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Bio-dynamism

Insights into the Biosimilars market: An overall perspective

2013

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Foreword

Considered a major hope for the effective treatment of several diseases that have no cure till date, development of biotech medicines has been embraced as a core research and development area across some of the largest and populous economies in the world.

With rising healthcare costs, the impending patent cliff and a relatively slow pace of development of generics, development of biologics is regarded as one of the most promising frontiers in pharmacotherapy, with biologics expected to have a global market to the tune of US$ 3.7 billion by 2015.

Benchmarking against the performance and regulation in the leading nations of the world indicates that the value generation opportunity of biosimilars is dependent on several factors, including speed of development, clarity in regulation, ease of access and particularly the roles of all stakeholders. Potential aside, there remain regulatory challenges, success of clinical trials as well as safety and efficacy tests which are characterized by a huge investment outlay.

In this paper, we attempt to bring out recent developments in the segment (particularly partnerships / collaborations / alliances), the opportunities that players could potentially exploit and the regulatory dynamics in key global markets.

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Understanding the biosimilar pathway

Broadly classified as a follow on or modified biologic, by definition, biosimilar can be a "copy of" or "similar to" the biological drug whose patent has expired, but not identical to the biological drug. Unlike chemical-based generic small molecule drugs, biosimilars are large complex drugs involving the use of living cells resulting in challenges around uniformity and consistency. In common parlance, biobetter, biosimilar and antibodies are quite often used interchangeably.

However, there is a vital distinction between these classes.

With each class having different characteristics, it becomes imperative to understand the distinction between "highly similar" or "completely interchangeable" products, the defining factors being the following:

- whether it can be substituted without a doctor's prescription?
- does it produce the same clinical result with safety and efficacy?
- is it similar to the reference product?

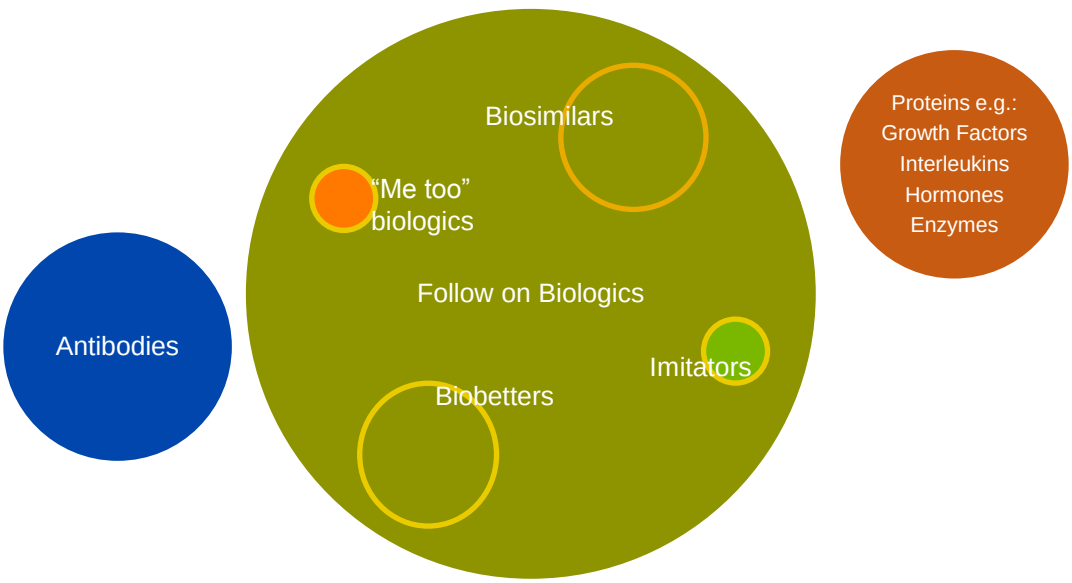


Figure 1: The figure above illustrates that follow on biologics encompasses biosimilars, biobetters, imitators (a copy of the original product but different in terms of quality, and sold in less regulated markets) and "Me too biologics" which are follow-on patented biologics without superior efficacy. Antibodies and Proteins are called novel biologics which are outside the gambit of follow on biologics

The global market for biosimilars is estimated to grow to US$3.7 billion by 2015 with the impending patent cliff being the key driver for development and collaboration activities across the globe.

Market dynamics

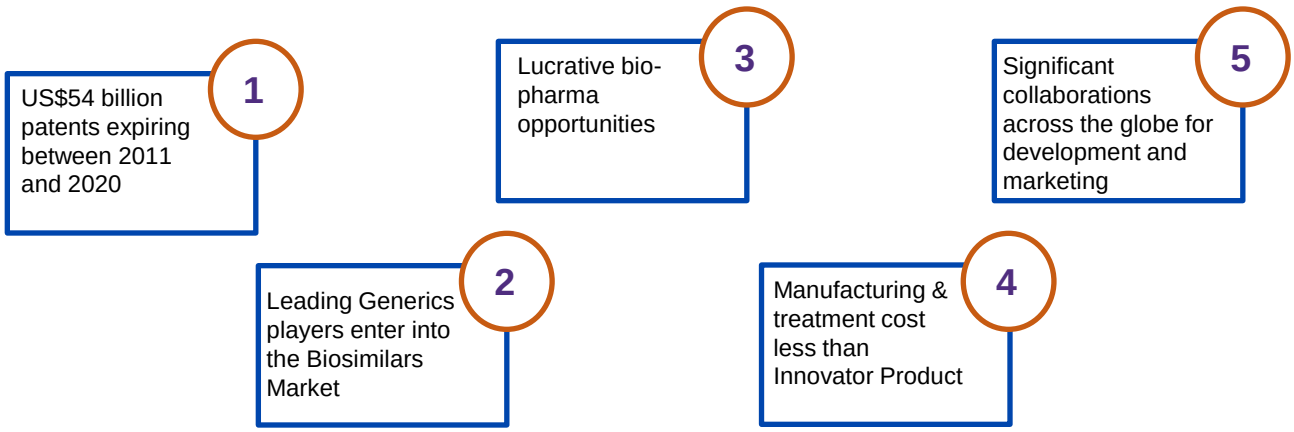
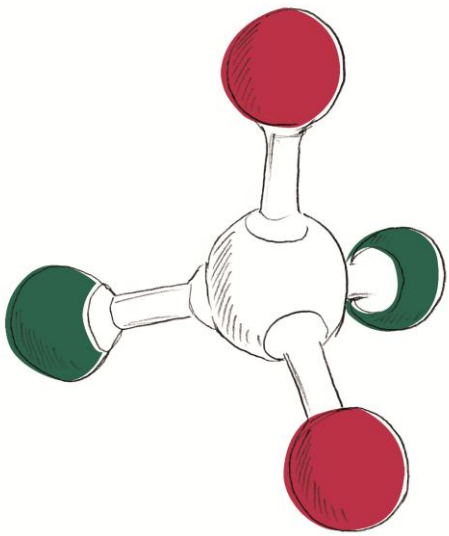


Figure 2: The figure above illustrates the market drivers that promote the growth of investments in the biosimilar segment

Patents for biologics are nearing expiry, creating an opportunity for the bio-similar products. In 2007, erythropoietin, with a global market size of around US$12.1 billion, lost its patent protection, followed by other key expiries of important drugs such as G-CSFs, Insulins and Interferons.



Market dynamics

It is estimated that between 2009 and 2019, 21 biologics with a market value of over US$50 billion will lose patent protection in the US alone (captured in the table below).

One of the key drivers promoting the development of biosimilars is that they are an affordable alternative to originator medicines (by around 20-25%). This is largely due to reduced number of clinical trials which in turn results in increased patient access and affordability of treatment.

Table 1: Value of Patent Expiries (US$) over a five year horizon

Biosimilar	2012	2013	2015	2016	2019	Originator
HUMIRA				5.5		ABBOTT & EISAI
ENBREL	6.6					AMGEN
EPOGEN		5				
NEULASTA			3.4			
NEUPOGEN		1.3				
AVONEX		2.3				BIOGEN IDEC
ERBITUX			1.6			BMS/ MERCK
HUMALOG		2				ELI LILY
AVASTIN					5.8	GENENTECH
HERCEPTIN					4.9	
RITUXAN			5.7			
CEREZYME		0.8				GENZYME
REMICADE		5.9				I&I
LUCENTIS					2.3	NOVARTIS
LANTUS			4.2			SANOFI-AVENTIS
REBIF		2.1				SERONO
Value in US$	6.6	19.4	14.9	5.5	13	59.4

Yearly alliance tally

While 2009 marked the beginning of the biosimilar era with five key alliances (albeit with the most powerful market players), a spate of such collaborations continued in the next three years with 17 alliances in 2010, 12 in 2011 and 15 alliances in 2012. While 30% of the alliances were structured as acquisitions, the remainder were collaborative agreements for development, licensing and/or marketing.

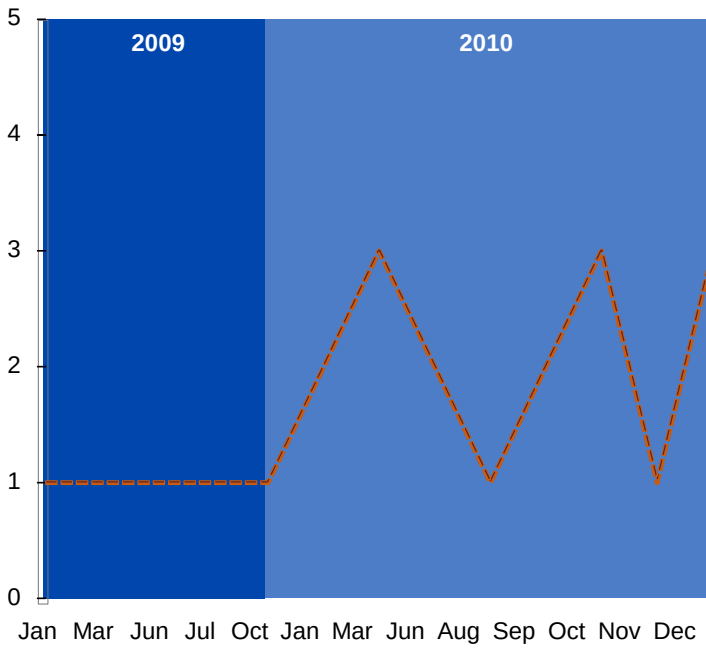


Figure 3: Top five deals of the year in the biologics/ biosimilar space

2009

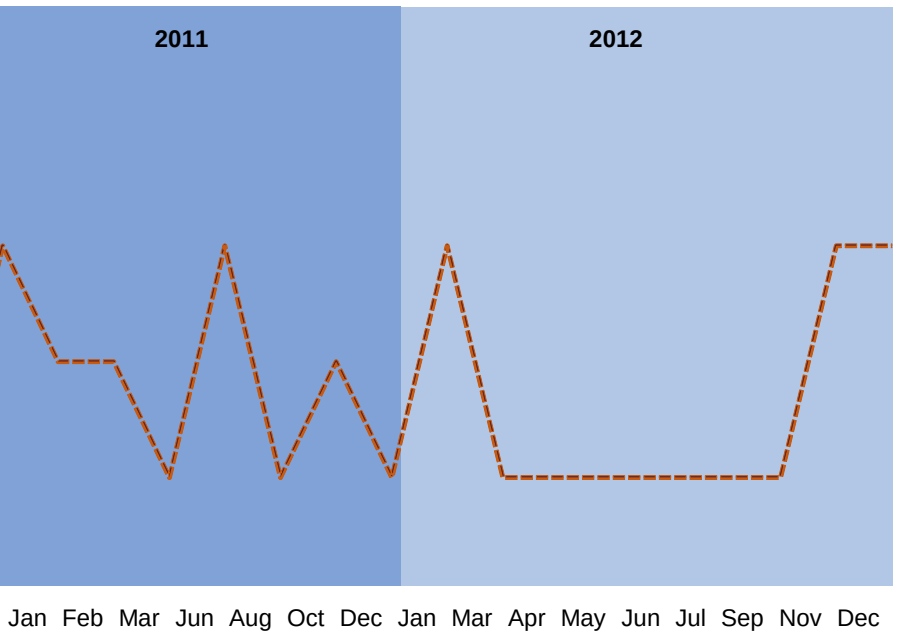
Deal	Value
Merck –Insmed	US$130 million
Teva-Lonza	N/A
Mylan-Biocon	N/A
Sanofi Aventis – Shanta	N/A
Hospira-Celltrion	N/A

2010

Deal	Value
Teva-Ratiopharm	US$3625 million
J&J- Crucell	US$2400 million
BI – MacroGenics	US$2160 million
Cephalon – Mesoblast	US$2050 million
BI-f star	US$1720 million

Yearly alliance tally

Geographic concentration of the deal activities indicates that 40% of all deals originate in the US, which also continues to lead in terms of the development potential with 45% share of all targeted alliances, followed by Europe (18%), India (12%), Japan and South Korea (both at 12 %).



2011

Deal	Value
Teva-Cephalon	US$6800 million
Grifols-Talecris	US$3400 million
Astellas-Aveo	US$1400 million
Amgen-Biovex	US$1000 million
Merck –Hanwha	US$720 million

2012

Deal	Value
Samsung – Biogen Idec	US$300 million
Actavis-Bioton	US$173 million
Bioton-Medipolis	US$7 million
Merck Serono – Dr Reddy's	N/A
CCM Pharma – Biotech	N/A

Typical collaboration formats

Global pharmaceutical industry has historically evidenced a number of strategic development collaborations to expand market reach, acquire pipelines, go-to-market quicker, reduce costs and mitigate risks associated with development activities. Such alliances allow generic players to make higher margins, Contract Research Organisations (CRO's)/ Contract Manufacturing Organisations (CMO's) to become stakeholders in upsides, while providing an opportunity for new entrants to enter through a strategic route by providing financial support.

Key alliance

In early 2012, Samsung and Biogen entered into a joint venture to develop and market biosimilars. Samsung contributed US$255 million for an 85% share and Biogen contributed US$45 million for a 15% share. Samsung was the major contributor in the JV while Biogen agreed to contribute its expertise in protein engineering and biologics manufacturing.

Key fallout

Once touted as a pioneer deal in 2009, the Biocon Pfizer insulin alliance turned into one of the biggest setbacks in the history of alliances in the biosimilar arena.

Generic
Teva
Mylan
Hospira
Ranbaxy

CMO
Lonza
Biocon
Celltrion
Pfenex

Pharma
Daiichi Sankyo
Dr. Reddy's
Pfizer

Biotech
Coherus Bioscience
Merck Serono
Biocon

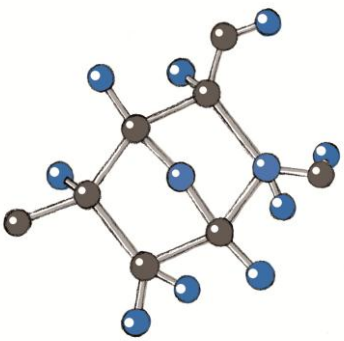
Pharma
Merck

CRO
Paraxel

New Entry
Samsung
DM Corp

CMO
Quintiles
ORF Genetics

The global competitive landscape



	EUROPE	JAPAN	USA
INNOVATOR	Boehringer Ingelheim		Amgen, Biogen Idec, Merck, Pfizer
GENERIC	Actavis, Gedeon Richter, Hospira, Mylan, Sandoz, Stada		Watson Pharma, Momenta Pharma
CRO/CMO	Bioton, Lonza, Medipolis	UMN Pharma	Harvest Moon Pharma, Parexel, Quintiles
OTHERS		Fujifilm	

Sandoz (Europe)

- global biosimilar sale in 2010 was US$185 million, a growth of 63% over 2009
- only company to have 3 biosimilars marketed in Europe
- 8-10 biosimilars are currently at various stages of development

Stada (Germany)

- collaboration agreement with Gedeon Richter for two monoclonal antibodies
- product pipeline includes monoclonal antibodies

Teva (Israel)

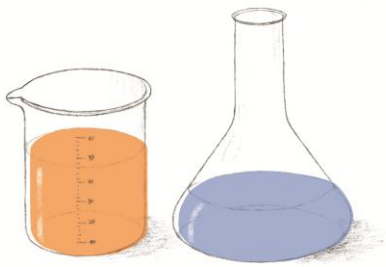
- acquired Cephalon in 2011 for $6.8 Bn
- Teva – Lonza JV has stopped the Phase 3 clinical trial of Rituximad version

Hospira (USA)

- two biosimilars in Europe i.e. Retacrit (Epoetin Zeta) and Filgrastim (Nivestim)
- agreement with Celltrion to develop and market eight biosimilars

The global competitive landscape

ISRAEL	KOREA	UK	INDIA
			AstraZenenca, DM Corp
Teva Pharma			Dr. Reddy's, Ranbaxy , Lupin
	Celltrion, CTC Bio		Biocon, Intas, Wockhardt, Zydus
	Samsung	GE Healthcare	



LG Life Sciences (South Korea)

- leading biosimilar maker with antibody biosimilars in the pipeline
- LG Lifescience and Machida to co-develop and commercialise biosimilars in Japan

Celltrion (Korea)

- expertise in regulatory requirements for global submissions
- product pipeline includes biosimilars for breast cancer, rheumatoid arthritis, crohn's disease and several other products

Watson (USA)

- focussed on developing and marketing biosimilar products for women's health and oncology
- partnership with Amgen to develop and commercialised several oncology biosimilar medicines

Amgen (USA)

- two biosimilars in Europe i.e. Retacrit clinical and commercial products in Japan
- partnership with Catalent for biosimilar development in Japan

The global competitive landscape

UMN Pharma (Japan)

- partnership with Catalent for biosimilar development in Japan
- at present, it has 3 manufacturing facilities in Japan focused on the development of influenza vaccines based on insect cells

Biocon (India)

- leader in biosimilars segment in India with strong position in insulin market
- plans to develop Glargine for which patent expires in 2014

Merck (USA)

- Merck and Hanwha Chemical of South Korea enter into partnership for development of the biosimilar version of Enbrel
- Merck –Paraxel strategic alliance for global clinical development of biosimilars

Dr Reddy (India)

- global biosimilar sale in 2012 was US$26 million, a growth of 45% over 2011
- early mover advantage with commercial presence in over 13 countries

Intas Pharma (India)

- launched five biogeneric products in India
- eight biosimilars and 4 monoclonal antibodies presently under development

Ranbaxy (India)

- expected to launch 3 biosimilars by 2015 mostly to treat cancer
- development agreement with Biovel Lifesciences and Pfenex

Emcure (India)

- portfolio of 5 biosimilar products
- manufacturing contract with Roche for biologic drugs such as Herceptin and Mabthera

Cipla (India)

- entered biologics market in 2010 through an agreement with Desano Pharma, China
- aims to develop biosimilars for Roche's Avastin & Herceptin and Amgen's Enbrel

Bioton (Poland)

- leading manufacturers of biosimilar insulin
- Bioton and Medipolis collaborate for developing biosimilars for diabetes

Wockhardt (India)

- sells insulin (Wosulin and Glaritus) and Epoetin (Wepox) in India
- several biogeneric products at different stages of development

While regulators are in the process of framing policies and guidance across the globe, the industry is facing several challenges such as product differentiation, meeting requirements for inter-changeability, increasing cost of good manufacturing practices, requirements on facility / manufacturing as compared to traditional drugs etc.

Country focus – Regulatory landscape

While there are threads of similarities for the regulatory norms for biosimilars across the globe, the country-specific regulatory portfolio is constantly evolving. Pharmacovigilance and stringency of the regulatory system varies from country to country.

With patient safety being the core concern for healthcare providers, bio-similar must go through sufficient clinical trials, and a well-designed regulatory framework must be developed across the globe for biosimilar approvals.

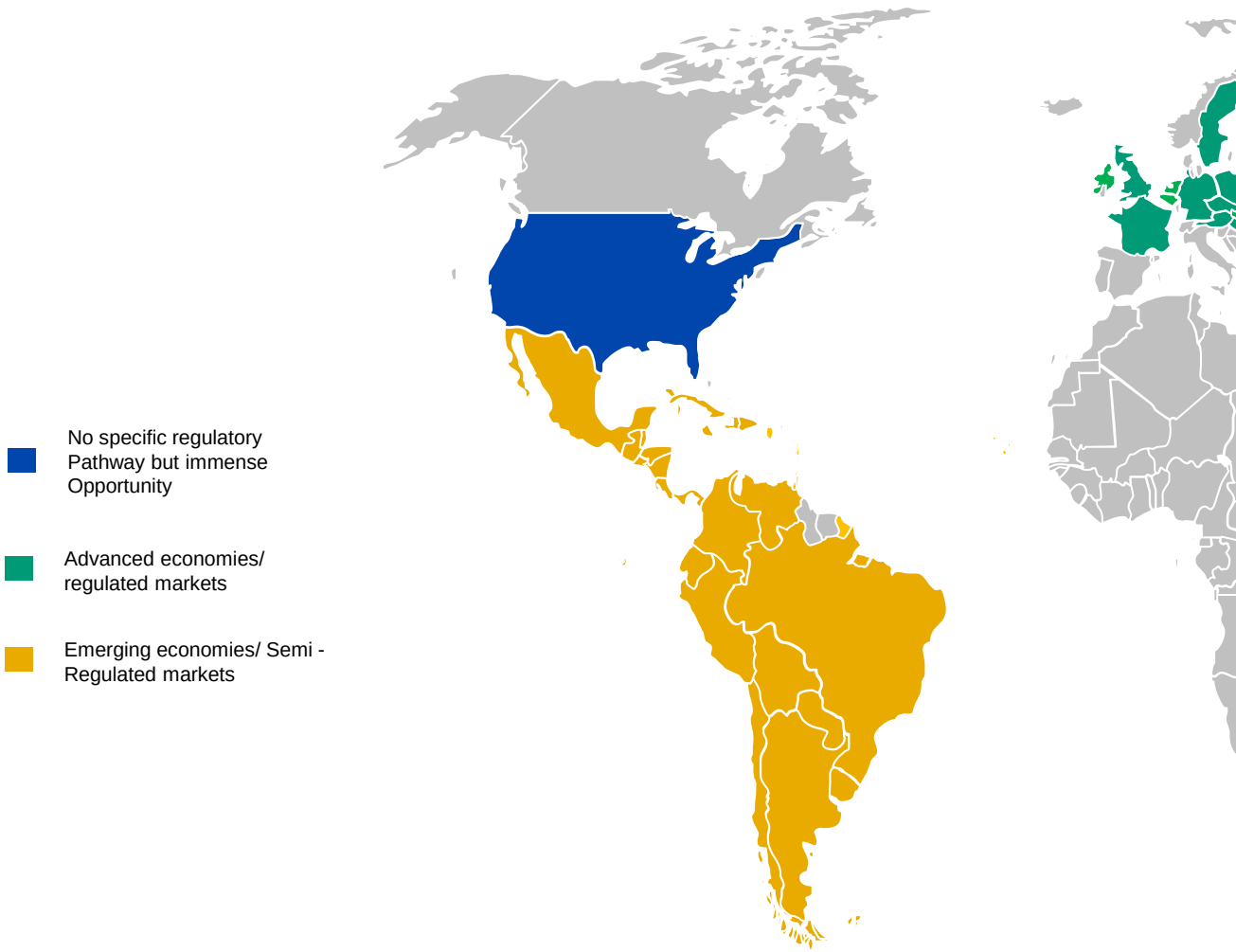
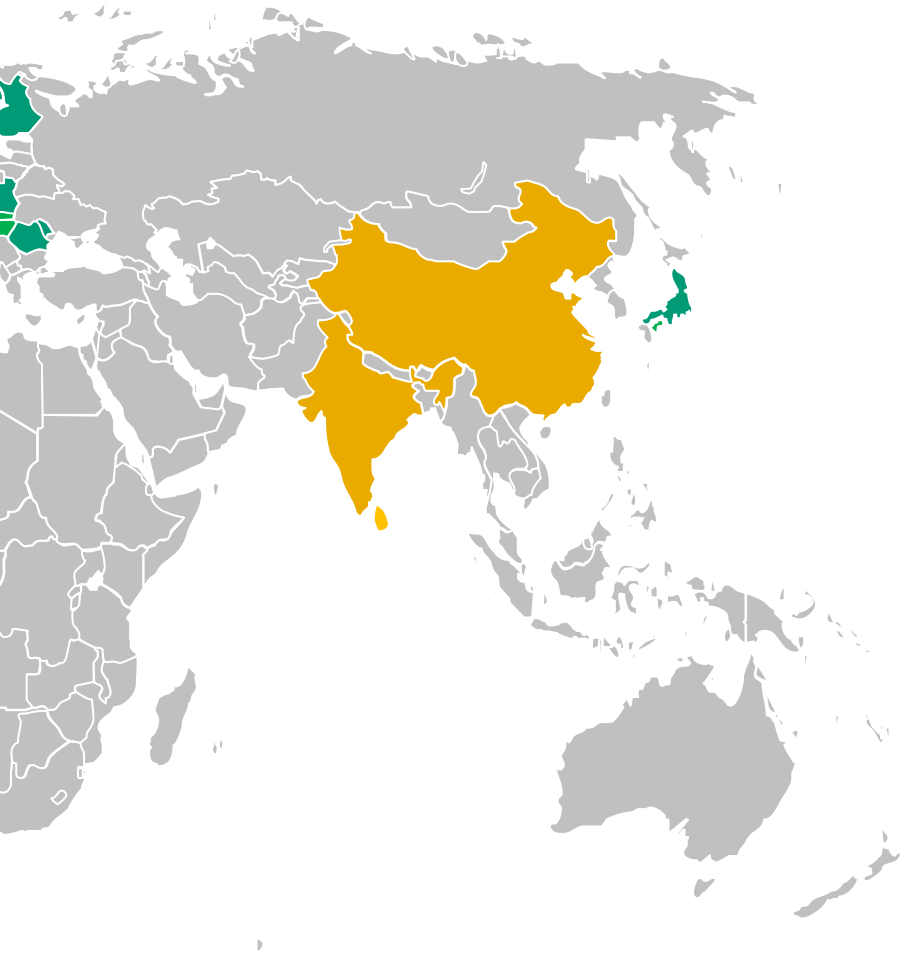


Figure 4: Global regulatory landscape in the biologics/ biosimilar space

Country focus – Regulatory landscape

In most markets apart from Europe, the regulatory framework for biosimilars is still very new as compared to the well-established approval processes for New Chemical Entities (NCEs) and small-molecule generics; in some cases it is non-existent, making global investments risky.



Benchmarking market dynamics

Market attributes						
	Europe	USA	India	China	Japan	Latin America
Market potential						
Clarity of regulatory guidelines						
Regulated/ Semi-regulated						

Europe
- Regulatory Authority: EMEA & CHMP
- regulated market with several biosimilars approved
- eight years data exclusivity +2 years market exclusivity +1 year market exclusivity for new indication within first eight years

China
- Regulatory Authority : SFDA
- current regulations lack clarity. Final guidelines to be finalised after the new drug regulation release
- follow the US regulatory pathway

USA
- Regulatory Authority : Public Health Service Act by BPCI
- yet to have an established regulatory pathway
- four years data exclusivity +8 years market exclusivity

Japan
- Regulatory Authority : MHLW & PMDA
- advanced economy with defined regulatory guidelines
- data exclusivity for branded biologics is 6 years
- follow the EU regulatory pathway

India
- Regulatory Authority: CDSCO, DCGI & DBT
- recently established guidelines to regulate biosimilars
- reference biologic should be licensed in India, if not it should be licensed or marketed for 4 years in a country with a defined regulatory pathway

Latin America
- Regulatory Authority : ANVISA in Brazil and COFEPRIS in Mexico
- semi regulated market for biosimilars
- understanding of biosimilars but a lack of a decision in requiring clinical trials in other regions
- in 2011, 23 Biosimilars registered in Mexico

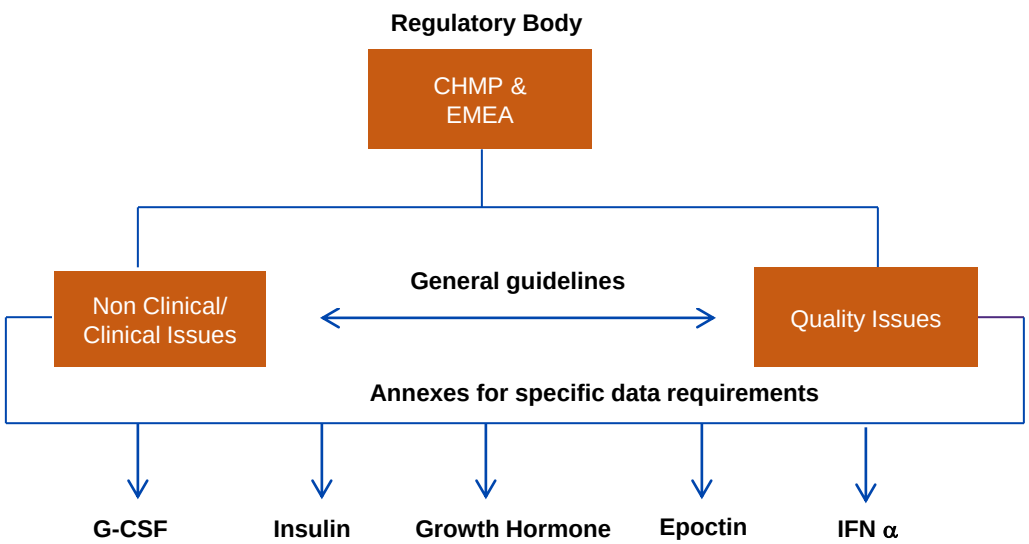
Benchmarking market dynamics

Europe

Europe was the first region to introduce and approve biosimilars in the year 2006 with the launch of Somatropin (human growth hormone) followed by Epoetin alpha (erythropoietin) in 2007 and Filgrastim (G-CSF) in 2009, launched and marketed by Sandoz - the only company with three marketed biosimilars in Europe. It is today is the largest biosimilar market in the world with 13 approved biosimilar products which account for nearly 80% of the global market share (Germany ranking highest within the EU).

The regulatory bodies for biosimilars in Europe are the Committee for Medicinal Products for Human Use (CHMP) and the European Medicines Agency (EMEA). The EMEA evaluates applications from different companies to market biologics and biosimilars for use in Europe.

The EMEA guidelines require detailed demonstration of quality, safety, and efficacy of biosimilar products. In case of any deviations from the guidelines, the applicants are required to justify this in their applications at the time of submission. The data exclusivity for biosimilar manufacturers is around 11 years in EU, comprising 8 years data exclusivity+ 2 years market exclusivity for new biologics and a 1-year extension for a new indication.



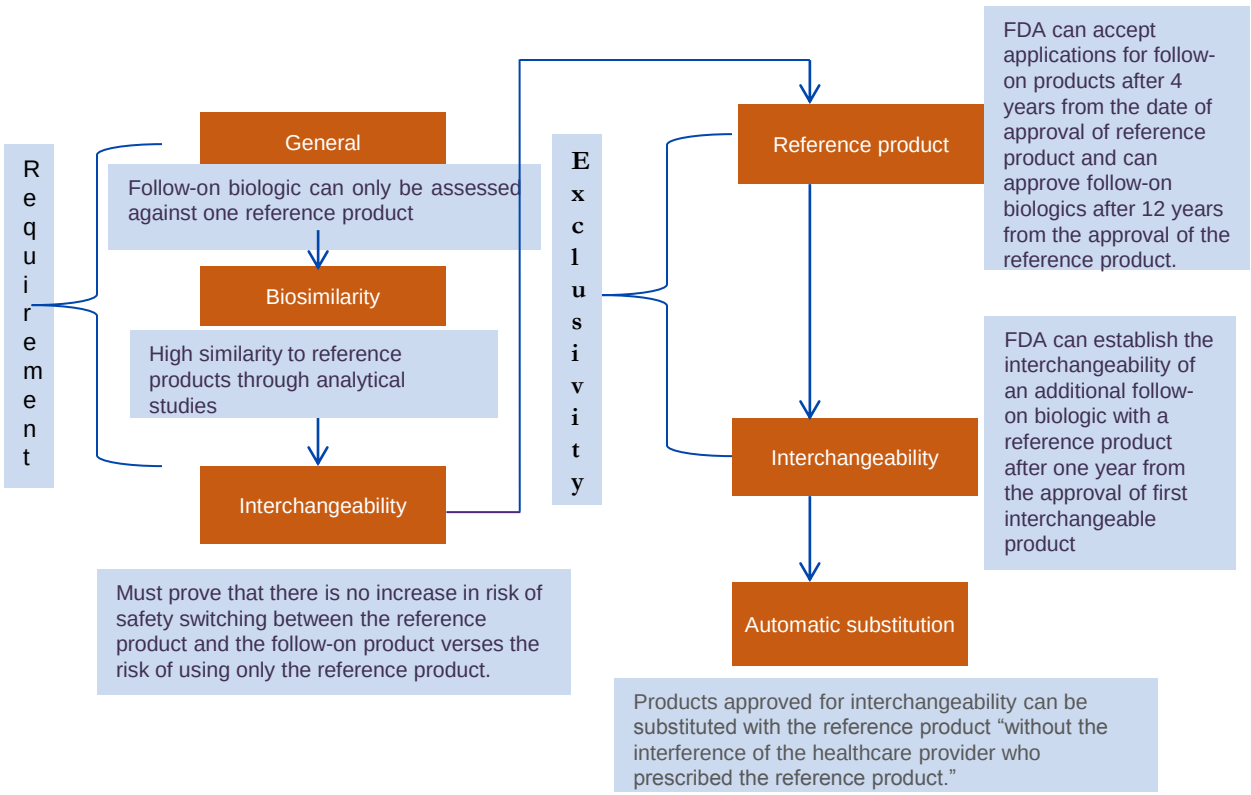
Benchmarking market dynamics

USA

In the US, biosimilars are defined as "follow-on bio-logics". The Public Health Service Act (PHS Act) was modified to create an abbreviated approval pathway known as Biologics Price Competition and Innovation Act (BPCI Act) for products that are confirmed to be "biosimilar" to or "interchangeable" with an FDA-licensed biologic. Under this Act, if a product is highly similar to an existing approved biologic then it is considered as a biosimilar. It allows only minor differences in clinically inactive components in terms of safety, purity and potency. The BPCI Act aligns with the FDA's policy of allowing dependence on known facts about a drug, which saves time and resources by avoiding unnecessary duplication of clinical testing.

In February 2012, the FDA issued three draft guidance documents on biosimilar product development. These documents help the industry to produce biosimilars of approved biologics which may result in low cost of end product and better access to consumers by enhancing competition. These guidelines aim to approve biosimilars by demonstrating that they are biosimilar to, or interchangeable with a reference product.

- the first guideline intends to help companies in establishing that a proposed therapeutic protein product is biosimilar to a biologic, for the submission of an application.
- the second guideline talks about the importance of analytical, physico-chemical and biological characterization in establishing the Biosimilarity of a product.
- the third guideline provides answers to common questions from companies interested in developing biosimilars.



Benchmarking market dynamics

India

The apex body governing the regulatory framework of biologics in India is the Central Drugs Standard Control Organisation (CDSCO), the office of Drug Controller General of India (DCGI) and the Department of Biotechnology (DBT). Apart from that, other competent authorities involved in the approval process are:

- Review Committee on Genetic Manipulation (RCGM)
- Genetic Engineering Appraisal Committee (GEAC)

Based on the current guidelines for similar biologics, here is a step by step process for an applicant who wants to commercially launch a biosimilar product in India

Selection of Reference Biologics (RB)

- RB should be licensed in India based on its safety, efficacy and quality
- in case it is not licensed or marketed in India, it should be licensed or marketed for 4 years in a country with a defined regulatory pathway
- the same reference biologic should be used throughout the studies
- it must demonstrate similarity

Manufacturing process

- manufacturing process should be consistent and robust
- complete description should be provided from development and characterisation of cell banks, stability of clones, formulation, purification and the consequences on product characterisation

Quality-based considerations

- the analytical methods should be chosen for establishing product comparability as per the critical quality attributes of the product
- product Characterisation to establish that the proposed biologic is similar in composition, size, structure and bioactivity
- product specifications and stability

Quality comparability study

- the applicant should submit a full quality dossier, conforming to the guidelines specified by CDSCO, to establish comparability of similar biologic against the RB

The DBT defines a bio similar as "a biological product or drug produced by genetic engineering techniques and claimed to be similar in terms of safety, efficacy and quality to a reference biologic, which has been granted a marketing authorization in India by DCGI on the basis of a complete dossier and with a history of safe use in India."

Data requirement for clinical trial

- Pharmacokinetic Studies
- Pharmacodynamic Studies
- Establish comparative safety and efficacy in relevant patient population
- Safety and Immunogenecity data -Pre-approval and post-approval assessment of safety
- Extrapolation of Efficacy and Safety Data to Other Indications

Market authorisation

- Submit application as per CDSCO guidance document for industry, 2008
- Submit the risk management plan which must include
  - Pharmacovigilance plan
  - Adverse Drug Reaction (ADR)
  - Post Marketing Studies
- The applicant should archive all the data up to the stage of clinical evaluation for a period of at least five years after marketing approval

Benchmarking market dynamics

Currently, multiple agencies govern the regulatory compliance for biologics and biosimilars in India. The government has proposed the Biotechnology Regulatory Authority of India (BRAI) Bill which will act as a single window clearance mechanism to regulate the research, manufacture, import and use of products of modern biotechnology. To what extent this is successful and efficient will only be governed by time and success in development and discovery.

While different stakeholders may have their own interests, it is for the regulator to develop policy and guidelines to strike a balance between innovation and competition. Patient safety, of course, remains the principle guiding light.

Conclusion

An effective market access strategy is the key for this extremely complex value proposition and needs to address the concerns and demands of all stakeholders. Despite the inherent risk, biosimilars have the potential to exceed benchmark returns from any other form of R&D, a primary reason for increased alliances in the last five years. Re-focussing strategy along the whole value chain, from science (optimising the clinical development program) to marketing (developing co-marketing strategies) is critical for unlocking the potential of biosimilars.

A potential solution in an increasingly challenging environment for biosimilars is innovative collaborative arrangements across the heterogenous geographical landscape, with each region in different stages of development. Biosimilars, expected to be a long-term game should be ultimately aimed towards patient safety, faster time to market and cost effectiveness.

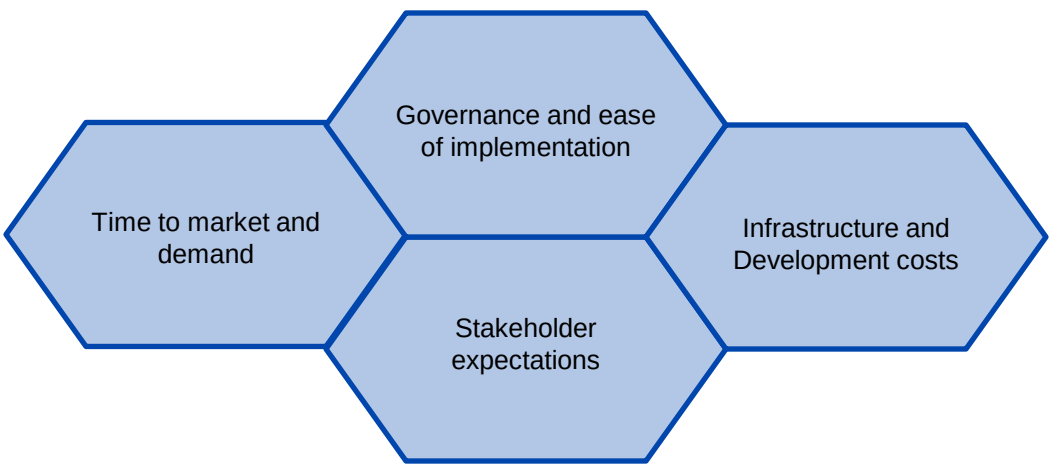
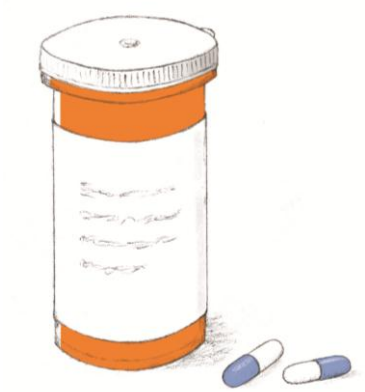


Figure 5: Critical success factors for realising the biosimilar potential

Appendix 1: Major classes of biological drugs

Product Class	Definition
Somatropin (growth hormone)	Non-glycosylated protein of 191 amino acids Used for growth failure, growth hormone deficiency, short bowel syndrome and HIV-related weight loss or wasting
Epoetin	Heavily glycosylated protein hormone of 165 amino acids that stimulated red blood cell production Used for treating anaemia in patients with chronic kidney disease or patients with cancer who are receiving chemo-therapy
Filgrastim (G-CSF)	Minimally glycosylated protein of 174 amino acids that stimulates the production of white blood cells Used to restore white blood cell levels and prevent infections in patients with cancer or who have had a bone marrow transplant
Insulin	Peptide of 51 amino acids Used in Type I and Type II diabetes
Interferon Alpha	Protein of 165 amino acids secreted in response to infection Used for chronic hepatitis B or C virus infection and cancers
Heparins	Glycosaminoglycans (mucopolysaccharides) – long, unbranched polysaccharides used to prevent blood coagulation
Monoclonal antibodies and fusion proteins	Based on the antibodies (immunoglobulins) the body uses to fight infection and cancer and which are involved in the development of immune conditions such as rheumatoid arthiritis and psoriasis
Interferon Beta	Glycoprotein of 166 amino acids secreted in response to infection Used in multiple sclerosis
Follitropin (FSH)	Glycoprotein consisting of two polypeptide chains that regulates growth, development and reproduction Used in fertilization medicine for women, and for men to induce and maintain spermatogenesis



Appendix 2: Drugs Vs Biologics

Differentiating Factor	Drugs	Biologics
Manufacturing Process	Chemical Synthesis	In a living system such as microorganism, or plant or animal cells
Method	Simple	Elaborate
Molecule Size	Small	Very large
Structure	Well defined and fully known	Complex, partially unknown
Sensitivity to physical factors	Low	High
Proneness to contamination during manufacturing	Low	High
Dosage	Weight or weight per volume	Units of biological activity
Reproducibility	Easy to establish	Difficult to establish
Development Cost	Low	Very high

Drug	Type	Revenue ($ billion)
Humira	Biologic	10.1
Avastin	Biologic	8.9
Enbrel	Biologic	7.3
Rituxan	Biologic	6.8
Crestor	Conventional Drug	6.3
Herceptin	Biologic	6.2
Remicade	Biologic	5.7
Lantus	Biologic	5.3
Seretide / Advair	Conventional Drug	5.2
Prolia	Biologic	5.2
Revlimid	Conventional Drug	4.8
Spiriva	Conventional Drug	4.6
Prevnar	Biologic (Vaccine)	4.4
Lyrica	Conventional Drug	4.1
VX - 950	Conventional Drug	3.7
Xarelto	Conventional Drug	3.6
Januvia	Conventional Drug	3.6
Atripla	Conventional Drug	3.5
Lucentis	Biologic	3.4
Truvada	Conventional Drug	3.4

Appendix 3: Glossary

Key Words	
ANVISA	Brazilian Health Surveillance Agency
BI	Boehringer Ingelheim
BLA	Biologic License Application
BPCI	Biologics Price Competition and Innovation Act
CDSCO	Central Drugs Standard Control Organization
CHMP	Committee for Medicinal Products for Human Use
CMO	Contract Manufacturing Organization
COFEPRIS	Federal Commission for the Protection against Sanitary Risks
CRO	Contract Research Organization
DCGI	Drug Controller General of India
EMEA	European Medical Agency
EU	European Union
FDA	US Food and Drug Administration
G-CSF	Granulocyte colony-stimulating factor
GEAC	Genetic Engineering Appraisal Committee
GMP	Good Manufacturing Practice
IFN	Interferon
J&J	Johnson & Johnson
JV	Joint Venture
MHLW	Ministry of Health, Labor and Welfare (MHLW)
NBRA	National Biotechnology Regulatory Authority
NCE	New Chemical Entities
PHS	Public Health Service Act
PMDA	Pharmaceuticals and Medical Devices Agency
RCGM	Review Committee on Genetic Manipulation
SFDA	State Food and Drug Administration (SFDA).

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- Biosimilars: Surveying the Market Landscape (www.slideshare.net/driceman/biosimilarsreport)
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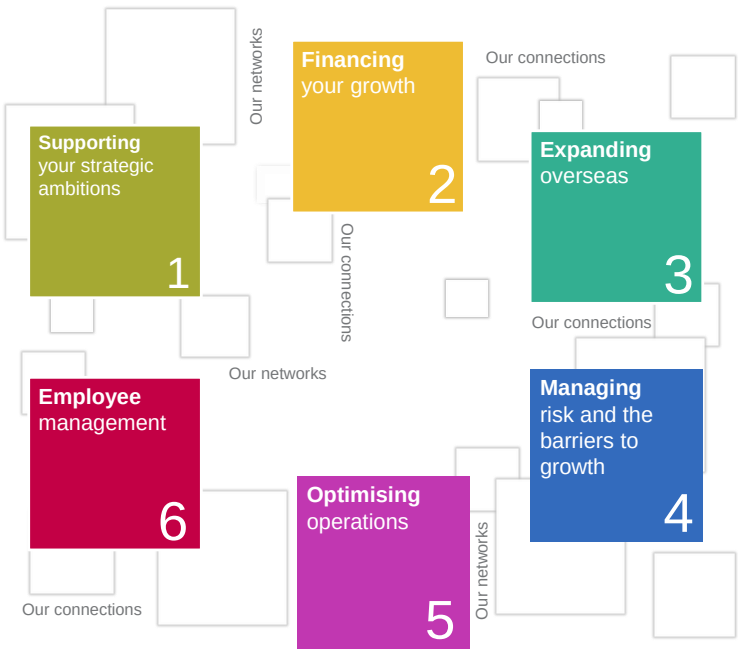

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