

Ms Sarah Rickwood, IMS Health: Savings from generics will start to decline in 2013

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The changing outlook for biosimilars comes at a time when the global pharmaceutical market is feeling the combined impact of two key events: a period of unprecedented patent expirations on many of the world's largest pharmaceutical brands, and a financial crisis that has required healthcare systems to make significant and sustained cost reductions. For payers in the advanced markets, limited economic growth and pressures on healthcare make the patent cliff a true generic dividend, enabling much needed savings to be realized.

However, as potential savings from generics start to decline in these countries over the next five-to-ten years, while the imperative to reduce expenditure continues to grow, payers face an urgent need to find new ways of rationalizing resources. Biologics - among the most expensive pharmacotherapies available and now approaching their own swathe of patent expirations - potentially represent the most lucrative source of savings on drug expenditure for Western nations after 2015.

Biosimilars may be the key that helps them to realize this opportunity. Biosimilars also bring clear potential for payers in the emerging pharmaceutical or "pharmerging" markets, such as Brazil, India and China. Here, the need to broaden healthcare coverage to large populations increasingly must be balanced against limited budgets and growing demand for innovative drugs. Biosimilars offer one way of widening access and enabling better value to be obtained from the money spent on healthcare. In some cases (such as South Korea, India and Brazil) they are seen as a key macroeconomic driver of growth, attracting foreign capital by creating manufacturing and R&D centers of excellence.

The imperative to find cost-effective alternatives to biologics reflects the growing demand for these specialty drugs. Since their origins in the 1980s, biologics have prospered into a \$138 billion market (2010), fuelled by such key launches as recombinant insulins, human growth hormone, alteplase, erythropoietins, granulocyte colony stimulating factors and then monoclonal antibodies, among others. Currently accounting for 16 percent of global pharmaceutical expenditure and significantly outpacing total branded sales, biologics will continue to out-perform the global market as more innovative products deliver new treatment options for a growing range of indications.

A number of top-selling biologic brands, including Herceptin, Enbrel, Humalog, MabThera, Remicade and Aranesp, are due to lose product patent protection over the next five years, opening up a wealth of new possibilities for biosimilars players. Key therapy areas such as cancer, diabetes and rheumatoid arthritis will spearhead this new wave of biosimilars, with attention focused on the real prizes of anti-TNF MAbs, MAb for oncology, and insulins.