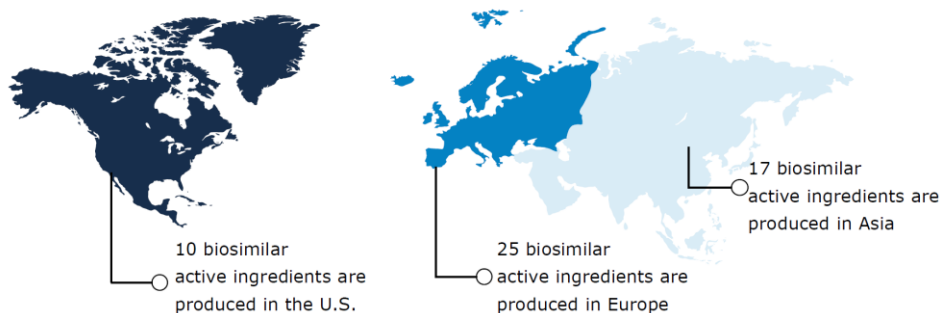


Biopharmaceuticals: Guaranteeing maximum supply reliability!

A strong production location is an essential prerequisite for supply and supply reliability as well as for investment and innovation. Pharmaceutical production in Germany is among the best in the world. Its major attributes include its well-trained specialists, excellent technical equipment and proximity to other industries. In particular, the highly complex production of biopharmaceuticals is an area where Germany can make out its strengths. In terms of the number of active ingredients produced, Germany is the leader in Europe and ranks second worldwide behind the U.S. (39 vs. 116). This favorable position should not be jeopardized by short-term cost-cutting measures such as those planned for biosimilars – copycat products of biopharmaceuticals after patent expiration – with automatic substitution in pharmacies planned as of 2022.

Production of biosimilars approved in the EU is set up globally – about half of them in Europe



Sources, status 01/2021: vfa (www.vfa.de/biosimilars);

EU Commission (https://ec.europa.eu/health/documents/community-register/html/reg_hum_act.htm?sort=a)

In total, there are now 46 biosimilars approved in the EU. About half of the biosimilar active ingredients are produced in Europe, 9 of them are (also) produced in Germany at the following locations: Biberach, Bovenau, Frankfurt a.M., Marburg, Uetersen and Ulm.

Benefits of a resilient biopharmaceutical production location in Germany



A Europe that focuses on technological progress and high environmental standards during production must look ahead and continue to establish itself as a high-tech production location of pharmaceuticals as well as strengthening supply chains. In its program for the German EU Council Presidency, the German government advocates for a resilient and competitive Europe:

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“During our Council Presidency, we will therefore discuss approaches to further improving the supply of pharmaceuticals, medical products and personal protective equipment in the healthcare sector. Together with the Member States, we want to reach agreement on tangible measures to achieve greater autonomy in the EU with respect to safeguarding the supply of medicines.

Source: <https://www.eu2020.de/blob/2360248/e0312c50f910931819ab67f630d15b2f/06-30-pdf-programm-en-data.pdf>

According to the regulations of the GSAV (Law for More Safety in the Supply of Pharmaceuticals), the Joint Federal Committee will develop concrete instructions for the substitution of biopharmaceuticals in pharmacies. Competition has long been in full swing and has already led to significant savings for the healthcare system in Germany: On average, biosimilars generated a 42% share of sales in 2019 in the relevant biopharmaceutical segment. The current market share of biosimilars at the end of 2019 was even significantly higher for many products (67% for etanercept, 74% for trastuzumab, 75% for infliximab and even 80% for rituximab biosimilars). Further political interventions, such as automatic substitution in pharmacies, are therefore neither necessary nor goal-oriented. This is because they restrict the therapeutic freedom of the treating physician, which is essential for the patient's adherence to therapy and therapeutic success.

The same mistakes must not be made with biopharmaceuticals that were made with generics of chemical synthetic drugs, which led to strong dependence on imports from Asia. This would contradict the declared goal of the EU for greater autonomy.

Consequently, the corresponding passage in the GSAV regarding the automatic substitution of biopharmaceuticals should be deleted from the law – as demanded by the majority of stakeholders in the health care system [[LINK](#)]:

- To maintain the therapeutic freedom of the treating physician!
- To ensure a resilient high-tech production location in Germany and Europe!
- To provide the maximum supply reliability of biopharmaceuticals for patients!