

PHARMA NEWS

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'Similar biologics' approved and marketed in India

There have been established guidelines for approving generic versions of small molecule chemical drugs in India for some time already. However, no specific guidelines for 'similar biologics', as the Indian regulatory authorities call these products, have existed in India until recently. This has been the case despite the fact that the requirements for granting regulatory approval for such 'similar biologics' required more data than for a simple generic drug application [1].

India announced the release of draft regulatory guidelines for 'similar biologics' at the BIO industry conference in Boston, USA, on 19 June 2012, and implemented them from 15 September 2012. The guidelines outline a simple abridged procedure for evaluation of 'similar biologics' which have been approved and marketed in India, Europe or USA for more than four years [2].

Biosimilars are firmly established in the EU as copy biologicals with a clear and effective route for approval [3]. It should be noted, however, that 'similar biologics' approved and marketed

in India have not been subjected to the same rigorous controls and have not necessarily been compared in direct clinical trials to the reference product as is demanded in Europe by the European Medicines Agency. They should not therefore be referred to as biosimilars according to the definition proposed by EMA:

'A biosimilar is a copy version of an already authorized biological medicinal product with demonstrated similarity in physicochemical characteristics, efficacy and safety, based on a comprehensive comparability exercise' [4].

The Central Drugs Standard Control Organization is responsible for the approval, i.e. marketing authorisation of medicinal products, including these so-called 'similar biologics', in India.

India has, by far, demonstrated the greatest acceptance of 'similar biologics'. According to our research at GaBi Online, the first 'similar biologic' was approved and marketed in India for a hepatitis B vaccine in 2000. In recent years over 50 biopharmaceutical products have been approved for marketing in India, with more than half of them being 'similar biologics' [5], see Table 1.

Table 1: 'Similar biologics' approved and marketed in India [5-7]

Product name	Active substance	Therapeutic area*	Launch date	Company
Basalog	Insulin glargine	Diabetes	2009	Biocon
Biovac-B	hepatitis B vaccine	Hepatitis B	2000	Wockhardt
Ceriton	epoetin alpha	Anaemia, Cancer, Chronic kidney failure	NR	Ranbaxy
Choriorel	chorionic gonadotrophin hormone r-hCG	Female infertility	NR	Reliance Life Sciences
Cresp	darbopoetin alpha	Anaemia, Cancer, Chronic kidney failure	Aug 2010	Dr Reddy's Laboratories
Epofer	epoetin alpha	Anaemia, Cancer, Chronic kidney failure	NR	Emcure
Epofit/Erykine	epoetin alpha	Anaemia, Cancer, Chronic kidney failure	Aug 2005	Intas Biopharmaceuticals
Epotin	epoetin alpha	Anaemia, Cancer, Chronic kidney failure	NR	Claris Lifesciences
Erypro	epoetin alpha	Anaemia, Cancer, Chronic kidney failure	NR	Biocon
Fegrast	filgrastim	Cancer, Hematopoietic stem cell transplantation, Neutropenia	NR	Claris Lifesciences
FostiRel	follitropin beta	Female infertility	Aug 2010	Reliance Life Sciences
Glaritus	insulin glargine	Diabetes mellitus	Mar 2009	Wockhardt
Grafeel	filgrastim	Neutropenia, Hematopoietic stem cell transplantation, Cancer	NR	Dr Reddy's Laboratories
Insugen	human insulin	Diabetes mellitus	NR	Biocon
Intalfa	interferon alpha-2b	Carcinoid tumour, Chronic hepatitis B, Chronic hepatitis C, Hairy cell leukaemia, Chronic myelogenous leukaemia, BCR-ABL positive, Follicular lymphoma, Malignant melanoma, Multiple myeloma	Apr 2007	Intas Biopharmaceuticals
Mirel	reteplase (tissue plasminogen activator)	Myocardial infarction	2009	Reliance Life Sciences

(Continued)

Table 1: 'Similar biologics' approved and marketed in India (Continued)

Product name	Active substance	Therapeutic area*	Launch date	Company
Myokinase	streptokinase	Acute myocardial infarction, Deep venous thrombosis, Acute pulmonary embolism	NR	Biocon
Neukine	filgrastim	Neutropenia, Hematopoietic stem cell transplantation, Cancer	Jul 2004	Intas Biopharmaceuticals
Neupeg	peg-filgrastim	Cancer, Neutropenia	Aug 2007	Intas Biopharmaceuticals
Nufile	filgrastim	Cancer, Neutropenia	NR	Biocon
Peg-grafeel	peg-filgrastim	Cancer, Neutropenia	10 May 2011	Dr Reddy's Laboratories
Reditux	rituximab	Leukaemias, Lymphomas, Rheumatoid arthritis	30 Apr 2007	Dr Reddy's Laboratories
Relibeta	interferon beta-1a	Multiple sclerosis	NR	Reliance Life Sciences
Reliferon	interferon alpha-2b	BCR-ABL positive, Carcinoid tumour, Chronic hepatitis B, Chronic hepatitis C, Chronic myelogenous leukaemia, Follicular lymphoma, Hairy cell leukaemia, Melanoma, Multiple myeloma	2008	Reliance Life Sciences
Religrast	filgrastim	Neutropenia	2008	Reliance Life Sciences
Relipoietin	epoetin alpha	Anaemia, Autologous blood transfusion, Chronic kidney failure, HIV	2008	Reliance Life Sciences
Shankinase	streptokinase	Arterial occlusions Deep vein thrombosis, Pulmonary embolism	Jun 2004	Shantha Biotechnics/Merieux Alliance
Shanferon	interferon alpha-2b	BCR-ABL positive, Carcinoid tumour, Chronic hepatitis B, Chronic hepatitis C, Chronic myelogenous leukaemia, Follicular lymphoma, Hairy cell leukaemia, Melanoma, Multiple myeloma	Apr 2002	Shantha Biotechnics/Merieux Alliance
Shanpoietin	erythropoetin	Anaemia, Chronic kidney failure	Jan 2005	Biotechnics/Merieux Alliance/Shantha
Wepox	epoetin alpha	Anaemia, Cancer, Chronic kidney failure	Mar 2001	Wockhardt
Wosulin	human insulin	Diabetes mellitus	13 Aug 2003	Wockhardt

*Therapeutic area taken from company information or from originator product information on EMA website; NR: not reported.

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