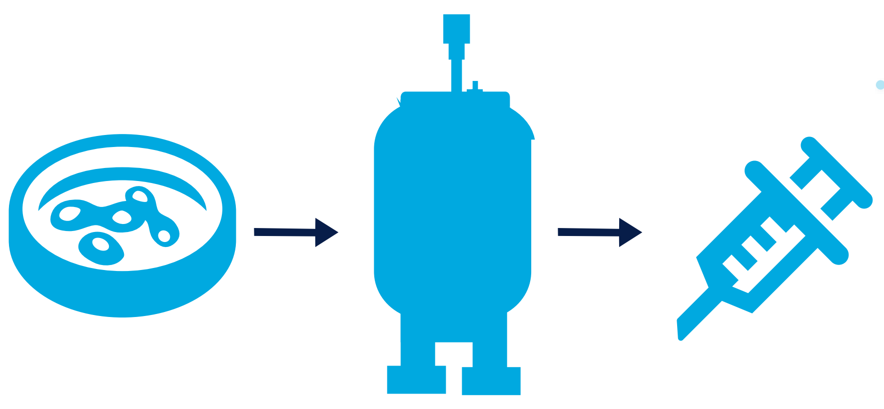
IN A WORLD WITH MULTIPLE BIOLOGICS AND BIOSIMILARS, KNOWLEDGE IS POWERFUL MEDICINE

abbvie

BIOLOGICS HAVE REVOLUTIONIZED THE TREATMENT OF MANY SERIOUS, CHRONIC AND LIFE-THREATENING DISEASES



Biologics are complex medicines made from living organisms or cells. Examples include vaccines, insulin, hormones and monoclonal antibodies[1]

More than

350 MILLION PEOPLE

Worldwide have been treated with biologics for conditions such as diabetes, rheumatoid arthritis, Crohn's disease and certain cancers[1]

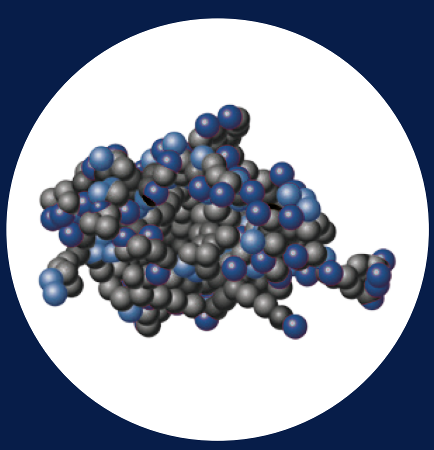
BIOLOGICS ARE COMPLEX MEDICINES[1]

COMPLEXITY BY THE NUMBERS:

ASPIRIN
(CHEMICAL MEDICINE):

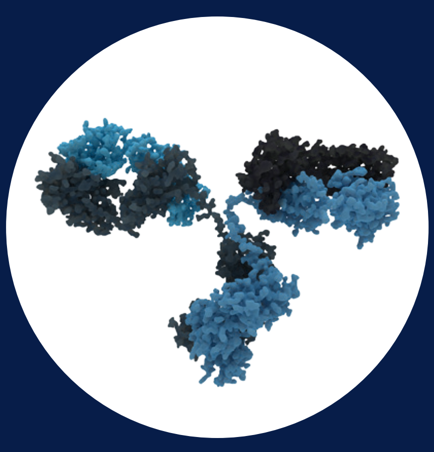
21 ATOMS

INSULIN
(LESS COMPLEX BIOLOGIC):



788 ATOMS

MONOCLONAL ANTIBODY
(MORE COMPLEX BIOLOGIC):



MORE THAN
20,000 ATOMS

Biologics are made by living organisms and are highly sensitive to manufacturing conditions

The process for manufacturing a biologic is extremely complex—requiring up to **250 TESTS** compared to **50 TESTS** for a conventional medicine[1]

THE COMPLEX WORLD WITH MULTIPLE BIOSIMILARS

900

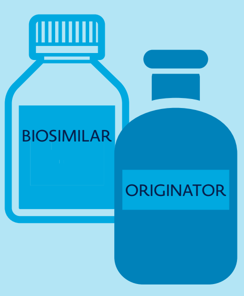
biologic medications, including biosimilars, non-comparables and biobetters are in clinical development[2]

More than

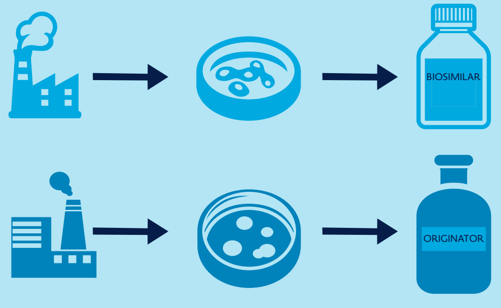
400

companies worldwide are developing biosimilars[2]

BIOSIMILARS ARE NOT GENERIC VERSIONS OF ORIGINATOR BIOLOGICS



It is not possible to create an identical copy of an originator biologic[3]



Biosimilars made by different manufacturers will differ from the originator medicine and from each other

The smallest change to the starting materials and manufacturing processes can make a significant difference in the complex structure and function[4]

IMMUNOGENICITY IS KEY TO DETERMINING THE SAFETY AND EFFICACY OF BIOSIMILARS[5]

Immunogenicity is an unwanted immune response to a therapeutic protein, such as an originator biologic or biosimilar[6]

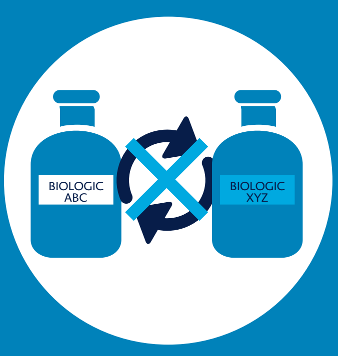
Immunogenicity can decrease efficacy of the biologic medicine or may induce severe side effects by neutralizing factors which are made inside the body[7]

A biosimilar can have a different immunogenicity profile than the originator biologic it is designed to mimic[8]

Only clinical studies can appropriately detect immunogenicity*; such studies should be conducted in the patient-population most sensitive to slight changes in the immunogenicity profile[5]

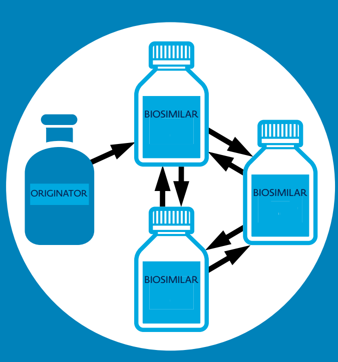
*Extrapolation of immunogenicity data is only possible from high-risk to low-risk patient populations and in clinical settings[9]

SWITCHING FROM AN ORIGINATOR BIOLOGIC TO A BIOSIMILAR IS A CHANGE IN MEDICATION



Switching between originator biologics in patients whose symptoms are well-controlled on their current biologic had an impact on clinical response in a study of patients with Crohn's disease and other inflammatory autoimmune conditions[10,11,12]

No long-term data on switching patients between an originator biologic and a biosimilar for reasons unrelated to clinical outcomes are available[13,14]



Repeated switches between an originator biologic and one or more biosimilars may increase immunogenicity, with potentially negative consequences for patients' health[5]

Medical associations recommend that a patient whose condition is well-managed on a biologic medicine not be switched to another biologic, including a biosimilar[15,16]

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