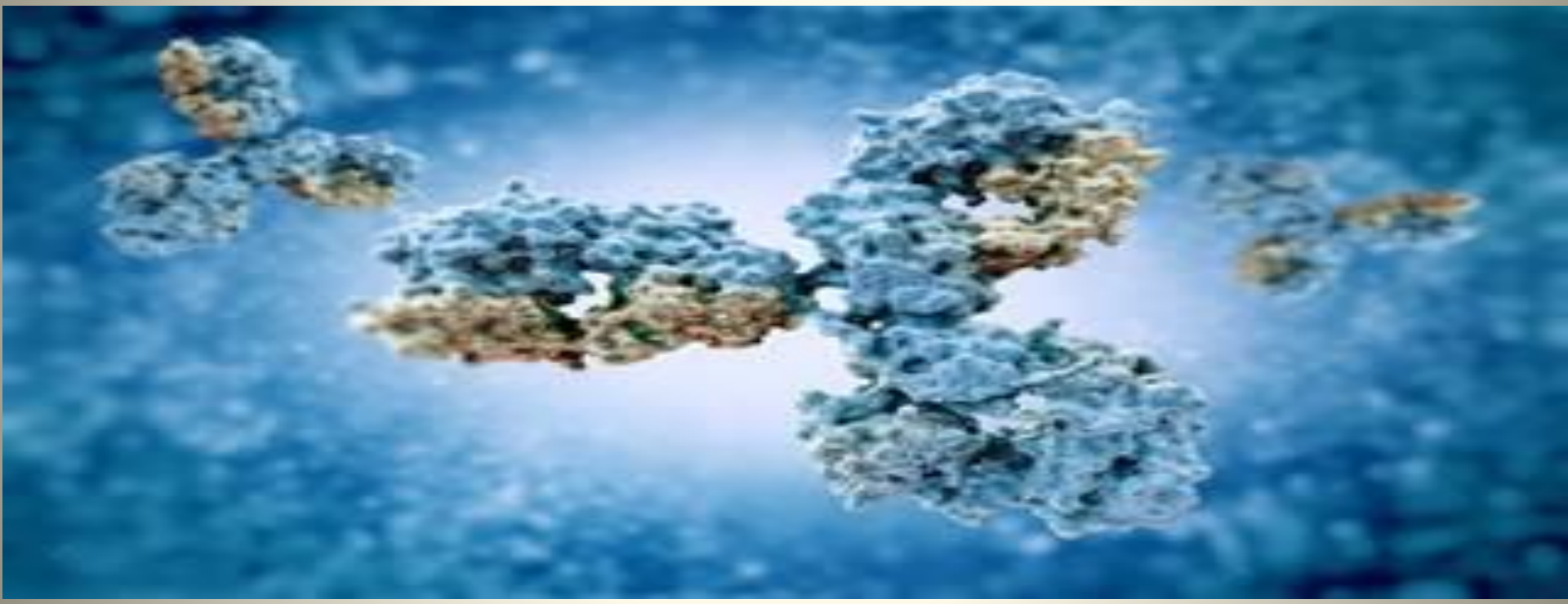
Global Biosimilar Market: Growth, Trends and Forecast 2021



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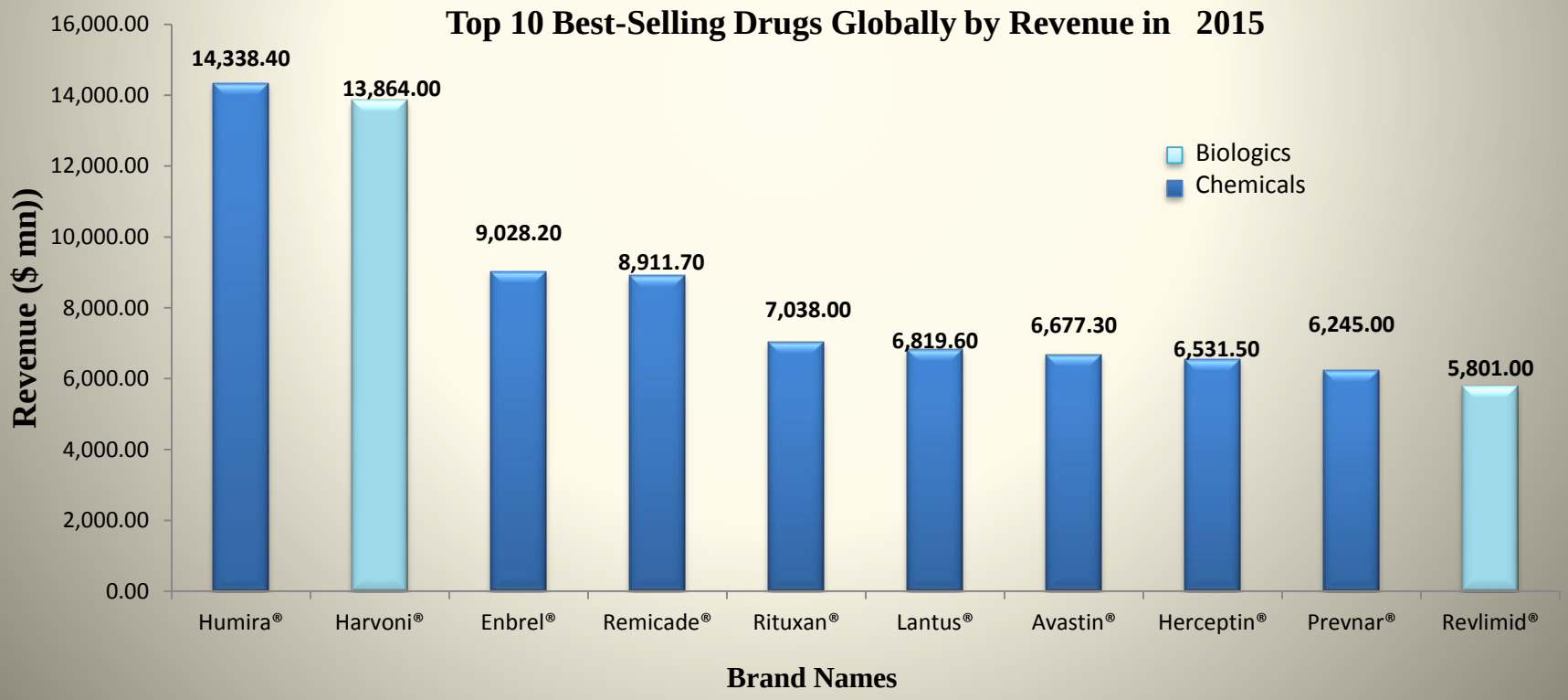
Agenda

- Introduction
- Research Question & Objectives
- Methodology
- PEST
- Market Overview
- Market Segmentation
- Regulatory Landscape
- Market Drivers & Restraints
- SWOT
- Conclusion

Introduction

- Biologics are reforming the treatment of diseases in many major therapeutic areas globally.
- Out of the top 10 selling pharmaceuticals in 2015, 8 were biologics.
- Major challenges faced by the industry is high cost of therapies.



Research Question

- What is the market potential of Biosimilars or Follow-on biologics?

Objectives

- To understand the regulatory framework in developed and emerging markets for the Biosimilars.
- To analyze the market growth of biosimilars in terms of its therapeutic area and geographical regions.
- To identify the key factors like strength, weakness, opportunities and threats which can influence the market growth.

Methodology

Type of study:

- Descriptive, Secondary / Desk Research

Data Collection Tool:

- Information is collected from a number of publicly available as well as organizations financial reports, and market research reports.
- Public sources involve publications by different associations and governments, annual reports and statements of companies, white papers and research publications by recognized industry experts and renowned academia etc.
- A observational study is done by data collection involving existing records.

Statistical Analysis Software:

- MS Excel

Study Duration:

- Three months

P

- Government pressure on FDA to fasten the approval rate of pipeline products
- Affordable healthcare

E

- Dependence on the financial market as well government funding to invest on research and development process
- Variation in currency

S

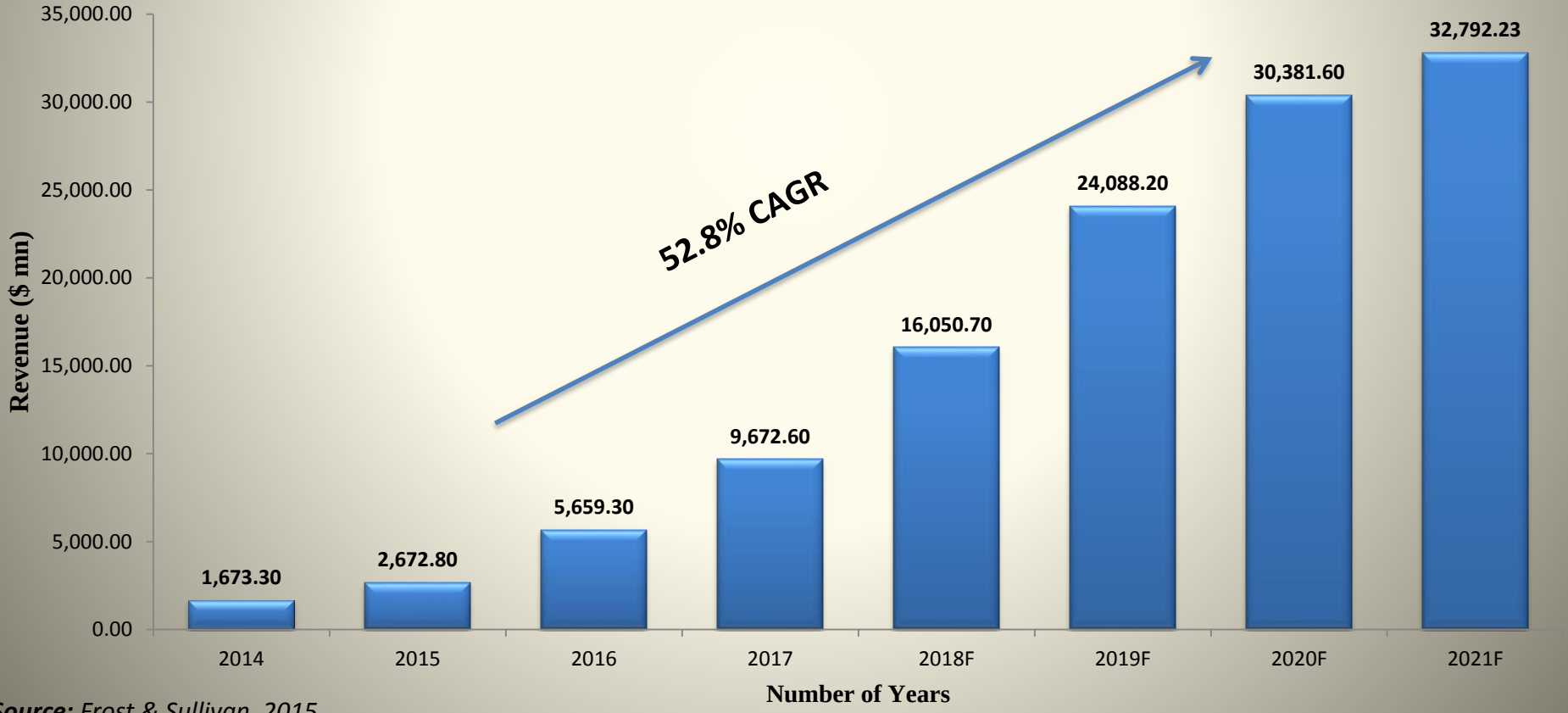
- Demographic changes: age, disease profile, wealth distribution

T

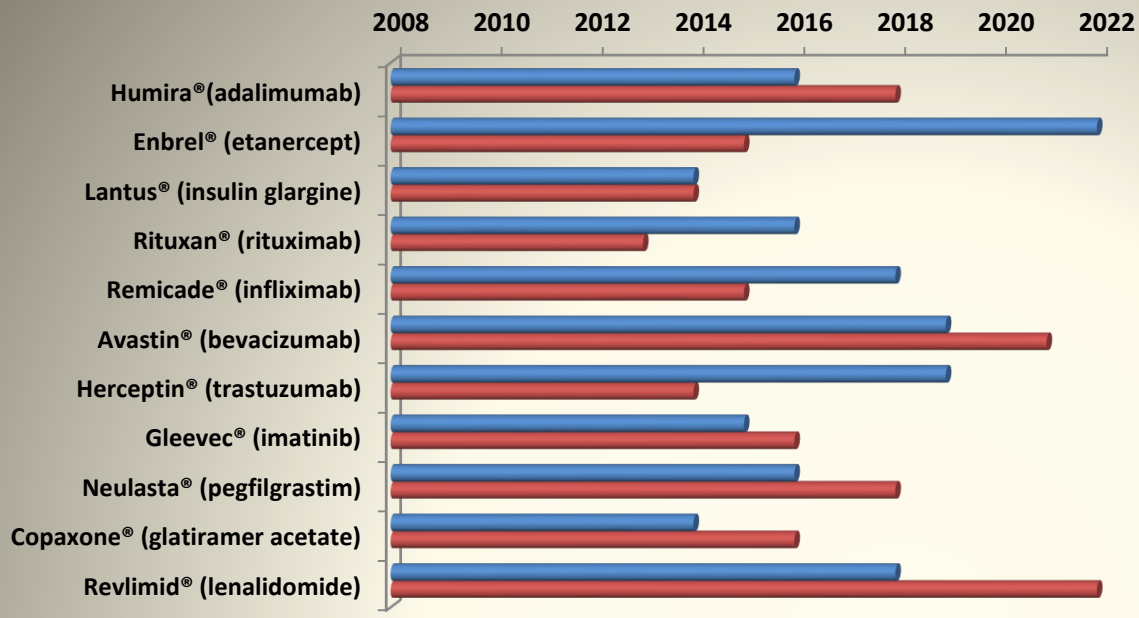
- Advancements in DNA recombinant technologies
- Cost-effective disposable bioreactors has added to reduce the idle time production time

Market Overview

- To overcome the escalating healthcare cost and provide accessibility to lifesaving medicines, biosimilars will play a significant role in the approaching future.

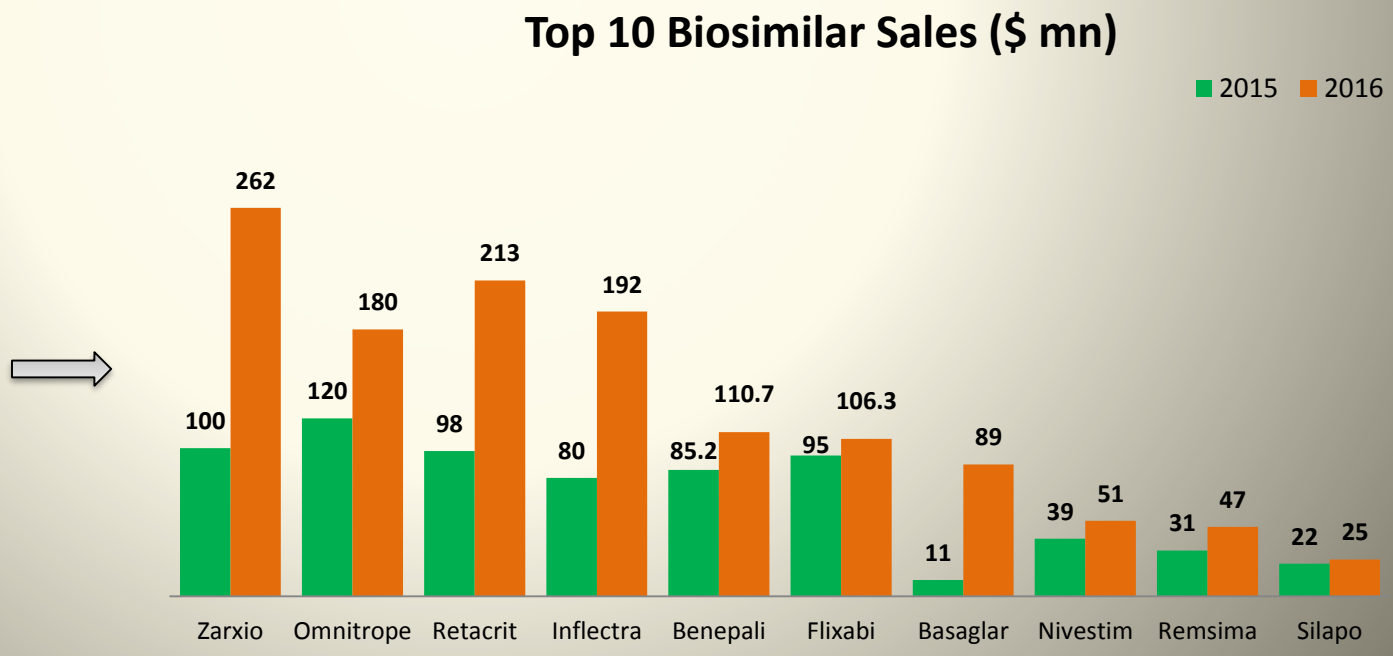


Source: *Frost & Sullivan, 2015*



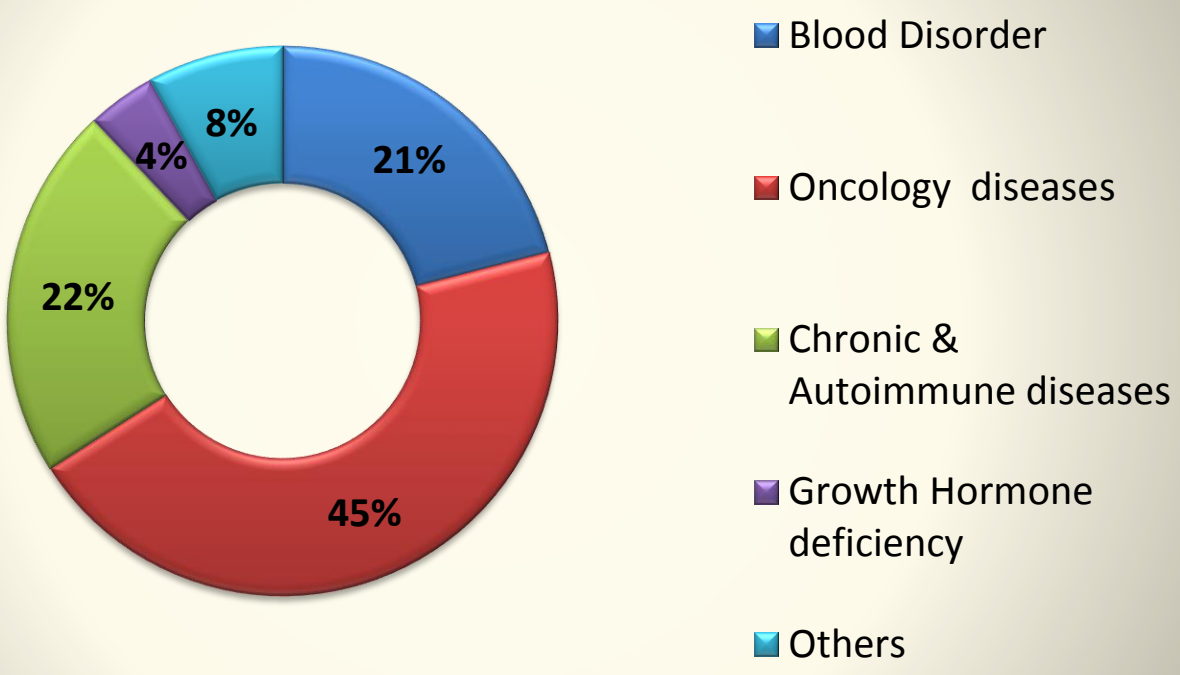
Biologics soon going to expire, opens the gate for biosimilars development

Sales revenue of top biosimilars products



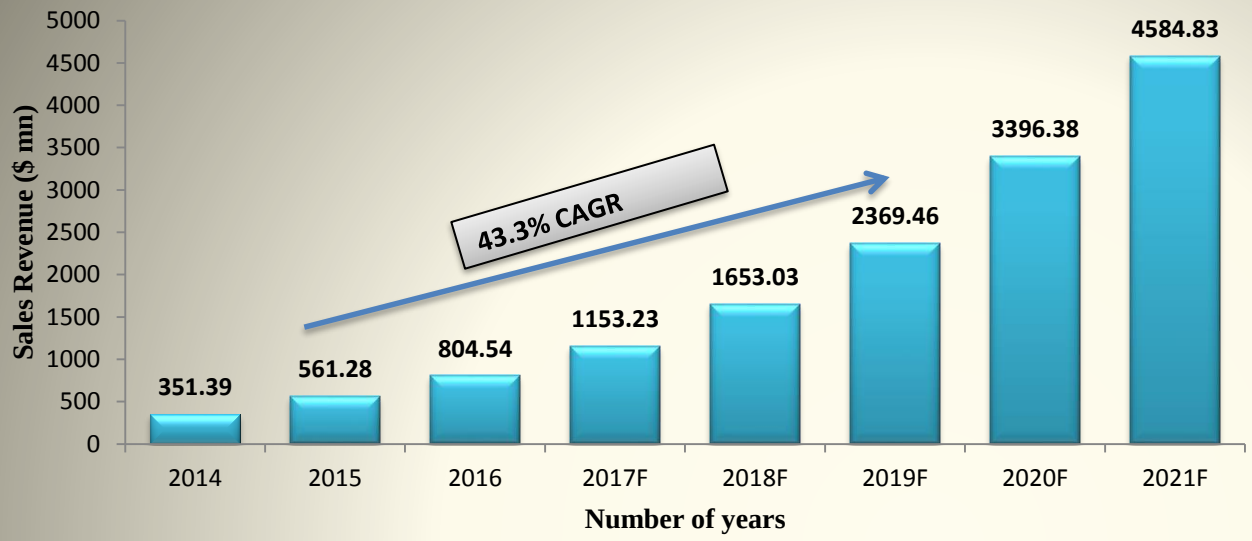
Source: Evaluate Database 2016

Global Biosimilars / Follow-On-Biologics Market by Therapeutic Area

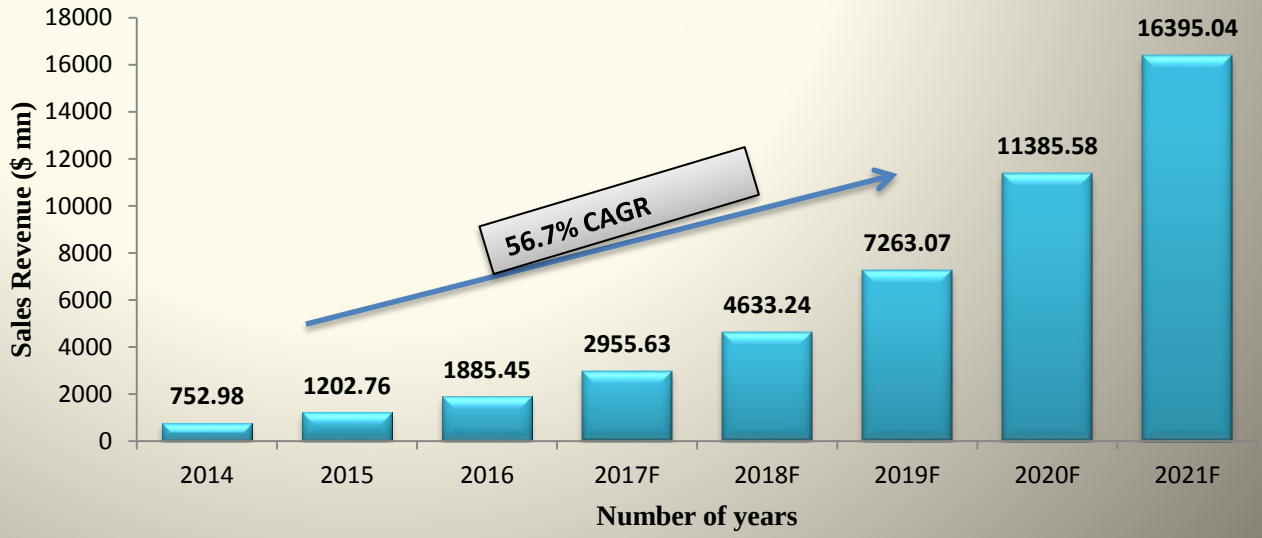


- Oncology biosimilars has captured the biggest market share, followed by autoimmune diseases.
- Market share of growth hormones is the lowest

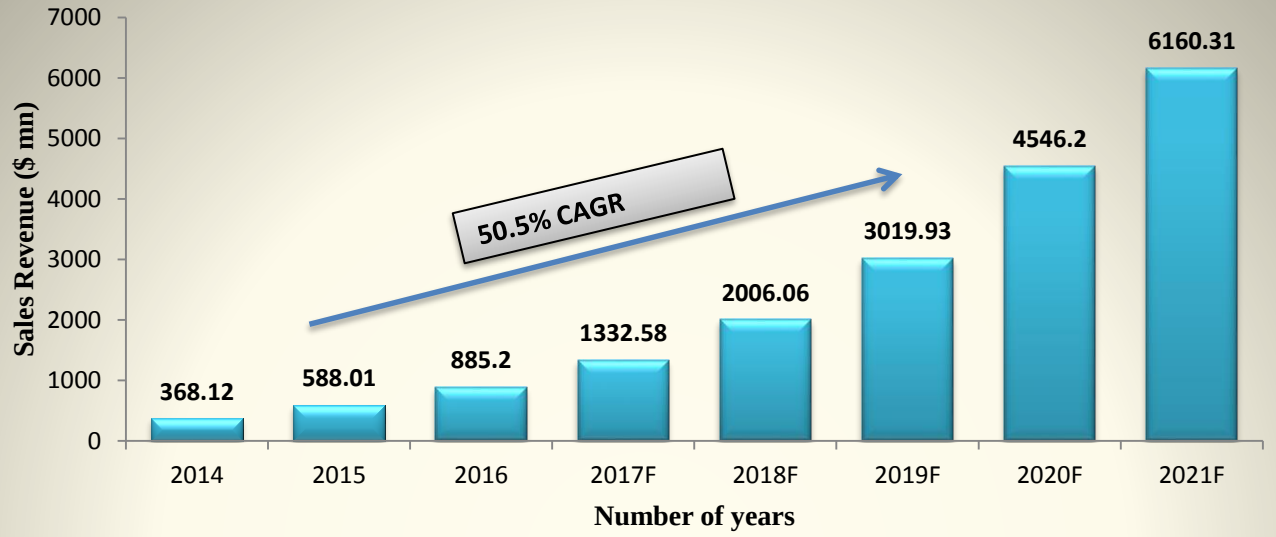
Blood Disorders



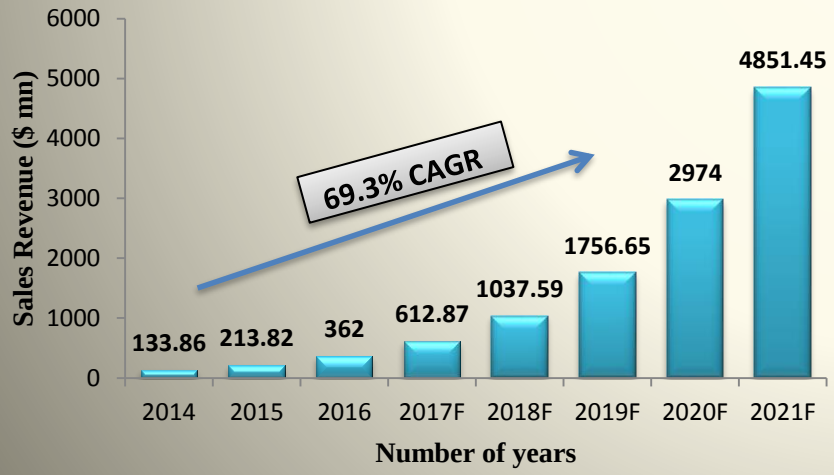
Oncology Diseases



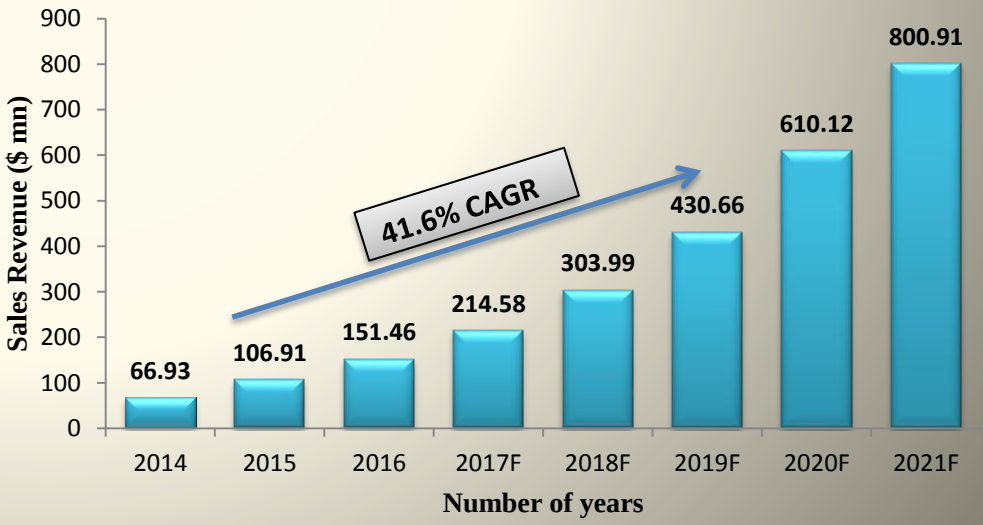
Chronic and Autoimmune Diseases



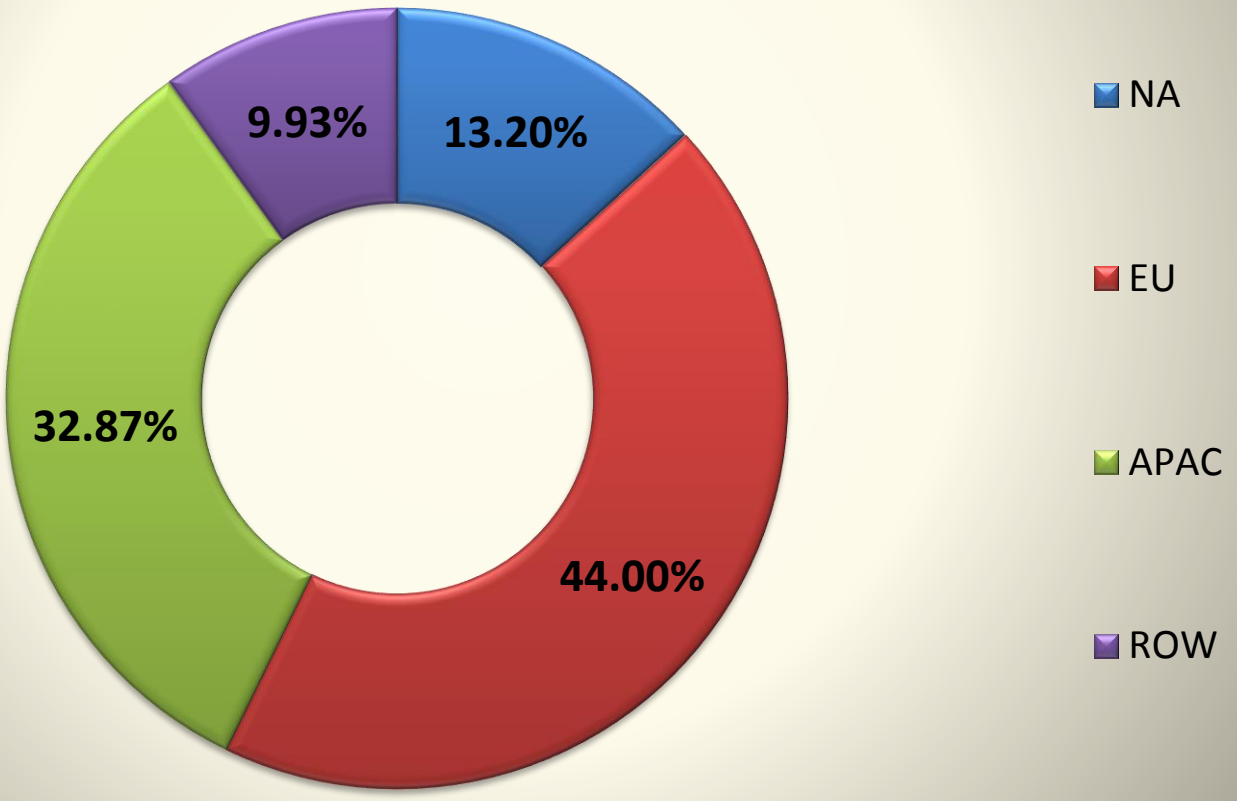
Others

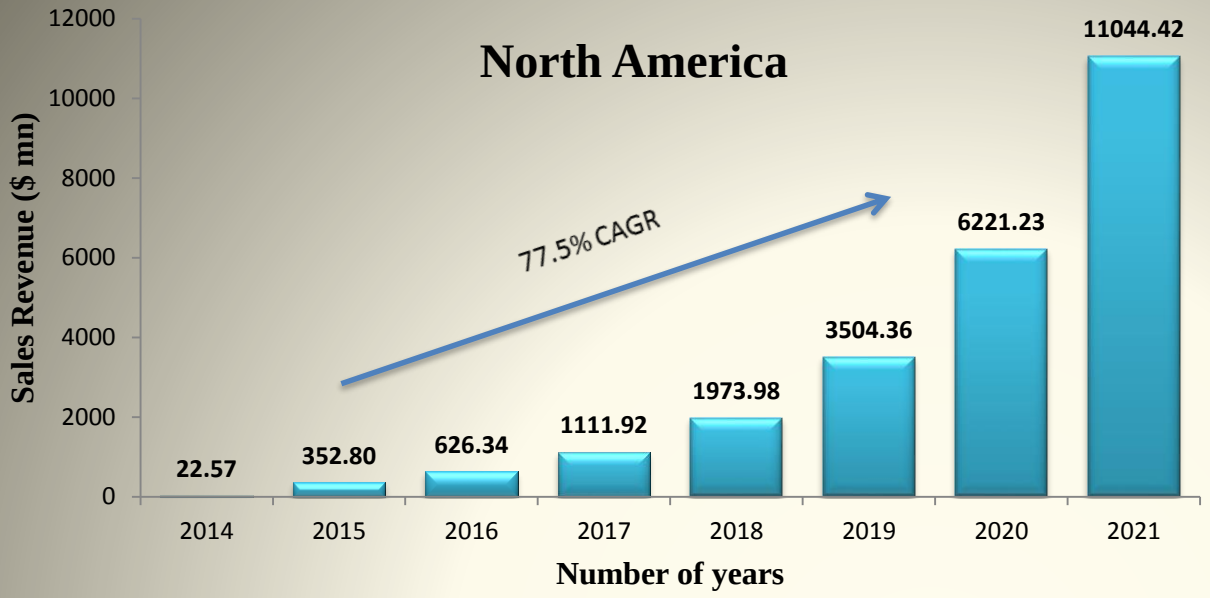


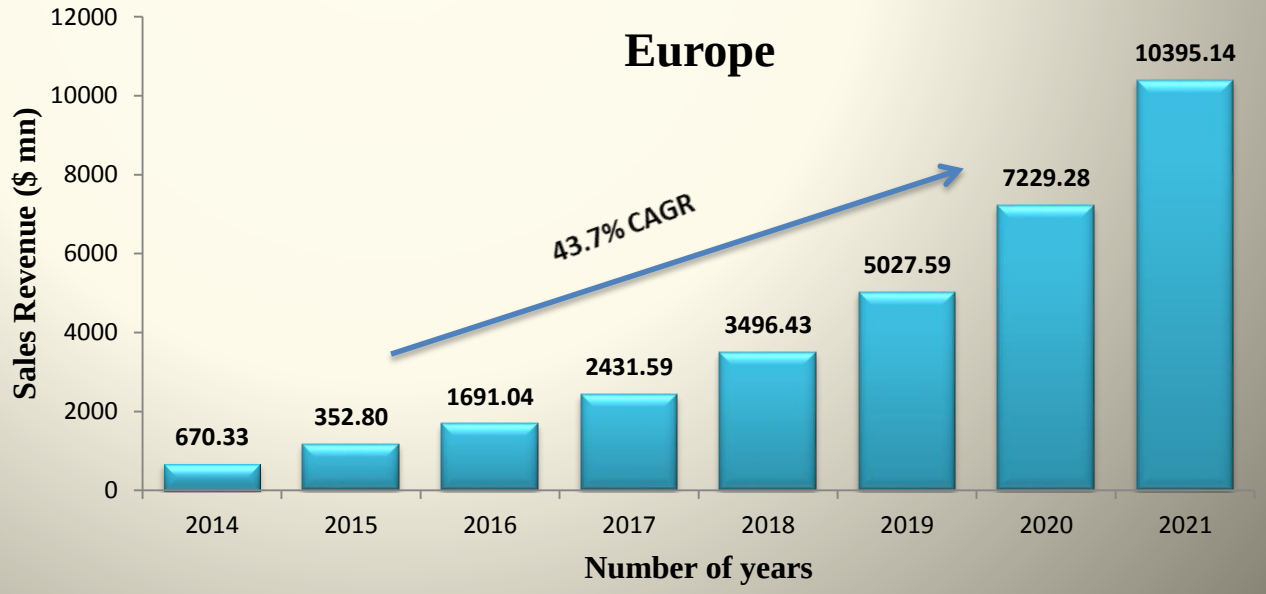
Growth Hormone Deficiency

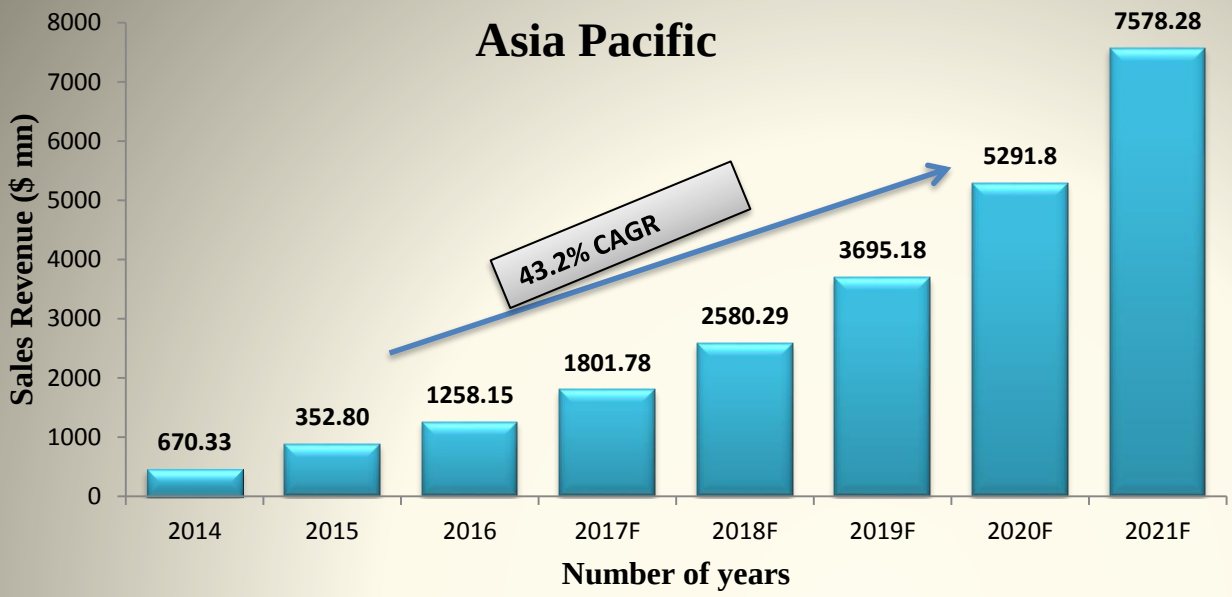


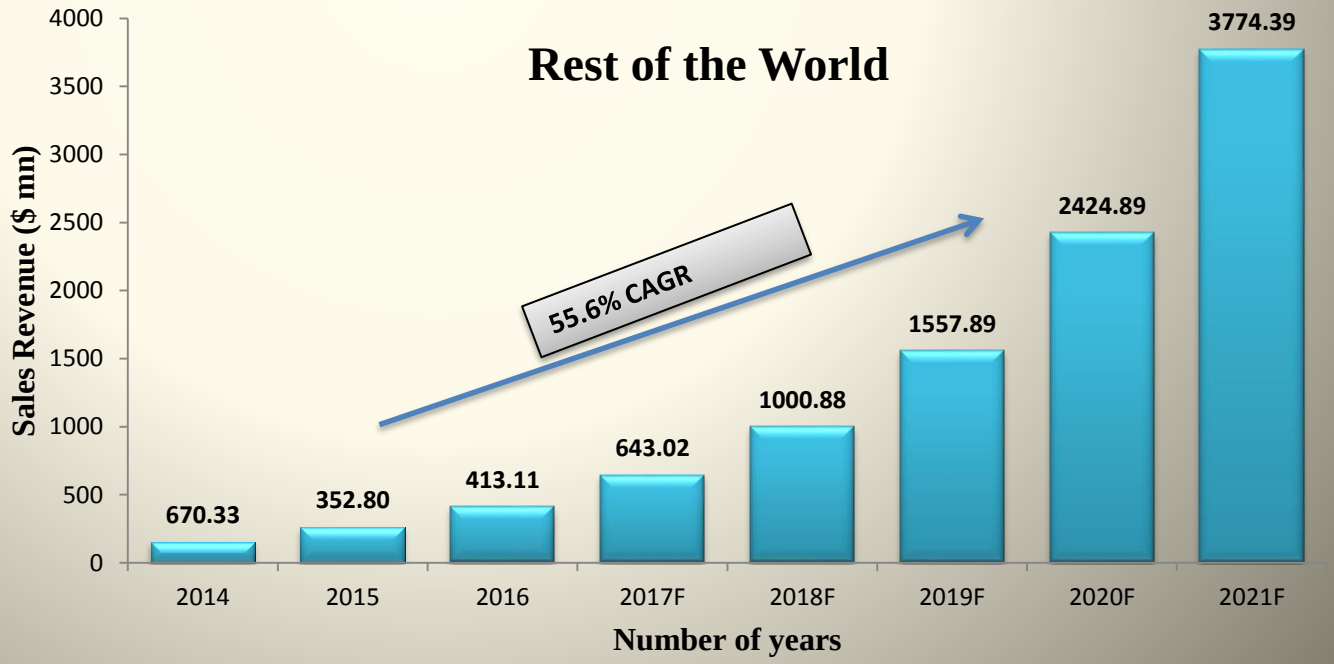
Global Biosimilars or Follow-On-Biologics Market by Geography




North America
Sales Revenue ($ mn)
12000
10000
8000
6000
4000
2000
0
77.5% CAGR
22.57
352.80
626.34
1111.92
1973.98
3504.36
6221.23
11044.42
2014
2015
2016
2017
2018
2019
2020
2021
Number of years


Europe
Sales Revenue ($ mn)
12000
10000
8000
6000
4000
2000
0
43.7% CAGR
670.33
352.80
1691.04
2431.59
3496.43
5027.59
7229.28
10395.14
2014
2015
2016
2017
2018
2019
2020
2021
Number of years


Asia Pacific
Sales Revenue ($ mn)
8000
7000
6000
5000
4000
3000
2000
1000
0
670.33
352.80
1258.15
1801.78
2580.29
3695.18
5291.8
7578.28
43.2% CAGR
2014
2015
2016
2017F
2018F
2019F
2020F
2021F
Number of years


Rest of the World
Sales Revenue ($ mn)
4000
3500
3000
2500
2000
1500
1000
500
0
670.33
352.80
413.11
643.02
1000.88
1557.89
2424.89
3774.39
55.6% CAGR
2014
2015
2016
2017F
2018F
2019F
2020F
2021F
Number of years

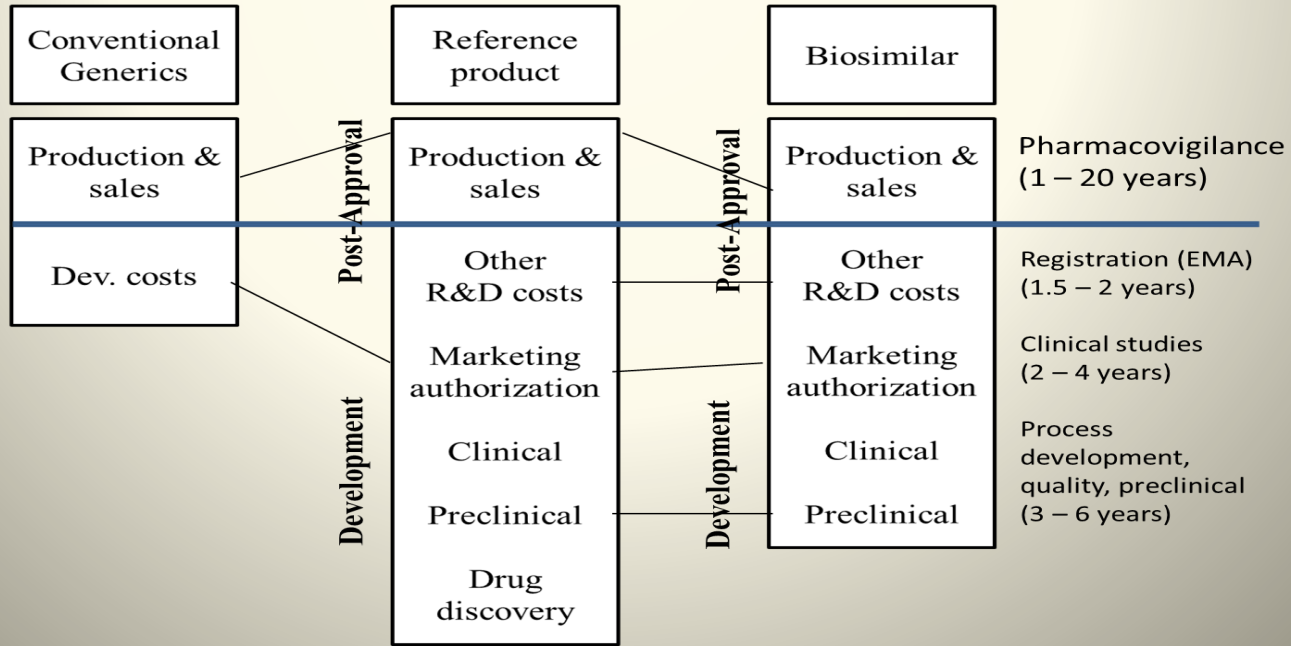
Regulatory Landscape

- Large and complex nature of biosimilars cannot be guaranteed to be identical to innovator biologics, which is a concern for the regulatory bodies to ensure the safety, efficacy and quality of the product.
- Guidelines have been issued in many countries for the biosimilars approval but still there is an existence of lack of transparency.

Country	Year	Regulatory Pathway
Europe	2003/2004	Legal Framework
Australia	2008	Adopted EU Guidance
Japan	2009	Final Guideline
Korea	2009	Guidelines
USA	2010	Legal Framework
India	2012	Guidelines
China	2015	Guidelines

European Medicines Agency (EMA)

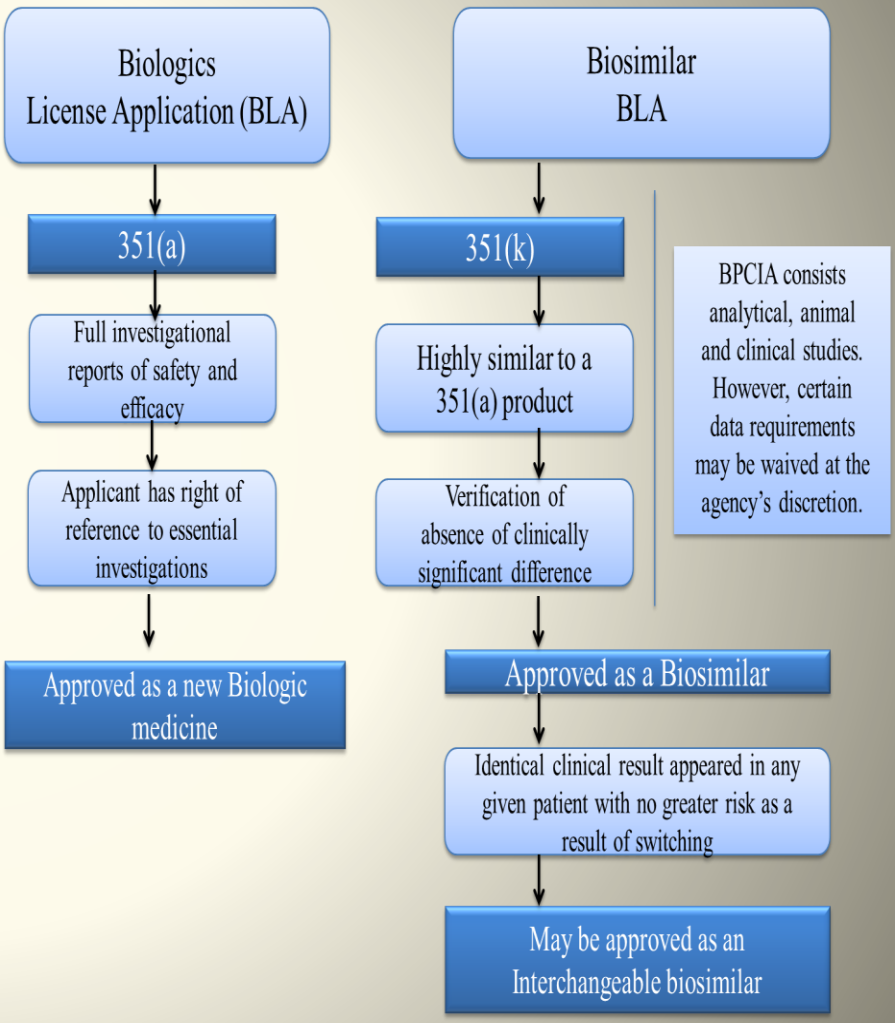
- EMA was the first to set up guidelines for a biosimilar
- The regulatory approval typically takes up to 6-8 years to reach into the markets
- First biosimilar was approved in Europe was Omnitrope® in 2006.
- Since than there are around 29 biosimilars are in the market



Active Substance	Name of biosimilar medicine	Date of European Commission authorization	Marketing authorization holder	Reference Product
SOMATROPIN	Omnitrope®	12-04-06	Sandoz	Genotropin®
EPOTIN	Abseamed®	28-08-07	Medice	Erypo®/Eprex®
	Binocrit®	28-08-07	Sandoz	
	Epoetin alfa HEXAL®	28-08-07	Hexal	
	Retacrit®	18-12-07	Hospira	
	Silapo®	18-12-07	Stada	
FILGRASTIM	Biograstim®	15-09-08	AbZ-Pharma	Neupogen®
	Ratiograstim®	15-09-08	Ratiopharm	
	TevaGrastim®	15-09-08	Teva	
	Filgrastim HEXAL®	06-02-09	Hexal	
	Zarzio®	06-02-09	Sandoz	
	Nivestim®	08-06-10	Hospira	
	Grastofil®	18-10-13	Apotex	
	Accofil®	18-09-14	Accord Healthcare	
INFLIXIMAB	Inflectra®	10-09-13	Hospira	Remicade®
	Remsima®	10-09-13	Celltrion	
FOLLITROPIN ALPHA	Ovaleap®	27-09-13	Teva	Gonal f®
	Bemfola®	27-03-14	Finox Biotech	
INSULIN GLARGINE	Abasaglar®	09-09-14	Eli Lilly	Lantus®
ETANERCEPT	Benepali®	18-01-16	Samsung Bioepis	Enbrel®

US Food and Drug Administration

- The Biologics Price Competition and Innovation Act (BPCIA) were registered into law in 2010, approval pathway.
- First biosimilar approved by US FDA was Sandoz Inc.'s Zarxio® on 2015.
- Biosimilars can get approval by using the abbreviated pathway under section 351(k) of Public Service Act under BPCIA (Biologics Price Competition and Innovation Act of 2009)



Source: *Trends in Biosimilar Report, Amgen 2017*

Biosimlars approved by US FDA

S. No.	Active substance	Name of Biosimilar medicine	Date of US FDA authorization	Marketing authorization holder	Reference product
1.	FILGRASTIM	Zarxio®	3/6/2015	Sandoz	Neupogen®
2.	INFLIXIMAB	Inflectra®	4/5/2016	Pfizer	Remicade®
3.	ETANERCEPT	Erelzi®	8/30/2016	Sandoz	Enbrel®

Source: *US FDA, 2016*

India

- Product Development
- Animal Toxicity Studies
- Clinical Trials
- Marketing and Manufacturing License
- 1st three commercial batches needs to be tested by NIB
- Post Approval Committee

Procedure	Time Period
RCGM approval for pre-clinical animal studies	45 days
DCGI approval for Human Clinical Trials protocol	45 days
DCGI examination of clinical trial data and response	90 days
DCGI & GEAC decisions (simultaneous)	45 days

Regulatory pathway for biosimilars in India

List of biosimilars approved in India

Company name	Product name	Active substance	India launch year
Biocon	Basalog	Insulin glargine	2009
Wockhardt	Biovac	Hepatitis b	2000
Wockhardt	Wepox	Epoetin alfa	March 2001
Wockhardt	Wosulin	Human insulin	13 August 2003
Sb/merieux alliance	Shanferon	Interferon alpha	2 April 2002
Sb/merieux alliance	Shanpoietin	Erythropoietin	January 2005
Sb/merieux alliance	Shankinase	Streptokinase	June 2004
Dr. reddy laboratories	Reditux	Rituximab	30 April 2007
Reliance life sciences	Relipoietin	Epotein alfa	2008

South Korea

- Twelve biosimilars have been approved and another 36 biosimilars are presently in the pipeline.
- To win the race in the domain of high-risk and complex development of monoclonal antibody (mAb) biosimilars with 17 mAbs present in the pipeline.

S No.	Biosimilar	Approval Date	Name of Company
1.	Etanercept	8-Sep-15	Samsung Bioepis
2.	Etanercept	11-Nov-14	Hanwha Chemical
3.	Trastuzumab	15-Jan-14	Celltrion
4.	Somatropin	Jan-14	Sandoz
5.	Infliximab	23-Jun-12	Celltrion
6.	Infliximab	4-Dec-15	Samsung Bioepis

Market Drivers

Cost-effective health care

Raising demand for alternatives

Loss of exclusivity drives new potential

Therapeutic Area

Prescribers support

Restraints

Regulatory ambiguity

Lack of transparency and structured pathways

Manufacturing complexity

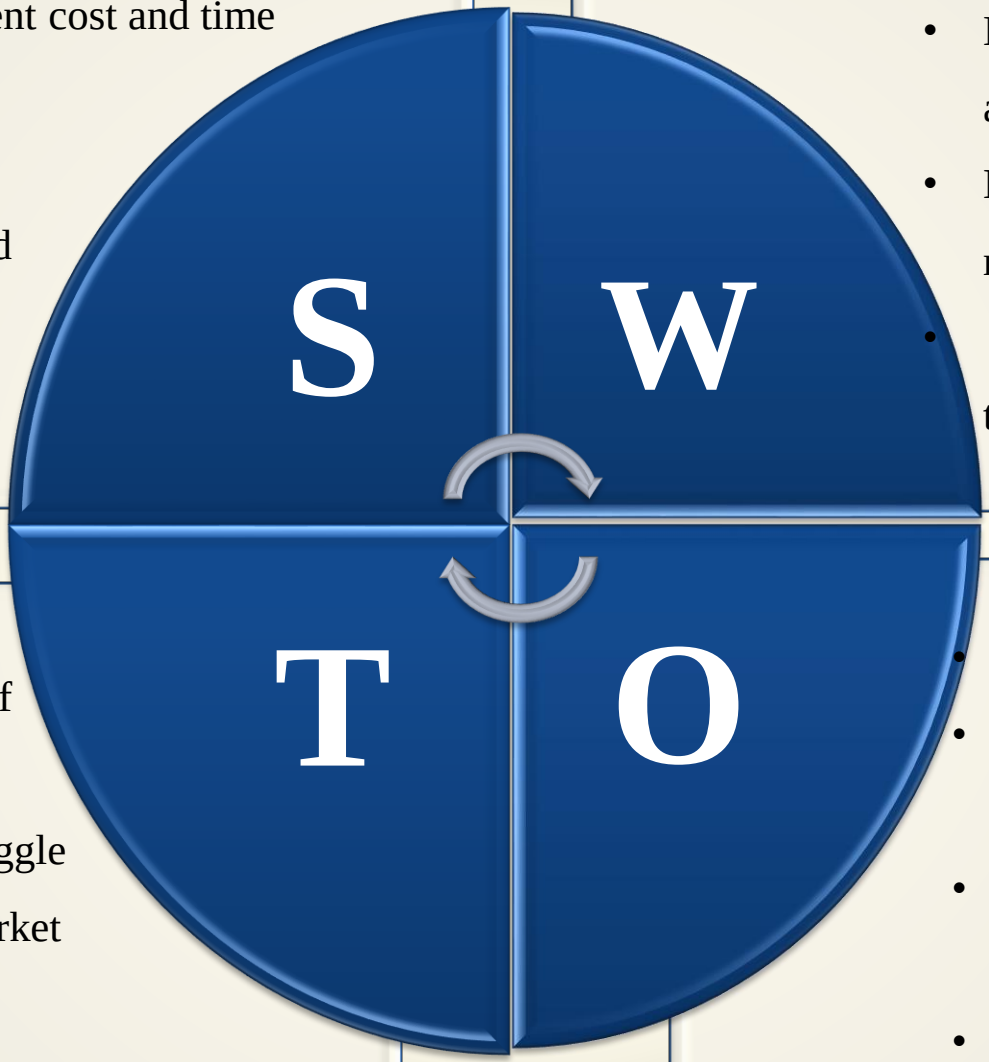
Complex as well as costly manufacturing

Competition

From generics, biologics

Reimbursement

Weak policies



- Cost effective
- Low development cost and time
- High ROI
- Easy approval
- Widely accepted
- Broad scope

- Ambiguity in regulatory framework
- Lack of awareness amongst Physicians
- Less affordable by middle-class
- Developing cost is more than small-molecule

- Large amount of investment
- Regulatory struggle in emerging market
- Heterogeneous regulatory environment

- Lack of accessibility
- Attention from the regulatory bodies
- Growth factor in biopharmaceuticals
- Alternative option used as life-saving

Conclusion

- Based on the study, biosimilars have an optimistic future ahead. It will provide an option of affordable alternatives of biologics. Regulatory bodies are majorly concern with the quality, safety and efficacy of the biosimilars. And to ensure that they are creating a pathway which is stringent as well as structured for the approval of the biosimilars.

Limitation of the study

- Literature review was time constrained and confined to the English language for the publically available secondary data, reports and other published documents.
- The result found may not be sufficient enough to proclaim any solid affirmation for the geographic or therapeutic opportunity.
- Status of study parameters may amend on continuous basis.


Thank You