

Future of Next Generation Biosimilar

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DISCLAIMER

- Employee of Abbott Health Care
- Content is solely my personal view and based on limited experience
- No conflict of interest
- Examples quoted here have nothing to do with any favor or criticism of any company/molecule/brand
- Out of scope : Regulatory Clinical and PV guidelines & Pathways

CONVINCE OR CONFUSE

Term	By	Definition
Similar Biotherapeutic products	WHO	A Biotherapeutic product to an already licensed reference Biotherapeutic product in terms of quality, safety and efficacy
Follow on protein products or Follow on biologics	USFDA Japan	A product highly similar to the reference product without clinically meaningful differences in safety, purity and potency
Subsequent entry biologics	Canada	A biologic drug that enters the market subsequent to a version previously authorized in Canada with demonstrated similarity to a reference biologic drug
Biosimilars	EMEA Korea India China Australia	Biological products which demonstrated its equivalence to an already approved reference product with regard to quality, safety, and efficacy

MAbs. 2011 Mar-Apr; 3(2): 107–110.

COST EFFECTIVE COPIES

- Copies of rituximab, trastuzumab, bevacizumab with a mutation of two or three amino acids in the Fc domain
- Resulting in extended pharmacokinetics
- Low Cost of treatment
  - lower cost of the products
  - less frequent administration regimens or lower dosages.

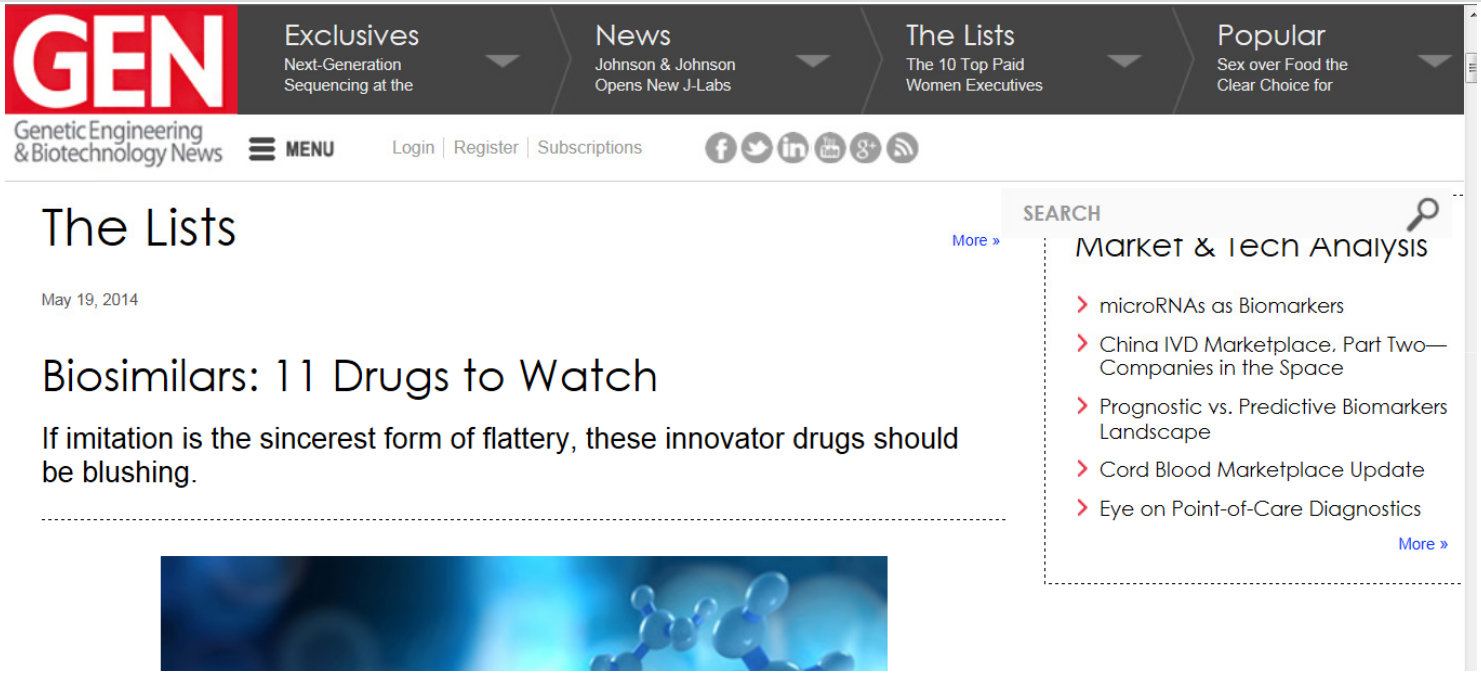
The EMA has pioneered the regulatory framework

The first wave of biosimilar antibodies were copies of current important therapeutic antibodies

✓ Rituximab, India (Reditux; DRL) - (Rituxan/Mabthera)

✓ Abciximab, S. Korea (Clotinab; Abu Abxis)-Centocor (Reopro)

ADVANCING TOWARD MULTIPLE BIOSIMILARS DEVELOPMENT MILESTONES



Herceptin (trastuzumab)- July 28, 2014, in Europe

Humira (adalimumab), 2016 in U.S

Neulasta (pegfilgrastim)

Remicade (infliximab)

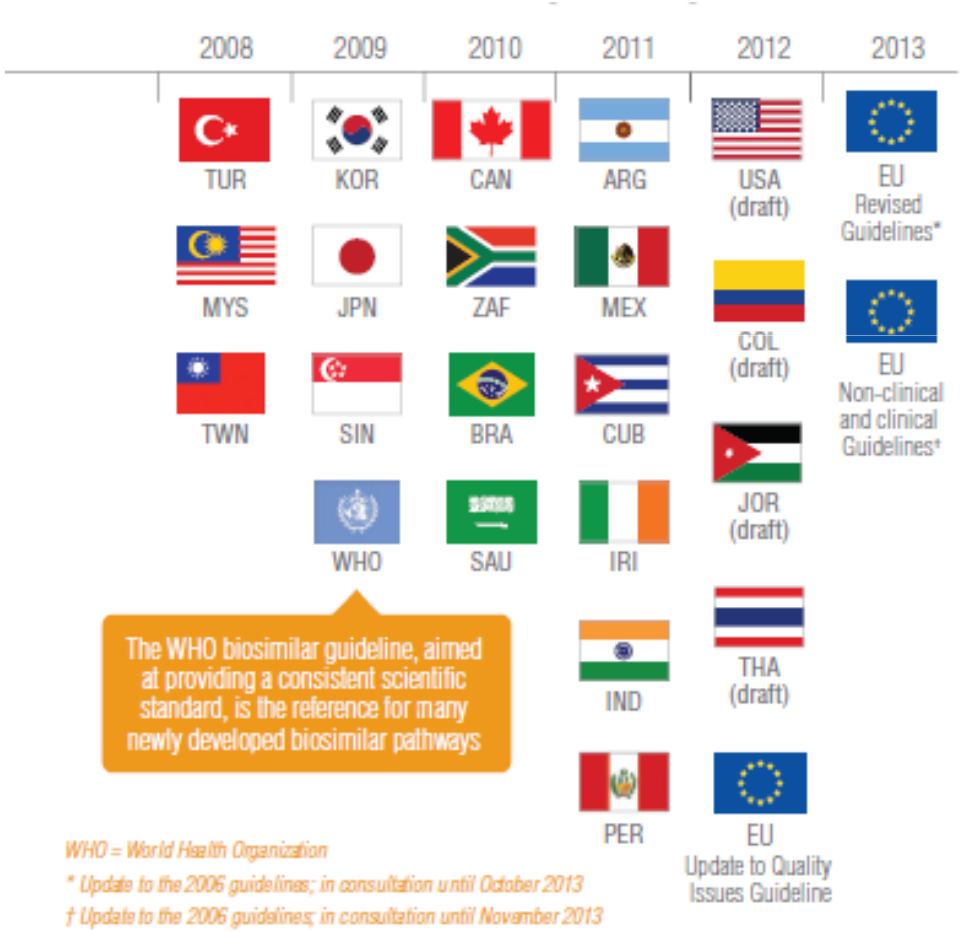
Neupogen (filgrastim)

Rituxan / MabThera (rituximab)

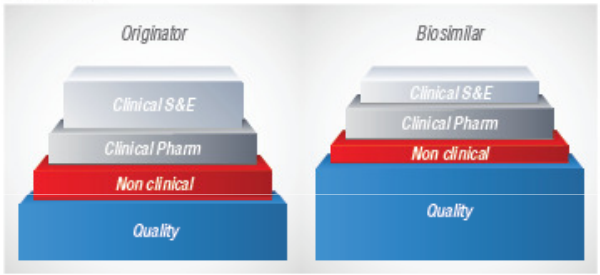
THE MANUFACTURING, REGULATORY, AND COMMERCIAL ISSUES

- Pose significant challenges and leave their short- and medium-term success an open question
- However, given the widespread adoption of small-molecule generics, these issues will not necessarily preclude the long-term acceptance and uptake of biosimilars
- Medical practices and reimbursement procedures will evolve to be more receptive to the use of biosimilars over time, assuming that experience with them is favorable

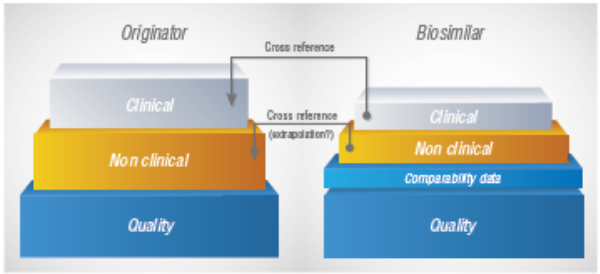
Biosimilar Regulations



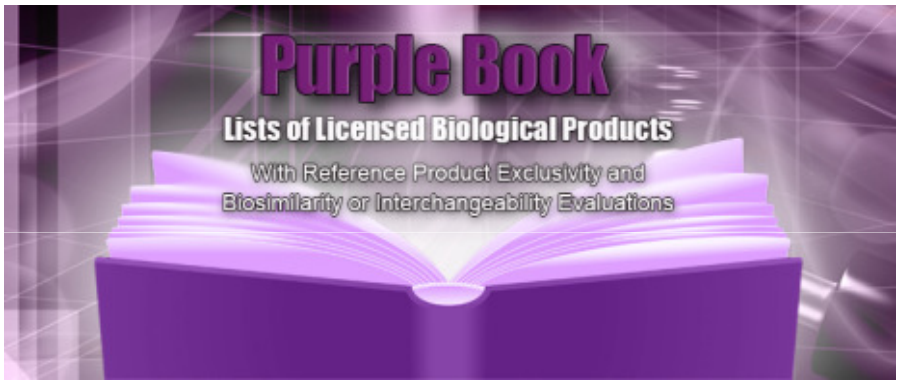
United States



European Union



FDA throws the (Purple) Book at biosimilars - Purple v. Orange (sept 2014)



orangebook
SEARCH FDA DRUG DATABASE

- Valuable reference tool in developing a biosimilar or interchangeable biologic product
- Lists biological products, including any biosimilar and interchangeable biological products licensed by FDA
- Orange Book lists small molecule reference listed drugs and their approved counterpart generic drugs

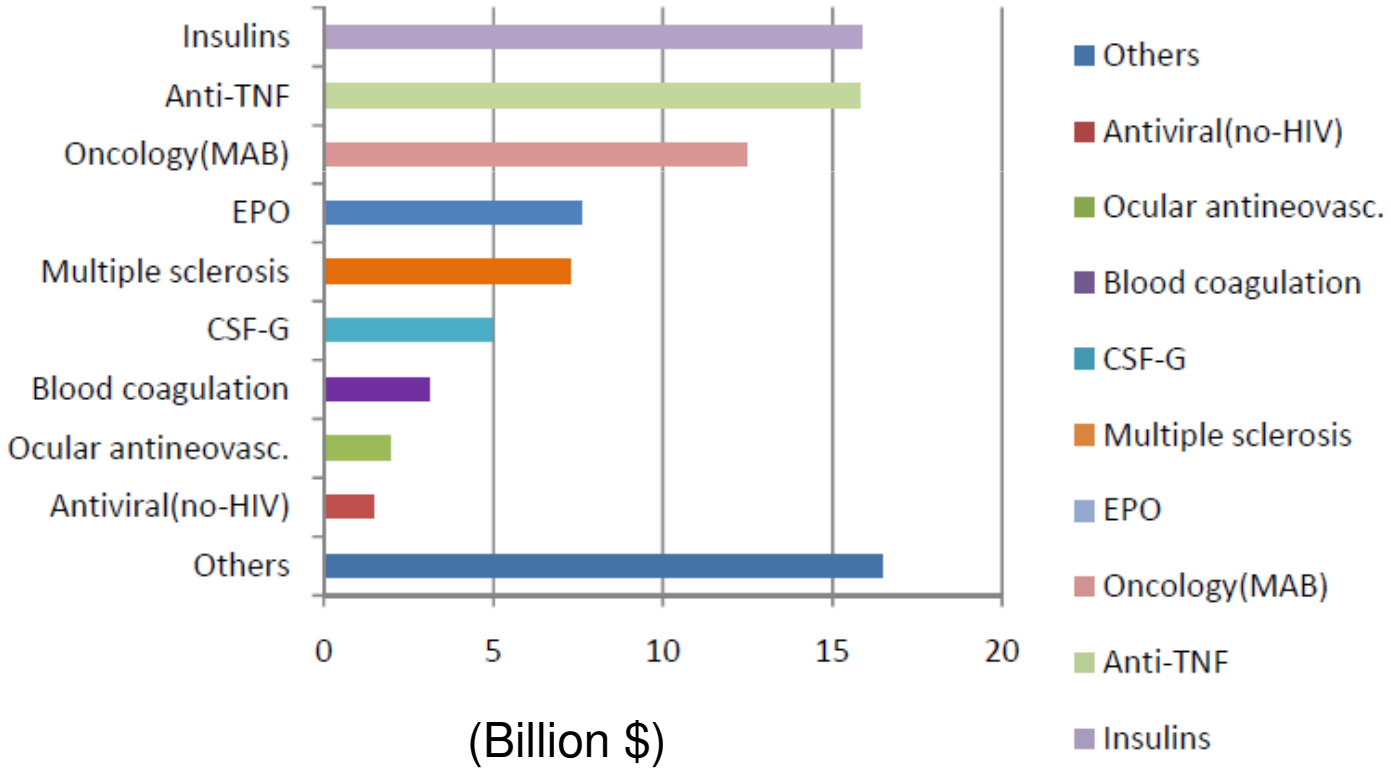
MARKET ATTRACTIVENESS SCORING AND SOLUTIONS

Parameter	Regulated markets	Semi-Regulated markets	Un-regulated markets	Market solution
Cost of R&D/ Production	Unfavorable	Favorable	Favorable	As market matures, international companies should shift R&D/ Production to semi- regulated markets
Manufacturing and Clinical Trial Capabilities	Favorable	neutral	Unfavorable	MNCs are pursuing partnerships with firms in low cost locations, for access to low cost manufacturing capabilities
Government Support of Industry	neutral	Favorable	Neutral	Numerous Biosimilars companies are coming up in countries with supportive governments for the sector such as India
Regulatory Rigidity	Unfavorable	neutral	Favorable	Pharmaceutical giants are navigating difficult regulatory paths in developed markets, while smaller companies are targeting developing countries
Attractiveness of Biosimilars to Physician/ Consumers	Favorable	neutral	Unfavorable	Due to the size and market potential of US and Europe, companies are patiently waiting for higher product adoption, while also aggressively marketing to developing countries

Sruthi Konangi et al /Int.J.PharmTech Res.2013,5(3)

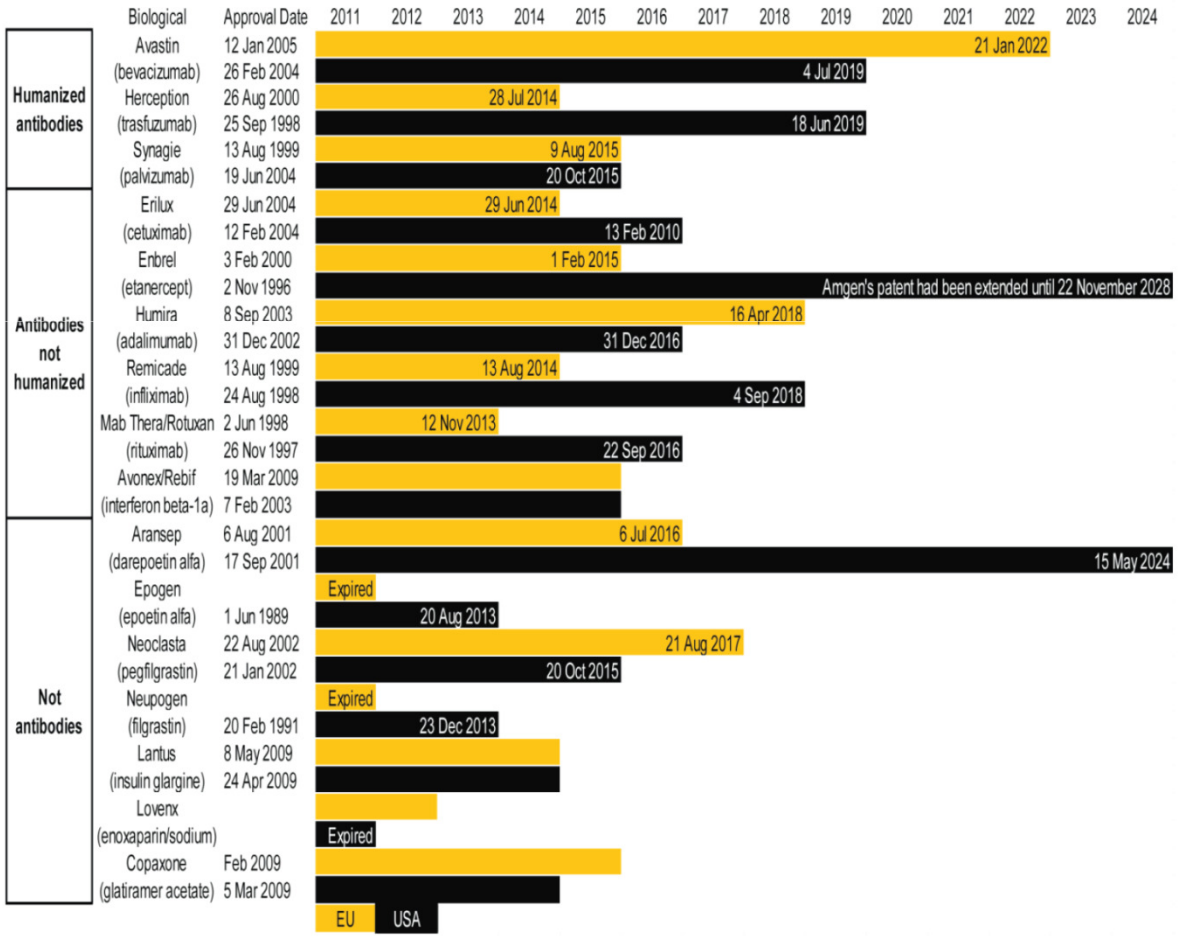
CORE THERAPY AREA IN BIOLOGICS

2015	2020
1,9-2,6 Bil US$	11-25 Bil US$



International Journal of PharmTech Research, Vol.5, No.3, pp 924-935, July-Sept 2013

BEST SELLING BIOLOGICS-UP TO ?



RISE OF SIMILAR BIOLOGICS IN INDIA

"SIMILAR BIOLOGICS" APPROVED IN INDIA

Product Name	Active Substance	Therapeutic Area	Company
Alzumab	Itolizumab	Psoriasis	Biocon
Basalog	Insulin glargine	Diabetes	Bicon
BioMab EGFR	Nimotuzumab	Head and Neck Cancer	Biocon
CanMab	Trastuzumab	Breast Cancer	Biocon
Grafeel	Filgrastim	Neutropenia, hematopietic stem cell transplantation, cancer	Dr. Reddy"s
Insugen	Human Insulin	Diabetes	Biocon
MabTas	Rituximab	Lymphoma, Non Hodgkin's Lymphoma	Intas Biopharmaceuticals
Nufil	Filgrastim	Cancer, neutropenia	Biocon
Filgrastim	Filgrastim	Neutropenia	Lupin
Peg-filgrastim	Pegfilgrastim	Cancer, neutropenia	Lupin
Peg-grafeel	Pegfilgrastim	Cancer, neutopenia	Dr. Reddy"s
Reditux	Rituximab	Leukemia, Lymphoma, Rheumatoid Arthritis	Dr. Reddy"s
Relibeta	Interferon beta-1a	Multiple Sclerosis	Reliance Life Sciences
Religrast	Filgrastim	Neutropenia	Reliance Life Sciences
Rituximab	Rituximab	Non-Hodgkin's lymphoma	Zenotech Laboratories

BICON (APRIL 2014 INVESTOR REPORT) : WORKING ON BIOSIMILAR VERSIONS OF BEVACIZUMAB (AVASTIN), ADALIMUMAB (HUMIRA), ETANERCEPT (ENBREL), PEG-FILGRASTIM (NEULASTA), RH-INSULIN, GLARGINE, LISPRO AND ASPART.

PATIENT SAFETY FIRST- TRANFORMING LIFE

- Worldwide, nearly 200 biologic medicines have transformed the lives of over 800 million patients with serious illnesses
- A “True” Biosimilar with a SMART approach
- Authorized biosimilars should be “as good, safe and efficacious as originator biologics.”




THANK
YOU !