vast portion of those sales (33% market share), hence it is still a largely immature market.

Europe is by far the most advanced in terms of biosimilars approvals, but despite being the only region to have passed a specific regulatory pathway for biosimilars, only a few manufacturers have launched products in Europe. In total, 13 biosimilars have been approved in Europe to date for somatropin, epoetin and filgrastim.

Market penetration naturally varies considerably between EU countries because of differing reimbursement policies, adoption and utilisation habits, prescriber influence and pricing, with Germany accounting for the greatest market share in Europe and indeed, worldwide. Omnitrope is the only biosimilar to have gained approval in the US market (launched in 2006) but with restricted indications.

One particular factor limiting the market penetration of biosimilars is legislation, which prevents substitution of an originator product with a biosimilar.

This often means that use is restricted to new patients and short-term indications. However, the opportunity for cost containment using biosimilars is significant.

Biography

Leandro Mieravilla pursued his MBA and he is the Global Speaker at International Congresses about Biosimilar and Biotechnology markets in: Canada, US, Europe and Latin America. Pharmaceutical / Biosimilar / Biotechnology global advisor of leading regional business development (biosimilar and biotechnology) companies. He has been working more than sixteen years in business development for Latin America and Asia-Pacific regions launching biotechnology and biosimilar products. He has been living and working in five countries for global and regional pharmaceutical companies since 1990s. Now living in Canada and working for local and global markets, he has a great reputation on the biosimilar market.

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