ACT4 BIOSIMILARS

Act4Biosimilars Regional Deep Dive Report

Europe

Why Act4Biosimilars?

Biologic medicines have **transformed the lives** of many patients. However, with increasing pressures on healthcare systems, **not everyone is able to access the treatments** they need.

Biosimilars help more patients gain access to biologic medicines, and earlier in the patient treatment cycle. **Improved access to biosimilars leads to:**

- Increased innovation by introducing competition
- Better patient outcomes
- Improved healthcare services

Act4Biosimilars is led by a multidisciplinary Steering Committee of patient advocacy leaders, healthcare professionals, biosimilar experts and industry leaders, representing views from around the world.

Driving Biosimilar Adoption

Act4Biosimilars is a global initiative that aims to increase patient access to biologic medicines by helping to accelerate the **4As of biosimilars:**

- **Approvability**
- **Accessibility**
- **Acceptability**
- **Affordability**

The Journey to 30-30-30

Act4Biosimilars' Mission is to increase global biosimilar adoption **by at least 30 percentage points in 30+ countries by 2030.**

The Action Plan

The Action Plan is the global roadmap for Act4Biosimilars, and identifies the most relevant challenges and opportunities for increasing biosimilar adoption under each of the 4As. It provides stakeholders around the world with the strategies, tools and activities needed to accelerate adoption.

Within the Action Plan there are 3 steps to help achieve the Act4Biosimilars goals

Step 1 **- Prepare:**

Laying the foundations for steps 2 and 3. Essential for building knowledge and relevant connections with key stakeholders.

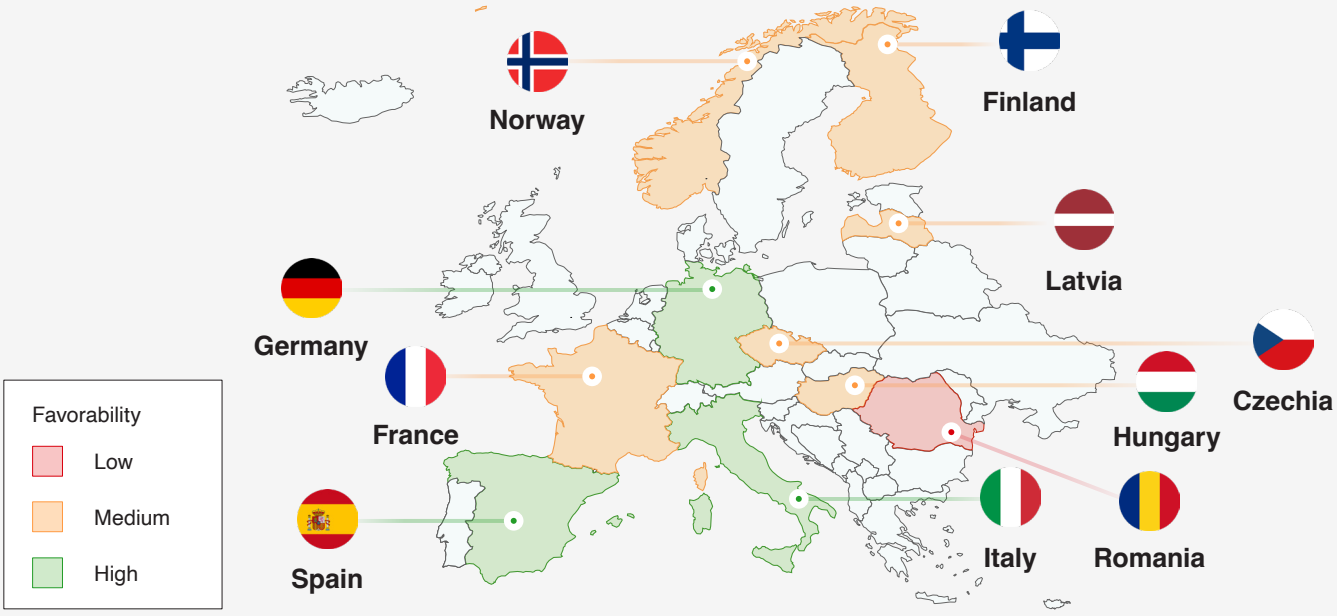
Step 2 **- Act:**

Using knowledge and connections created in step 1 to recruit supporters, educate stakeholders and advocate for change.

Step 3 **- Maintain:**

Building on progress made in step 2 to maintain momentum.

Taking action in Europe



This report developed by Act4Biosimilars outlines key challenges facing biosimilar adoption across Europe. The report covers European countries in the scope of tracking in the Act4Biosimilars Impact Index: Czechia, Finland, France, Germany, Hungary, Italy, Latvia, Norway, Romania, and Spain. This report complements the information in the Impact Index and provides guidance to help focus efforts that maximize impact and resulting in increased biosimilar adoption.

The challenges highlighted link to key initiatives in the Action Plan, which provides the strategies, tools, and activities needed to improve the adoption of biosimilars and achieve the Mission to increase biosimilar adoption by at least 30 percentage points in 30+ countries by 2030.

Across Europe, countries face significant and unique challenges across the 4As; Approvability, Acceptability, Accessibility, and Affordability. For each country, there is at least one challenge highlighted. The only exception to this is Approvability, as all countries covered in the report are regulated by the European Medicines Agency (EMA).

Summary of challenges facing Europe

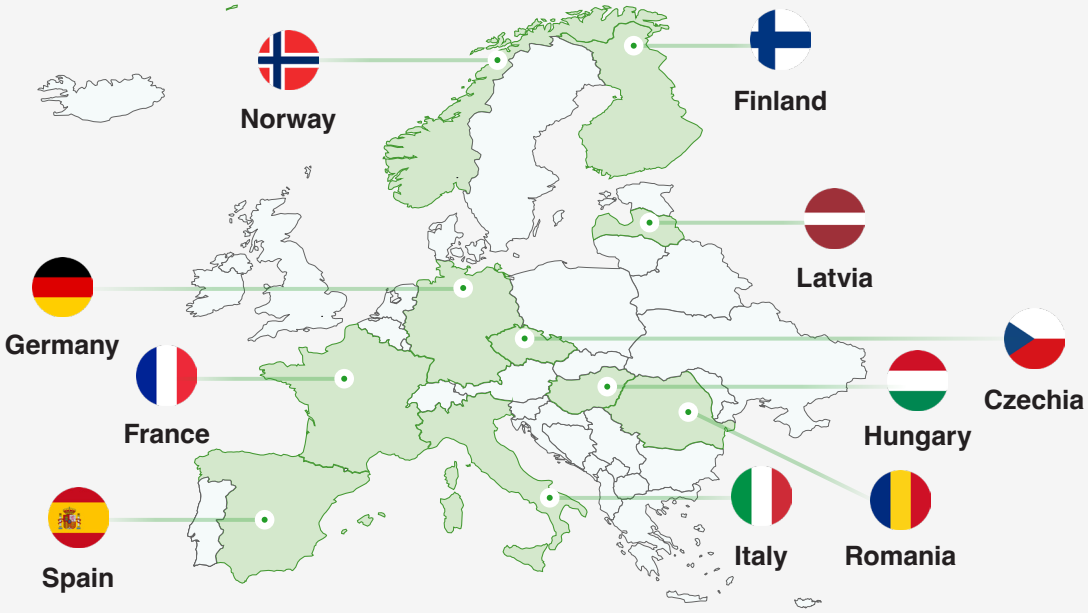
- Biosimilar adoption levels vary significantly across Europe due to differences in baseline use of biologics, biosimilar reimbursement, procurement, policies, and education.[1]
- On a per capita basis, Central and Eastern European markets lag behind Western European countries, with treatment guidelines and approaches to biosimilars considered as limiting factors.[2] Additionally, overall affordability of biologics limits the number of patients who can access these advanced treatments in Eastern Europe.[3]
- A clear east-west divide exists in physicians' knowledge and comfort when prescribing biosimilars. This is partly due to Eastern European national medicine agencies being less likely to have available information on biosimilars including transitioning on their websites in local languages.[4]
- Growth in access to biosimilars can be limited by the historic use of reference medicines. Despite significant list price reductions, subsequent confidential rebates, and increasing competition in markets, not all European countries have been willing or able to increase access to biologic medicines in available therapy classes.[5]
- While each country's healthcare system is unique, there is a need to share best practices to create equity across the region when accessing biologic medicines.
- Procurement practices across the continent have a strong price focus and sometimes only a single winner, which may over time impact the sustainability of biosimilars and decrease competition, as well as reducing supply reliability.[6]

Snapshot across the 4As

In the following section, challenges either unique to the region or representative of a broader global issue, have been outlined and illustrated with specific examples to demonstrate the impact.

Approvability

The European Medicines Agency regulates biosimilars in the EU and the European Economic Area. It has led the way with the development of processes for assessing and approving biosimilars. However, more urgent progress is needed. Advancements in analytical characterization studies should be considered, and in the future Phase III clinical trials should be required only when there is uncertainty from analytical studies or for complex indications.



The European Medicines Agency should explore opportunities for a more streamlined process

To streamline the approval processes for biosimilars, EMA should consider making use of the latest scientific advancements that deliver assessments of equal quality while greatly enhancing efficiency, such as analytical characterization studies.

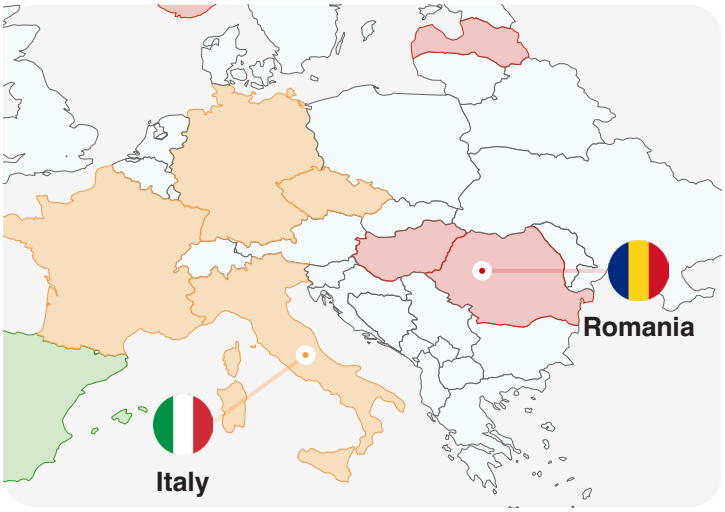
Want to take action?
Have a look at the Action Plan Key initiative, Optimize Regulatory Review Procedures.

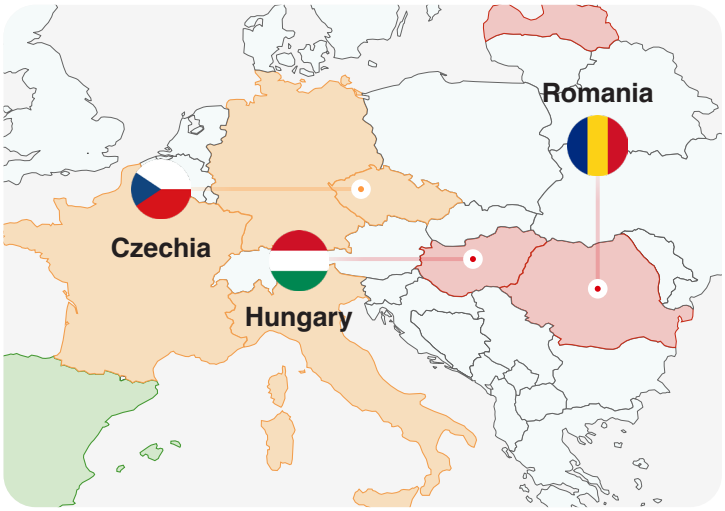
Providing data, such as demonstrating that analytical characterization is more sensitive than clinical trial results, will help EMA transition to more streamlined processes.

Streamlining the process and reducing the reliance on Phase III clinical trials would enable biosimilars to be developed more quickly and reduce the investment needed. A single biosimilar product requires an estimated investment of USD 150 million to USD 300 million over five years. This high development cost is in part due to purchasing reference medicines and conducting clinical development.[7]

Acceptability

Despite the emphasis of EMA that biosimilars approved in the EU are interchangeable with reference medicines, across Southern and Eastern Europe acceptance of biosimilars is low amongst patients and healthcare professionals. Low acceptability arises from a lack of education, which leads to confusion and denies patients who would otherwise benefit from transitioning having access to biosimilars. Comprehensive biosimilar educational programs developed through a multi-stakeholder approach are needed to increase trust in biosimilars and to counter disinformation.





Biosimilar education needs to target healthcare professionals at every level and from all specialties

In Romania, the level of acceptance varies among different specialties. Oncologists, hematologists, and endocrinologists are frequent prescribers, whereas rheumatologists and dermatologists are the most reluctant to prescribe biosimilars due to familiarity with reference biologics and lack of budgetary constraints, as these medicines are not paid from hospital budgets.[8]

Approximately 130,000 patients in Italy living with autoimmune diseases in the areas of rheumatology, gastroenterology, and dermatology do not have access to biologic medicines even when they are considered adequate for their clinical condition.[9] Biosimilars have the potential to increase access to these important treatments, but a lack of awareness and insufficient educational materials for healthcare professionals need to be resolved for biosimilars to fulfil their potential.

Healthcare professionals must be able to access educational materials in local language

Across Eastern Europe, there is a lack of information and guidance on biosimilars provided by national medicines agencies. According to one study, out of 31 European national medicines agencies analyzed, only 19 offered information about biosimilar medicines on their websites. Czechia and Romania are among the countries with no information or educational materials available.[4] There is a need to bridge this gap by expanding the information available at a national level and leveraging EU-level educational materials in local languages.

Want to take action?
Have a look at the Action Plan key initiative, Drive Publication of Authoritative Local Educational Content

Accessibility

For patients to have confidence in biosimilars, they must have access to clear information about treatment options and the process they choose to follow to initiate biosimilar treatment. Healthcare professionals play an important role in educating patients and keeping them informed. However, this is often undermined by pharmacy level substitution, which means that the healthcare professional is not informed of the substitution and patients may not always be informed or consulted. This can lead to confusion and even mistrust in biosimilars, which needs to be avoided.

Improve treatment compliance by avoiding forced and frequent switching between biosimilars

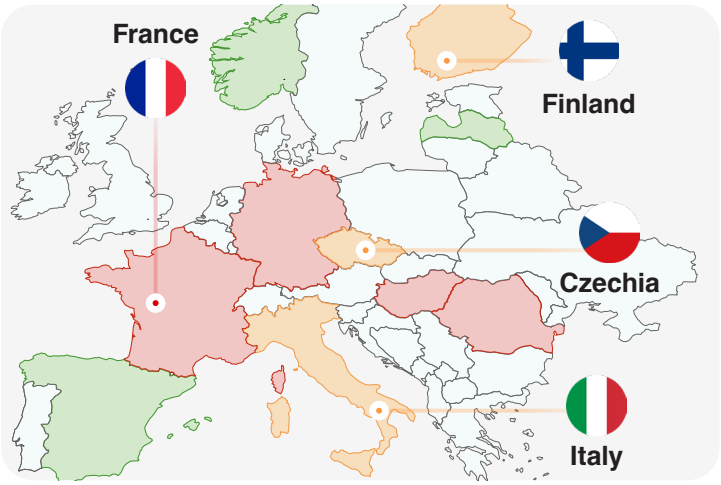
From 2024, Finland will implement wider pharmacy substitution with quarterly reference pricing. Authorities will handle reimbursed biologics as substitutable generics. Even though patients are entitled to use the same medication for six months, this scheme could impact the supply of medicines.[10] This is due to uncertainty in forecasting demand, supply, and pricing. Additionally, devices to self-administer the medication vary between manufacturers and if a patient's medicine is substituted multiple times, it could impact treatment compliance and concordance.

Want to take action?
Have a look at the Action Plan key initiative, Moving from Forced Transitions to Informed Transitions

Make communication on economic returns from biosimilars and prices to healthcare professionals more accessible and transparent

In France, there are multiple and varied incentives in place encouraging the use of biosimilars. Although these have proven highly effective, they can be complex. Associated economic returns for prescribers, departments, and hospitals can be difficult to follow and measure.[11] To encourage more commitment from healthcare professionals, these incentives should be simplified, and the direct benefits communicated more widely.

Finland suffers from similar challenges, as the country's information systems are difficult to navigate and do not yet support price or treatment cost visibility.[12] There is no single system where healthcare professionals can look for prices. A newly adopted regulation requires them to prescribe the most affordable biologic, however, as price visibility varies, it can be difficult for healthcare professionals to know which product to prescribe based on price.



To streamline access, fragmented biosimilar incentives and guidelines need to be harmonized

In Italy, there are differences in levels of biosimilar uptake between regions.[13] Despite national laws that regulate tender processes, individual regions have the autonomy to influence biosimilar adoption and can impact it through differing guidelines for healthcare professionals and pharmacists.

In Czechia, the implementation of public procurement for biosimilars is complex due to market fragmentation and a strong price focus. The regulations are binding only on hospitals directly managed by the Ministry of Health, and the private sector tends to choose not to implement them even though they may face sanctions over time.

Affordability

Across Europe, there is a preference for tenders based predominately on price and with only a single winner. Tender processes that give access to more than one option prevent 'race-to-the-bottom', pricing which limits competition and compromises the future market for biosimilars. Price-focused tenders may create multiple risks related to supply continuity and stifle competition. In contrast, multi-criteria and multi-winner tenders foster a competitive environment that supports a future market for biosimilars.

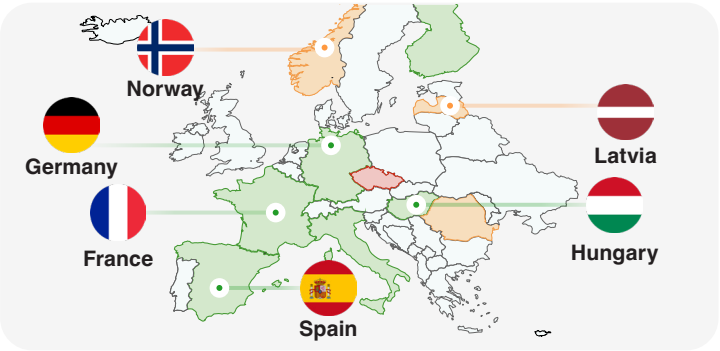
Reducing price-only and encouraging multi-winner tenders can help generate increased competition

In Norway, tenders for biosimilars often have a multi-winner set-up. However, one-winner tenders are not uncommon bringing with it a strong focus on price. This has impacted the number of biosimilar companies putting in bids for tenders. For example, in the 2024 tender process, some major companies did not bid.

In France, while tenders are conducted predominantly through sub-national purchasing organizations, price still plays a key role. The tenders are single-winner and competition-based but mainly focused on price, generally representing between 30% to 40% of the final decision.[14]

In Germany, biosimilars have not been subject to substitution and tendering so far and there are 'open house' contracts offering additional rebates to payers.[15]* In general, rebate contracts are still focused on price only in Germany, which can be destabilizing to competitive markets and discourage manufacturer participation.

In Spain, although tenders are mostly multi-winner, there should be more inclusion of technical and value-added criteria (such as services, stability, and packaging) to ensure the longer-term sustainability of both healthcare systems and industry. Regions such as Murcia, Cataluña, and Navarra are already doing this very successfully[16], whereas others like Andalusia and Valencia still have a way to go.[17] Tenders should be applied at the highest standard across the country, with a focus on those regions further behind in their implementation.



Avoid mandatory price reductions to guarantee long-term availability of biosimilars

In Latvia, the main criterion for entrance into the reimbursement list is price. The first biosimilar must be at least a 30% reduction in price compared to the reference product. The second and third biosimilars must be at least 10% cheaper than the first or second biosimilar and all subsequent biosimilars must have a further 5% decrease.[18] While this is increasing the market share of biosimilars, there needs to be caution around price-only tenders and how they could impact the long-term sustainability and availability of biosimilars.

A similar system is seen in Hungary, with mandatory price reductions depending on when a biosimilar enters the market. Additionally for certain molecules, there is a bidding system (biolicit) in place where the lowest priced biosimilar, and those within 10% of it, are reimbursed at 100% for patients; however, this currently does not cover all biosimilars.

Want to take action?
Have a look at the Action Plan key initiative, Increase Local Market Competition

Want to take action?
Have a look at the Action Plan key initiative, Introduce and Widen Adoption of Sustainable Biosimilar Pricing Policies

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