

PEST and NET analysis of biopharmaceutical industry

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- Biopharmaceutical industry is also called as biologic medical industry. It is distinct from chemically synthesized pharmaceutical products from petrochemical materials. Some representative products are biosimilars, cell therapeutic medicine, natural material-based medicine, vaccines, allergenics, gene therapies, tissues, blood components, or recombinant therapeutic protein.

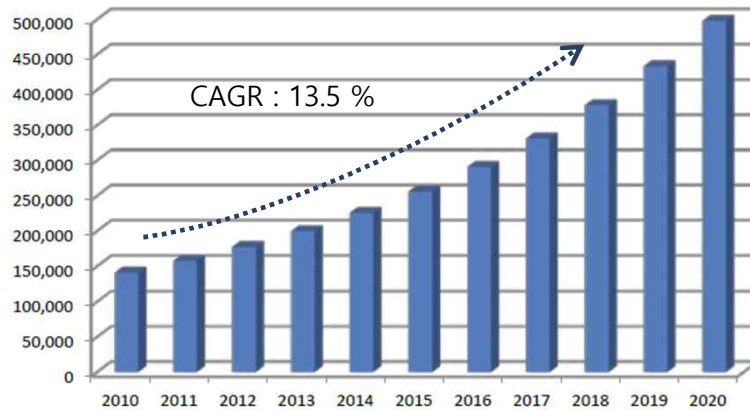


- source : <http://www.pmggroup-global.com/getattachment/b57c6a81-5f08-44f1-ab5a-792badc70196/GSK-Biologicals,-Singapore,-C-Q-of-Vaccines-Manufa.aspx>

ICI meeting 2015

December
13-15, 2015
Tel-Aviv, Israel

Global Market of Biologicals



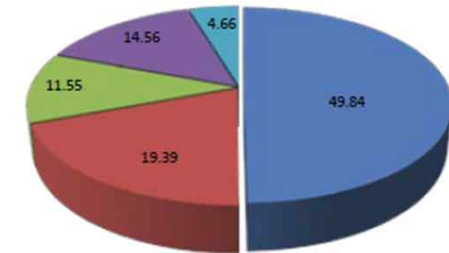
Year	2010	2011	2012	2013	2014	2015
Market size (unit : 0.1 billion\$)	1408	1577	1773	1997	2257	2558
Year	2016	2017	2018	2019	2020	
Market size (unit: 0.1 billion\$)	2906	3312	3784	4335	4979	

< global market size of biologicals >

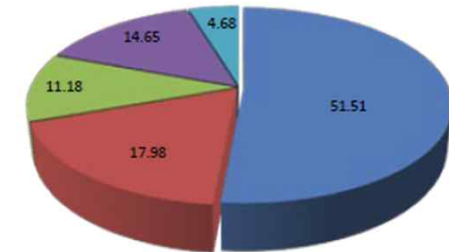
< global market share over regions of biologicals >

year	N. America	Europe	Asia-Pacific	S. America	Others	total
2010	49.84	19.39	11.55	14.56	4.66	100
2015	51.51	17.98	11.18	14.65	4.68	100
2020	53.62	16.83	10.63	14.34	4.58	100

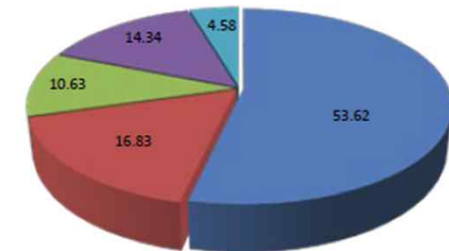
2010



2015



2020

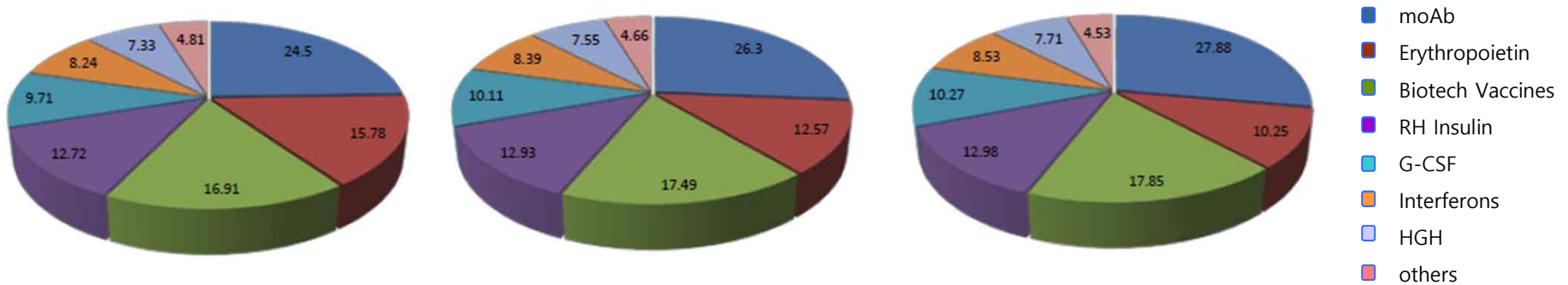


source : Industry Experts, 2013. 7

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Market Size of Biologicals



year	moAb	Erythropoietin	Biotech Vaccines	RH Insulin	G-CSF	Interferons	HGH	Misc.	total
2010	24.50	15.78	16.91	12.72	9.71	8.24	7.33	4.81	100
2015	26.30	12.57	17.49	12.93	10.11	8.39	7.55	4.66	100
2020	27.88	10.25	17.85	12.98	10.27	8.53	7.71	4.53	100

[Market Size over Products of Biologicals]

source : Industry Experts, 2013. 7

NET Analysis of Biologicals

Drivers & Restraints

- N** New concept target therapeutic agents needed
- N** Increasing orphan drug, self-immunity, cancer drug needs
- N** Increasing expectation of natural substance-based medicine
- E** Increasing marketing strategy from improved technology for effective results
- E** Increasing governmental policies for natural substance-based medicine
- T** Increasing Biosimilar R&D due to patent expiration
- T** Active R&D of natural substance-based therapeutic agents

Drivers

- N** Small number of products
- N** Difficult to get proper biomaterials
- E** Social, religious, and ethical issues
- E** Strict governmental regulation
- E** Private genetic info exposure
- T** highly efficient technology needed
- T** Limitation to discover new targets
- T** Lack of scientific proof regarding natural substance-based agents

Restraints

PEST Analysis of Biologicals

Social

- Aging population increase
- miniaturization, individualizing of bioeconomy paradigm shift
- Ethical issues in the process of securing biological resources
- low-cost health care due to growing healthcare needs (reevaluation of the efficacy of natural products)
- Scientification, standardization of natural substance for globalization
- Preparing for next generation biopharmaceutical drugs due to patent expiration

Economy

- Has analysed that biotechnology and bioeconomy gets serious
- Innovation and personalized medicine and income increase
- Reduction of efficacy of R&D investment in pharmaceutical industry
- Gradual strengthening of market entry for developing countries due to developed safety, efficacy, and manufacturing processes

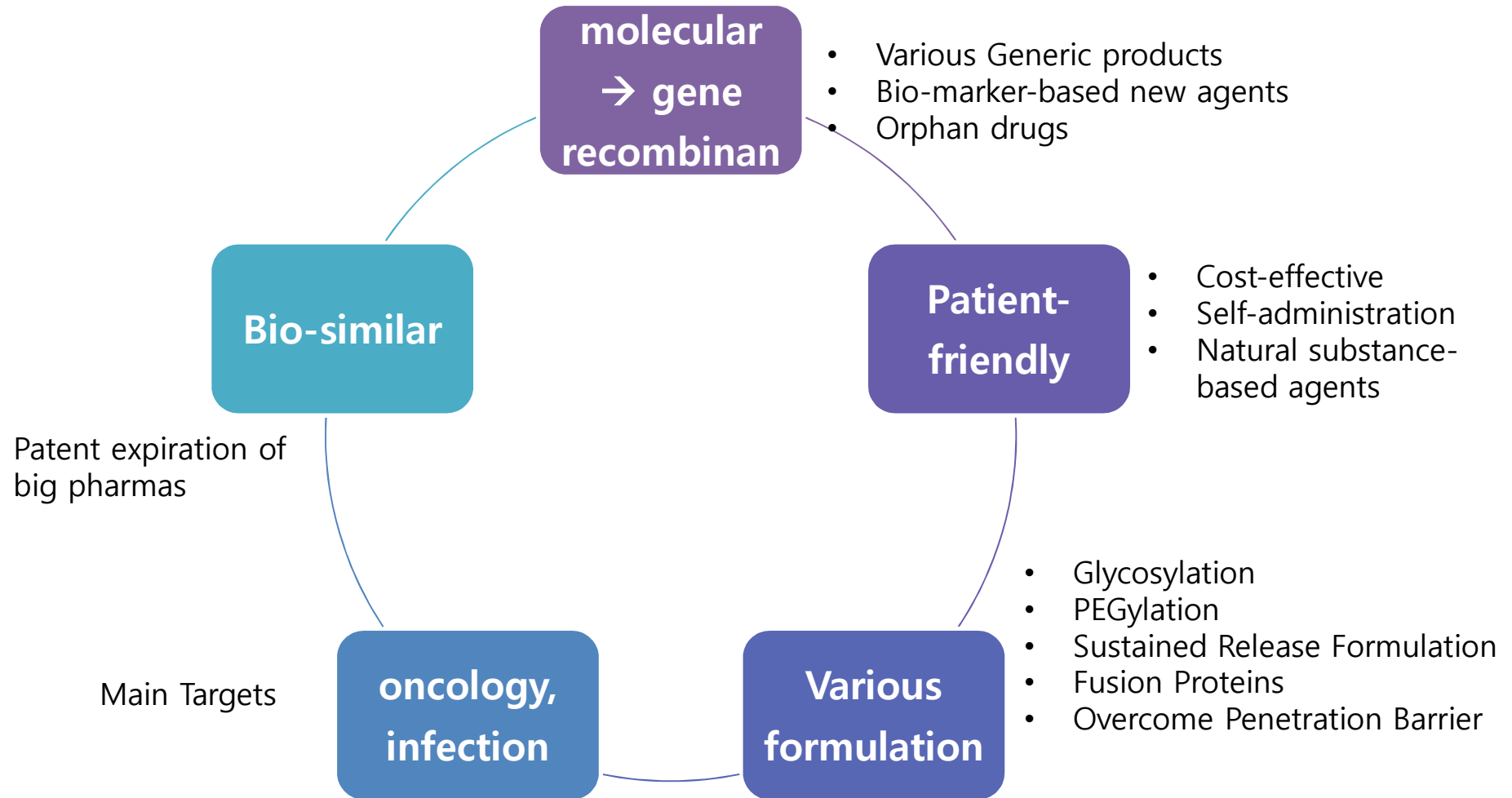
Policy

- Designate biopharmaceutical industry as a national growth engine sectors
- Various policies supporting biosimilar industry in accordance with the medical savings
- Not unified permit procedures among countries
- Overlapping investment of national research and development projects

Technology

- Low clinical trial success rates
- Difficult to find out initial target
- Absence of toxicity of active metabolites
- Stagnation of initial clinical phases due to immaturity of market
- Needs of complex understanding required for biosimilar technologies
- bio-safety issues for biosimilar products

Technological trend of biologicals



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