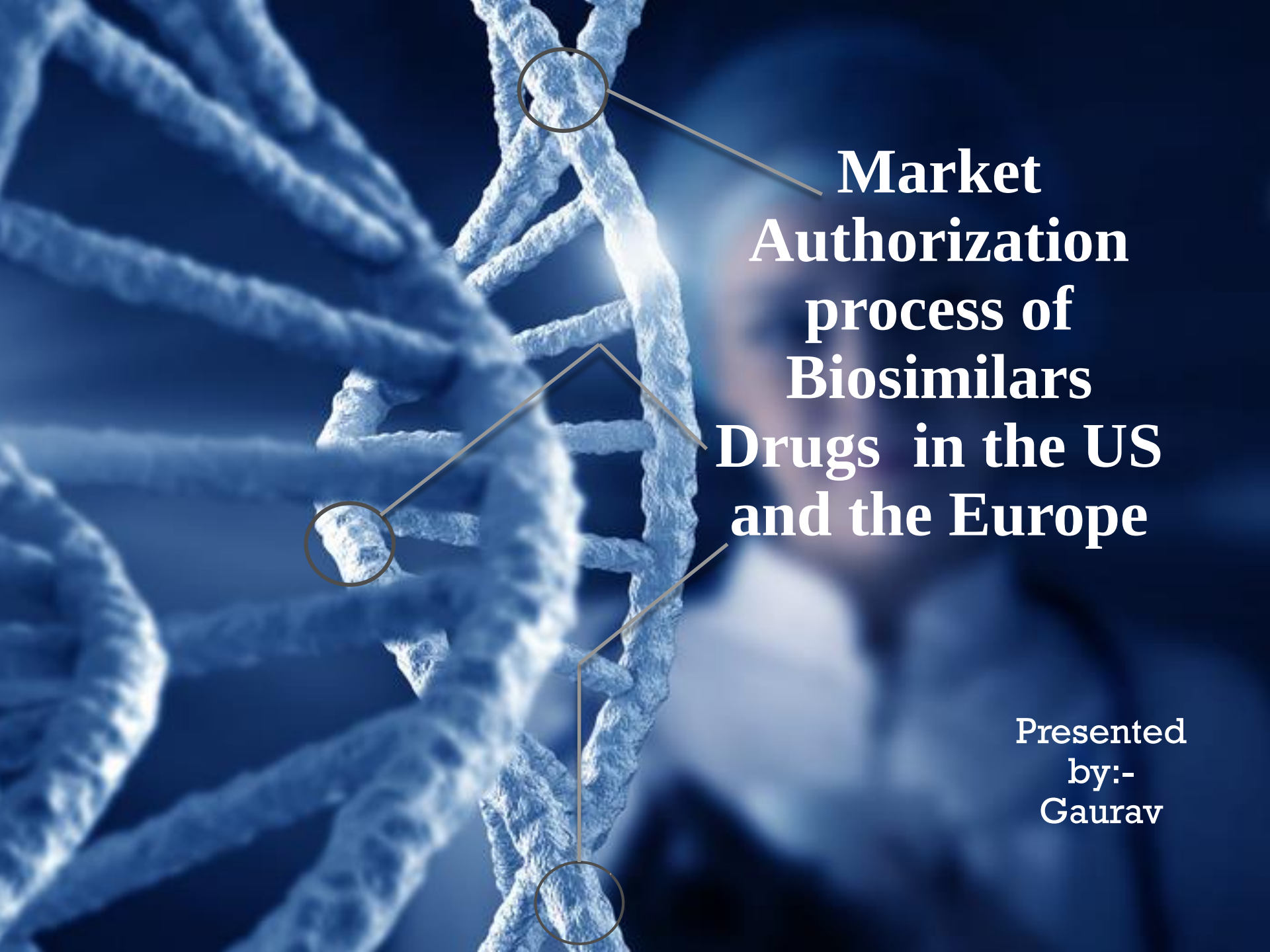
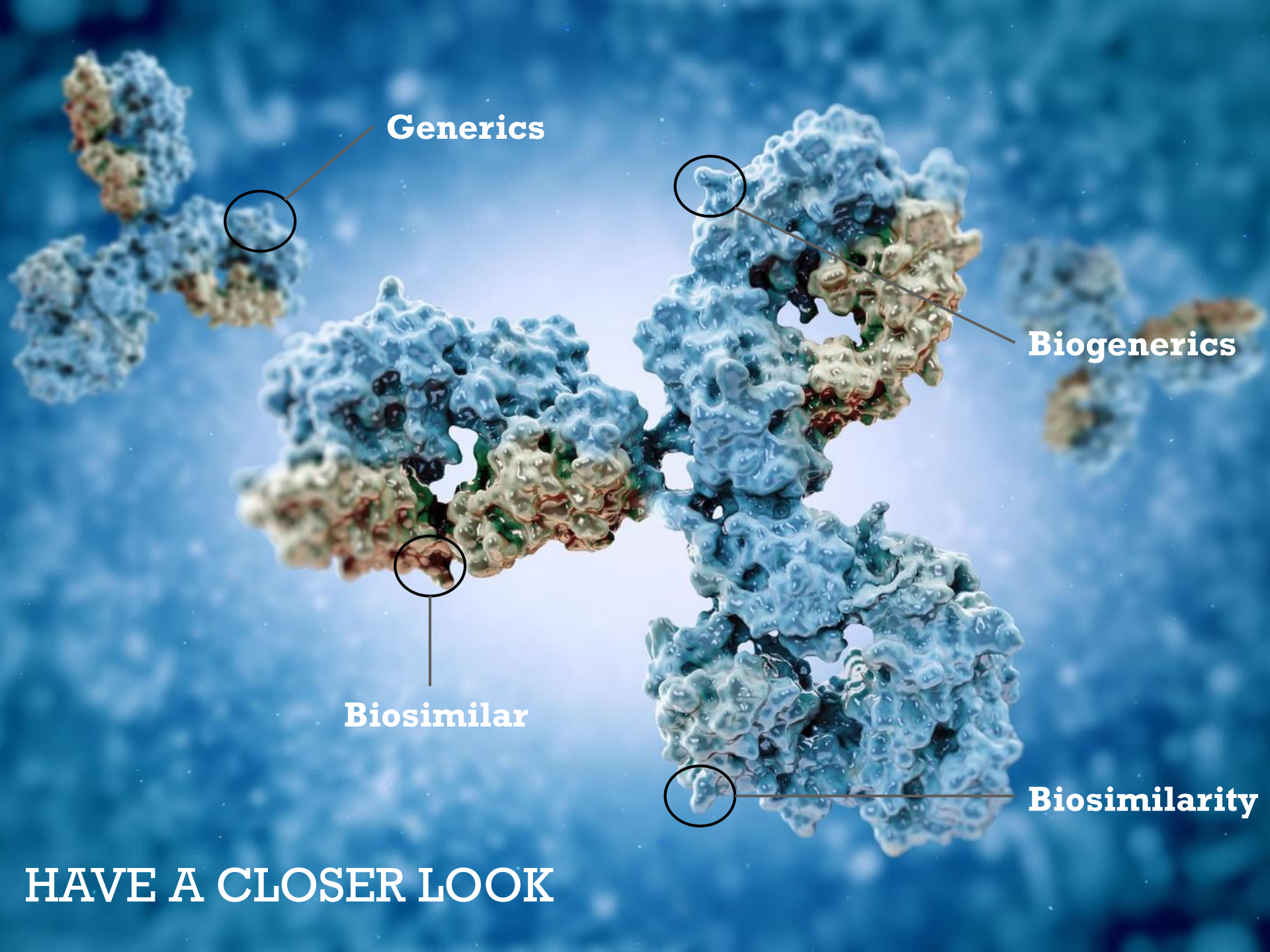


Market Authorization process of Biosimilars Drugs in the US and the Europe

Presented by:-
Gaurav



HAVE A CLOSER LOOK

BIOSIMILAR

- ✓ Biosimilars attempt to copy the original technology leading to the production of innovative biotechnology medicines to obtain a product which is similar to the original one.
- ✓ Different terms;

  US: Follow –on Biologics

  Europe: Biosimilars

Biosimilar	A 'biosimilar' medicine is a biological medicine that is similar to another biological medicine that has already been authorized for use and it does not have any meaningful differences from the reference medicine Note: Article 8 of Directive 2001/83, as amended
Bio-similarity	The PHS Act defines bio-similarity "to mean that the biological product is highly similar to the reference product and there are no clinically meaningful differences between the biological product and the reference product. Note: Section 7002(b)(2) of the Affordable Care Act, amending section 351(i) of the PHS Act.

RESEARCH OBJECTIVE

- **Criteria for approval of biosimilars in the US and Europe**
- **Difference in approval process in these countries**

RESEARCH METHODOLOGY

- It is a secondary research and all the information has been taken from the published "scientific journals and other technical literature both paid and unpaid. The information is taken only from reliable sources.
- **Study type –** Retrospective
- **Type of data -** Secondary data
- **Collection of data -** Secondary data from article and journal
- Published journals
- Company websites
- Research papers

DIFFERENCE BETWEEN BIOSIMILAR AND GENERICS DRUGS

Parameters	Generics	Biosimilars
Production source	Chemical synthesis	Living organisms, i.e. cultured yeast, bacteria or animal/plant cells
Active pharmaceutical ingredient	Must be identical to the reference product	Same primary amino acid sequence, the biosimilar active pharmaceutical ingredient is not identical to the reference product
Testing	Chemical test	Clinical trails is necessary (PHASE III)
Characterization	Non-comparative	Compared with reference product
In vitro non-clinical testing	No	Yes, compared with the reference product
Non-clinical animal testing	No	•Comparative PK/PD (if PD marker is available) in relevant species •One comparative repeat dose toxicity study in relevant species. If the relevant species is non human primates, FDA/EMA generally do not require an in- vivo non-clinical study unless it is absolutely needed


Agency approving biosimilars
Comparison of US and European biosimilar regulation and litigation

AGENCY APPROVING BIOSIMILARS

- ✓ EMEA
- ➢ Guidelines generated in consultation
- Within CHMP and working parties
- External: i)scientific advisory groups

  ii) National competent authorities

  iii) Patient groups

  iv) Universities

  v) Academic societies

- ✓ USFDA

Criteria	EMEA	USFDA
First biosimilar approval	Omnitrope(somatropin) 2006	Zarxio (filgrastim-SNDZ)2015
In vivo toxicology study	Not required routinely, rather more depend on in vitro evaluation SAR	Routinely required although agency can waive this
Biosimilar review process	Non-therapeutically aligned structure in centralized CHMP review	Therapeutically aligned structure with multiple level of supervision and oversight
Legal pathway	A separated branch of generic pathway (DIRECTIVE 2001/EC, article 10.4)	Biological price competitive and innovation act (BPCI 2009)
Exclusivity periods	10 years of exclusivity to the originator product	12 year of exclusivity to the originator product
Pharmacovigilance	All product require pharmacovigilance plan that can be identified product name and batch	FDA encourages post marketing safety monitoring

CONCLUSION

- Europe has been way ahead of the other countries including US in terms of developing biosimilars. Regulatory requirements for the approval of biosimilar products are similar but slightly different in terms of:-
- Definitions of biosimilarity
- The scope of the guidelines
- The choice of the reference product
- The data required for product approval and some other aspects
- On the patent side, because of the significant differences in the legal framework , US biosimilar litigation is not as standardise as Europe .


THANK YOU……