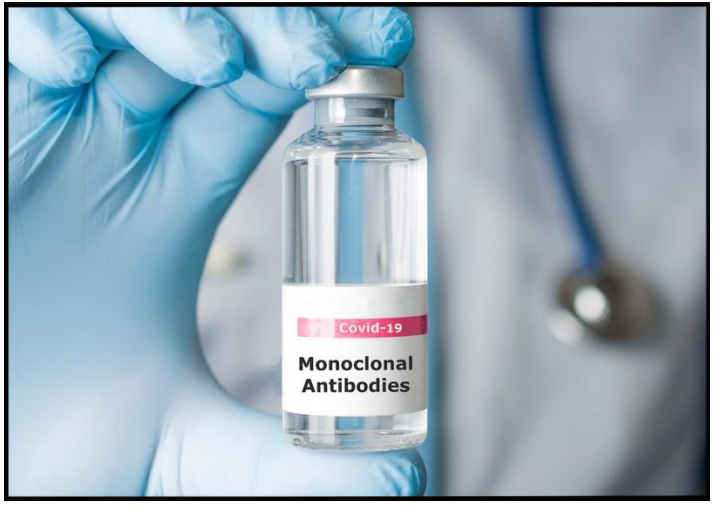
Biologic medicines is important for treatment of many diseases



Biological medicines, also known as biologics, have become increasingly important in the treatment of various diseases. These advanced therapies are derived from living organisms and are designed to target specific components of the immune system or disease pathways. For patients, biologics offer a better chance of receiving effective treatment for conditions that previously lacked viable medication options. This includes diseases such as certain types of cancer, autoimmune disorders, and chronic inflammatory conditions. By harnessing the power of biology, these medicines can provide more precise and personalized treatment, leading to improved outcomes and quality of life for many individuals

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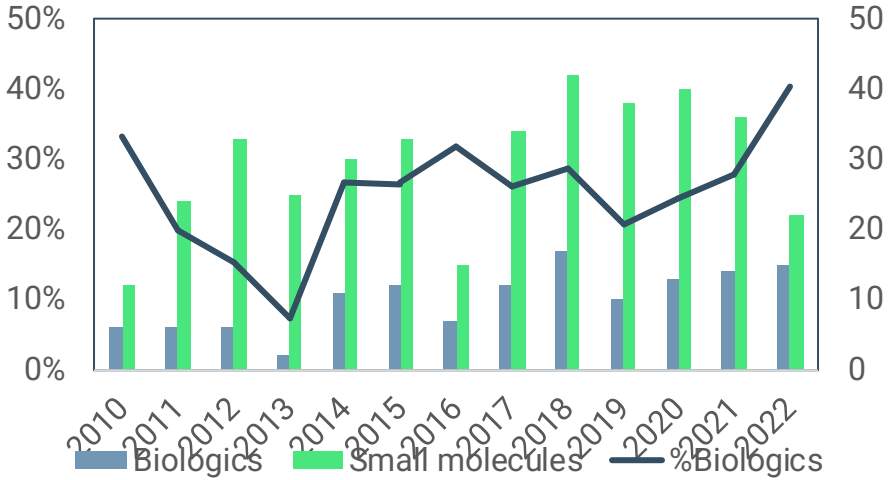
An increasing part of pharmaceutical products



Biologics are becoming a bigger part of the world of medicine. In recent years, about 30% of new drugs approved by the FDA's Center for Drug Evaluation and Research (CDER) have been biologics. In 2022, this number hit a record high of 41%.
The graph shows the drugs accepted by CDER and does not include products approved by the Center for Biologics Evaluation and Research (CBER). If these are included, more than half of the drugs approved by the FDA in 2022 were biologics.
What's exciting is that many of these new biologics are cutting-edge treatments. They include fusion proteins, bispecific antibodies, antibody-drug conjugates (ADCs), siRNA, mRNA, gene therapy using viral vectors, CAR-T cells, and even a product to replace the microbiome. This shows that there are more and more complex biological molecules available to treat diseases, offering hope for better and more effective treatments in the future.

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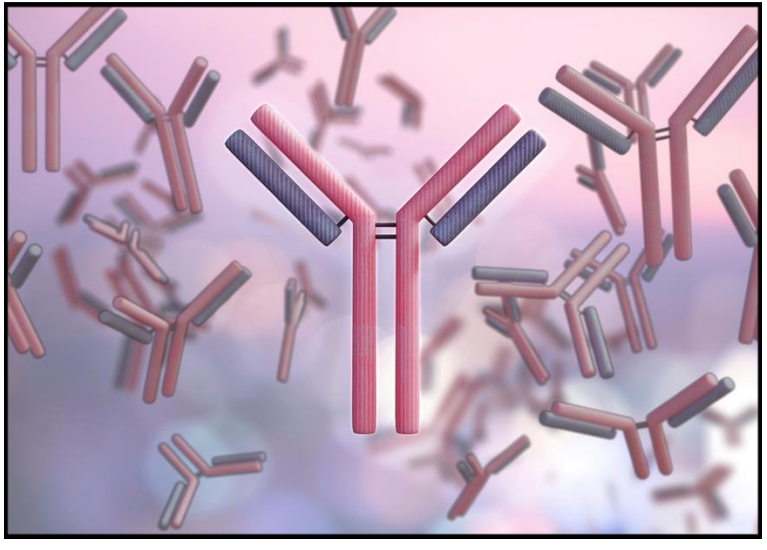
What are biologics?



The active substances in biological medicines are produced in, or extracted from, biological sources such as living cells. These medicines are often referred to as protein medicines due to their composition. Certain vaccines also fall under this category.
The field of biologics is advancing rapidly, with new types of treatments, including stem cells and gene therapy, on the horizon for use in healthcare. These innovative therapies hold great promise for treating a wide range of conditions, offering more targeted and effective solutions compared to traditional medications. As research continues to progress, the potential for biologics to revolutionize medical treatment and improve patient outcomes grows ever stronger.

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The difference between biologics and other medicines

Biological drugs are like intricate puzzles; their complex molecules need to maintain their specific structure to function properly. These molecules are large and don't easily pass through cell membranes, making them sensitive and requiring careful handling and hard to administer.

Currently, biologics are administered through injections or intravenous (IV) drips because they would be broken down in the digestive system if taken orally. Scientists are working hard to find new ways to deliver these medicines, such as nasal sprays, patches, and even oral formulations. However, this is a tricky challenge because the body has trouble distinguishing between proteins as food or medicine

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The development of biological medication

Insulin, one of the first biologics, revolutionized the treatment of diabetes and paved the way for the development of various other biological medicines. Since then, the field of biologics has expanded significantly, introducing several types of advanced therapies. Among the most important are TNF-alpha inhibitors, which play a crucial role in managing autoimmune diseases, and antibodies against cancer, which have transformed oncology treatments
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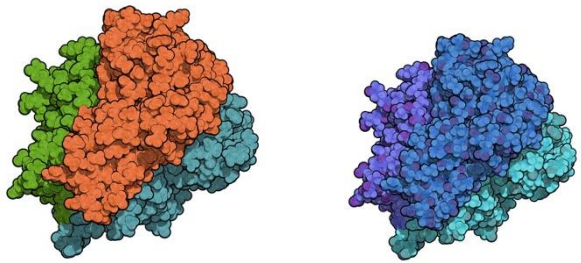
Biosimilars



Companies have started developing biosimilars, which are cost-effective alternatives to original biologics. These medicines closely resemble already approved biological treatments in terms of structure, function, effectiveness, and safety. The first biosimilar was approved in the EU in 2006.

When the patent for a biologic medicine expires, other companies can create similar copies, known as biosimilars. These biosimilars are typically less expensive for healthcare providers because their development is based on existing knowledge of the original medicine.

This concept is also common among medicines in tablet form, known as generic medicines. For example, ibuprofen is sold under various brand names by different companies. Biosimilars and generics both provide more accessible and affordable treatment options while maintaining high standards of efficacy and safety.
Some examples of biosimilars include Inflectra (infliximab-dyyb), Mvasi (bevacizumab-awwb), Zarxio (filgrastim-sndz), and Semglee (insulin glargine-yfgn)

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RealHope focusing on safe handling of biologics

RealHOPE is an exciting four-year research project focused on understanding how drugs are handled in real-life situations. By studying these events, the project aims to develop better methods for simulating them. The ultimate goal is to create more robust protein drugs that are safer for patients.

Funded by IMI, EU Horizon2020, and EFPIA companies, RealHOPE is working to improve the safety and effectiveness of protein-based medicines, making treatments more reliable and beneficial for everyone.

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We need to handle biologics carefully

Biologics are sensitive to cold and heat

Biologics are more sensitive than traditional medicines and require special care. Unlike most traditional medications that can be stored at room temperature, biologics need to be kept in a refrigerator at temperatures between +2°C and +8°C. This careful storage is crucial to maintain their effectiveness.

Pharmaceutical companies rigorously test biologics to see how they handle different temperatures. They also research whether these medicines can be safely frozen and thawed.

Sometimes biologics can be stored at room temperature for a while. Typically, room temperature is defined as below 30°C, but sometimes it's specified that the medication shouldn't be stored above 25°C and then it is important to follow those instruction. One example is that you should not leave your drugs in a hot car during the summer.

Most biologics should not be frozen although there are exceptions. For the refrigerated biologics it's important to protect them from freezing. If they freeze, they can be damaged and may not work properly. So, always make sure your they are stored in the fridge, but never in the freezer.

Taking these extra steps ensures that your biologic medicines remain safe and effective, providing the best possible treatment

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Handle with care - do not shake or dropp

Biologics are like delicate treasures—they need to be handled with care. These medicines are sensitive to shocks, shaking, and falls. So, whether you're transporting them or storing them at home, it's important to be gentle and avoid dropping or shaking the packaging.

The proteins in biologics can interact with different surfaces, like solid surfaces, liquids, or even air bubbles. These interactions can change their structure and cause them to clump together. For example, shaking a vial can create air bubbles that make the proteins stick together. Other actions, like pumping or flowing through tubes, can also cause these proteins to clump.

Even the silicon oil used on syringes to make injections easier can interact with the proteins, potentially affecting their stability.

In short, treat your biologics with the same care you'd give to a fragile piece of art. This ensures they stay effective and safe for use

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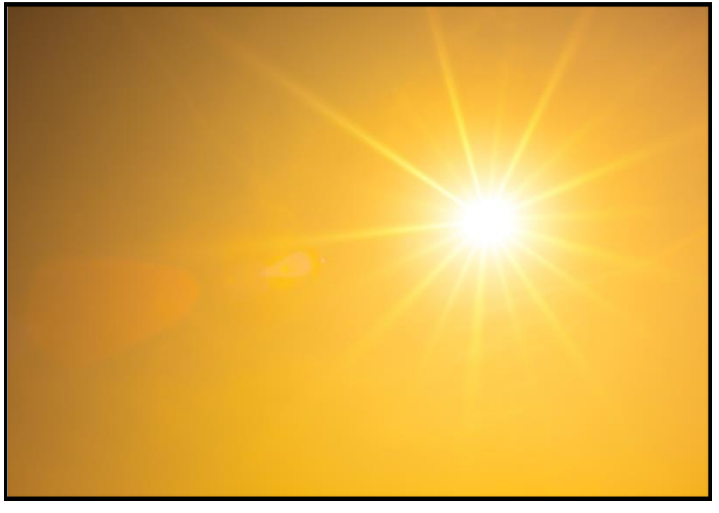
Biologics can be sensitive to light



Biologics are sensitive to light, so it's important to keep them protected. Always store them in their original packaging and only take them out when you're ready to use them. Never place your biologics in direct sunlight.

Light exposure can cause chemical changes in the proteins, leading to damage. This can make the medicine less effective. Even some additives in the medicine can be affected by light.

So, to keep your biologics safe and effective, always store them away from light. This simple step helps ensure your medicine works as it should.

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One last word always follow instructions

Since biological medicines are sensitive, it is important that you follow the storage instructions

you find on the leaflet included inside the packaging. If you are unsure where to find this information, we have made a video for you to watch via this link.

You can also ask at the pharmacy or talk to your rheumatology clinic if you need help.

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