European Commission

# Capacity building to support the uptake of biosimilars in a multistakeholder approach

## AUGMENT Biosimilars
## Country fiche CROATIA

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augment biosimilars

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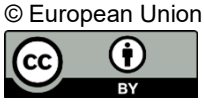

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Annex 7.4

# AUGMENT Biosimilars country fiche: Croatia 2025

## Capacity building to support the uptake of biosimilars in a multistakeholder approach

The AUGMENT Consortium produced this country fiche as part of the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach (HADEA/2023/OP/0040)" commissioned by the European Health and Digital Executive Agency (HaDEA). The AUGMENT Consortium consists of the Austrian National Public Health Institute (Gesundheit Österreich Forschungs- und Planungs GmbH / GÖ FP), as consortium lead; the Polish Agency for Health Technology Assessment and Tariff System (Agencja Oceny Technologii Medycznych i Taryfikacji / AOTMiT), the Medical University Sofia (MUS), and the NOVA National School of Public Health in Lisbon.

In this project (abbreviated AUGMENT Biosimilars project), the AUGMENT Consortium performed a **comprehensive study** which aimed to offer a **mapping and** an **analysis of existing policies and practices** to encourage biosimilar uptake and competition in 32 European countries (all European Union (EU) and European Free Trade Association (EFTA) Member States, and the United Kingdom). In the analysis, the impact of biosimilar policies on improving patient access to medicines as well as barriers and facilitators in the policy implementation will be studied. For further information see biosimilars.goeg.at.

Key terms related to biosimilar policies can be found in the project's Glossary.

**Contributors**

This country fiche was produced by GÖ FP based on information the PPRI network was used, and findings from systematic and narrative literature reviews.

This country fiche has not been validated by national experts.

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# 1 Summary of biosimilar policies and practice in Croatia 2025

**Key stakeholders**

In Croatia, the **Ministry of Health** prepares pharmaceutical legislation and acts at the same time as pharmaceutical pricing authority and procures some medicines centrally. The **Croatian Health Insurance Fund** (HZZO) supported by a Reimbursement Committee decides on the inclusion of pharmaceuticals into reimbursement. Croatia's **national Agency for medicinal products and medical devices (HALMED)** provides some information about biologicals and biosimilars online for health professionals and the public. A **competition authority** (AZTN) enforces competition regulation and supports competition in the sector and all markets in general.

**Health professionals are organised in associations**. Doctors prescribe biosimilars and decide regarding switching. They, together with pharmacists dispensing the medicines are the main information source for **patients.** There is no specific biosimilar industry association.

**Major biosimilar policies and practices**

A major biosimilar policy in Croatia is **the biosimilar price link**, defining a 25% reduction for the first biosimilar to enter the market and a 5% reduction for each following biosimilar (compared to the previous one). **External price referencing** is in place and applied for biosimilars as for other medicines.

**Tendering** of biosimilars is performed in the inpatient sector **both on facility level and on centralised level** by the Ministry of Health. **Tenders must be reopened** when a biosimilar enters the market.

In reimbursement, biosimilars are included in the **reference price system** (RPS). In general, the reimbursement procedures for biosimilars are the same as for other medicines, and HTA is also done for biosimilars.

There are two positive lists. The "A-list" contains hospital medicines, which mostly can also be prescribed in the outpatient sector. The "B-list" contains medicines for use in the outpatient sector. **Co-payments for biosimilars exist**, as these are mainly reimbursed at a rate of 75%.

Switching patients on treatment with a biological is recommended but uncommon, and so naïve patients are often prescribed the biosimilar in the first place when available. **Biosimilar substitution by the community pharmacist is not allowed.**

**Impact analysis**

Some literature on biosimilar policy implementation and impact is available for Croatia pointing towards the possibility to **generate fewer expenses using biosimilars**. Biosimilars entering the market in Croation have shown to increase utilisation and reduce price for TNF-alpha inhibitors. However, no impact analysis could be identified.

**Barriers, facilitators and good practice examples**

Biosimilar uptake was reported to be low in comparison to other countries, and this was contributed to hesitancy by prescribers, in particular towards prescribers, and opposition expressed by the originator medicines industry. There is room for extending demand-side measures for biosimilars, though some biosimilar policies are in place.

**Highlights and learnings**

**Tenders must be re-opened** when a biosimilar comes to the market which encourages biosimilar competition.

An interesting learning is that in some cases **pharmaceutical companies cover the co-payment** (of 25%) for several biologics and biosimilars which would otherwise be applicable to the patient (or a supplementary insurance).

# 2 Key data regarding biosimilars in Croata

**First biosimilar medicine** launched (i.e. brought on the market):
Epoetin in January 2013.
*Source*: Medicines for Europe 2023

Number of the **biosimilars marketed**:
16 molecules with biosimilars available, as of end 2022.
*Source*: Medicines for Europe 2023

# 3 Stakeholders involved in and targeted by biosimilar policies in Croatia

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Legislator | Ministarstvo zdravstva Republike Hrvatske / Ministry of Health (MOH) | Prepares legislation. | |
| National regulatory authority | Agencija za lijekove i medicinske proizvode (HALMED) /Agency for medicinal products and medical devices of Croatia | Implements regulatory provision regarding biosimilars, quality assurance and pharmacovigilance. | HALMED 2024b (Medicinal products database)<br>HALMED 2024c (Biological and Biosimilar Medicinal Products) |
| Pharmaceutical pricing authority | Agencija za lijekove i medicinske proizvode (HALMED) /Agency for medicinal products and medical devices of Croatia | Determines the price for medicines including biosimilars. | |
| Pharmaceutical reimbursement authority | Hrvatski zavod za zdravstveno osiguranje (HZZO) / Croatian Health Insurance Fund<br>(supported by the Reimbursement Committee) | Decides on inclusion into reimbursement. | |
| Procurement agency | Ministarstvo zdravstva Republike Hrvatske / Ministry of Health (MOH) | MoH was appointed as the central body for the implementation of certain public procurement procedures. | See above. |
| HTA agency / body | Hrvatski zavod za zdravstveno osiguranje (HZZO) / Croatian Health Insurance Fund<br>(supported by the Reimbursement Committee)<br><br>Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi (AAZ) / Agency for Quality and Accreditation in Health Care, Croatia (AAZ) | HZZO conducts HTA. Provides guideline on HTA. | AAZ 2011 (HTA guideline) |
| National competition authority | Agencija za zaštitu tržišnog natjecanja (AZTN) / Croatian Competition Agency | Enforces competition regulation and supports competition in all markets in general. | |
| National patent office | Državni zavod za intelektualno vlasništvo Republike Hrvatske / State Intellectual Property Office of the Republic of Croatia | Granting and managing patents on biologic medicines | |
| Doctors | *Represented by:*<br>Hrvatska liječnička komora (HLK) / Croatoin Medical Chamber<br>*Medical societies:*<br>• Hrvatsko društvo za dijabetes i bolesti metabolizma / Croatian Diabetes Society<br>• Hrvatsko društvo za gastroenterologiju (HDGE) / Croatian Society for Gastroente-rology<br>• Hrvatsko društvo za hematologiju / Croatian Society for Hematology<br>• Hrvatsko onkološko društvo (HOD) / Croatian Oncology Society | Prescribe biosimilars and decide regarding switches. Inform patients about biosimilars. Several medical societies in disease areas with biologics use identified (see left). | |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| | • Hrvatsko reumatološko društvo (HRD) / Croatian Society for Rheumatology | | |
| Nurses | *Represented by:*<br>Hrvatska Udruga Medicinskih Sestara / Croatian Nurses Association | | |
| Community pharmacists | *Represented by:*<br>Hrvatska Ljekarnička Komora/Croatian Chamber of Pharmacists<br>Hrvatsko Farmaceutsko Društvo/Croatian Pharmaceutical Society | Dispense medicines, inform patients. | |
| Hospital pharmacists | *Represented by:*<br>Hrvatsko Farmaceutsko Drustvo / Croatian Pharmaceutical Society - Hospital Pharmacy Section | Procure medicines, inform patients. | |
| Patient organisations | *Represented by:*<br>Koalicija Udruga u Zdravstvu (KUZ) / Coalition of Associations in Healthcare of Croatia<br>*Disease related:*<br>• Hrvatsko društvo za dijabetes i bolesti metabolizma / Croatian Diabetes Society<br>• Hrvatska udruga oboljelih od Crohna i ulceroznog kolitisa / Croatian Crohn's and Colitis Association<br>• Hrvatska udruga leukemija i limfomi (HULL) / Croatian Association of Leukemia and Lymphoma Patients<br>• Društvo hemofiličara Hrvatske (DHH) / Croatian Hemophilia Society<br>• Hrvatska udruga reumatoidnih bolesnika / Croatian Rheumatism Association | Patient organisations in diseases with biologics use and organisations with specific advocacy or education work on biosimilars identified (see left). | |
| Consumer organisations | *Represented by:*<br>POTROSAC - Društvo za zaštitu potrošača Hrvatske / POTROSAC – Croatian Consumer Protection Association | | |
| Biosimilar industry<br>Generic industry | *Represented by:*<br>Hrvatska udruga poslodavaca (HUP) / Croatian Employers' Association (CEA) | | |
| Pharmaceutical industry in general | *Represented by:*<br>Udruga proizvođača lijekova (UPL) / Association of Drug Manufacturers (UPL) | | |
| Pharmaceutical industry for new biological medicines | *Represented by:*<br>Inovativna farmaceutska inicijativa / Innovative Pharmaceutical Initiative (IFI) | | IFI 2024 (Position paper on switching to and among and biosimilar medicines)<br>IFI 2017 (Position paper on public procurement for medicines |

Source: Stakeholder mapping done by GÖ FP (AUGMENT Consortium)

# 4 Biosimilar policies and practices in Croatia

Below, information on different biosimilar policies and practices is provided (and in some cases, also on further medicines, e.g., on generics or other biosimilars – presented in the grey shaded lines in the tables). Note that the information relates to the year 2024, to the national level and to outpatient and inpatient sectors, unless specified differently.

## 4.1 Pricing and procurement policies 2025

### Biosimilar price link

| | |
|---|---|
| A **biosimilar price link** is in place. | Yes, in place. |
| It applies for the following situations: | All biosimilars entering the market. |
| Price reduction of the first biosimilar compared to the reference product | Minus 25% compared to reference product. |
| Price reduction of the second, third and further biosimilars | Minus 5% compared to previous biosimilar. |
| Price reduction for the reference product | None. |
| Any further specificities | None. |
| **Generic price link** | Yes, in place. |

Source: PPRI 2025, HALMED 2025a

### External price referencing

| | |
|---|---|
| **External price referencing** is applied for biosimilars. | Yes, in place. |
| If yes, it is applied for the following situations: | EPR is applied using the average price of the compared countries in the basket. |
| Any specificities | None. |
| **External price pricing** is in place for other medicines than biosimilars. | Yes, in place. |

Source: PPRI 2025, Medicines for Europe 2025

### Tendering

| | |
|---|---|
| Some (or all) **biosimilars are procured through tendering** (or tendering-like) processes. | Yes. |
| If yes, the scope with regard to the care sector: | Inpatient sector only. |
| **Tendering biosimilars in the inpatient sector** | |
| Scope of biological medicines tendered | |
| Institutional framework | Conducted both on facility (i.e. hospital) level and national level<br>In principle, a unified public procurement procedure under the MoH framework. But for new biosimilars to be included in the reimbursement list, which has not yet been contracted through the unified procedure of the MoH, the hospital conducts its own procurement procedure. The procedure is routine and legally grounded |

| | |
|---|---|
| Information available on procurement procedures and practices | Tender contracts are awarded by active substance. Tender contracts for biologics must be reopened once biosimilar medicines enter the market some months after the marketing authorisation of the biosimilar medicine. Contracts are awarded to one winner only based on the lowest price criterion, prices by competitors are made transparent. |
| **Tendering biosimilars in the outpatient sector (or tendering-like policies)** | |
| Scope of biological medicines tendered | Not applicable as not in place. |
| Institutional framework | |
| Information available on procurement procedures and practices | |
| Generics are tendered (or procured through competitive tendering-like policies). | Inpatient: Yes.<br>Outpatient: In principle no, but some tendering-like procedures of health insurance was reported |

Source: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2025, Medicines for Europe 2025

## 4.2 Reimbursement policies 2025

### Reference price system

| | |
|---|---|
| Biosimilars are **included into the reference price system (RPS)** applied in the outpatient sector. | Yes, biosimilars are included in the RPS. Clusters by ATC-5 and ATC-3. |
| If yes, how many and under which specifications | For establishing the benchmark price, only medicines in the cluster with at least 5% market share in volume in the cluster for a defined time period are considered. |
| If publicly accessible, indicate URL of RPS list | |
| When were first biosimilars included in the reference price system? | |
| Any further specificities | |
| In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered? | Yes, in place. Medicines included on the reimbursement lists - cluster formed at 3rd to 5th levels of ATC for outpatient medicines and ATC-5 for inpatient medicines. |

Source: PPRI 2025, Medicines for Europe 2025, HALMED 2025a

### Inclusion into reimbursement and co-payments

| **Reimbursement in the outpatient sector** | |
|---|---|
| Apart from their potential inclusion into the reference price system (see above), biosimilars are **included in outpatient reimbursement** (positive list). | Yes, the reimbursement procedure is the same as for other medicines. There are two medicines lists (see below). |
| If yes, how many and date of inclusion into reimbursement, if known) | |
| Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list | |
| Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use | |
| Indicate URL of outpatient positive list | Lists of medications - gov.hr |
| Co-payments for biosimilars for outpatient use | Yes, many biologic originator and biosimilar products are reimbursed at 75%. In principle, patients do not pay out of pocket the difference, because this is then covered the company. |
| For medicines for outpatient use in general (other medicines than biosimilars) | A national positive list (with part A and part B) is in place. Full (100%) coverage for all |

| | |
|---|---|
| Positive list for medicines in general<br>Percentage reimbursement rates are in place<br>Co-payments for reimbursable outpatient medicines | medicines in the reimbursement list. Co-payments are charged for funded medicines in the outpatient sector.<br>The costs of A list are fully covered by the social health insurance, when prescribed. The costs for medicines on the B list are partially covered by social health insurance. The difference is paid by the insured person or a supplementary insurance. All medicines from the B list can be prescribed in the outpatient sector. |
| **Reimbursement in the inpatient sector** | |
| Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level | Yes, in national reimbursement list (A-list for hospital use, of which most medicines can also be prescribed in the outpatient sector, see above). |
| Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use | |
| Indicate URLs of hospital pharmaceutical formularies, if publicly accessible | Lists of medications - gov.hr |
| Co-payments for biosimilars for inpatient use | Yes, *"many biologic originator and biosimilar products are reimbursed at 75%. Patients do not pay out of pocket. MAH pay an additional 25%".* |
| For medicines for inpatient use in general (other medicines than biosimilars):<br>Hospital pharmaceutical formularies<br>Co-payments for medicines for inpatient use | A national list is in place.<br>Full (100%) coverage for all medicines used in hospitals.<br>No co-payments are charged for funded medicines in the inpatient sector. |

*Source*: PPRI 2025, Medicines for Europe 2025, Gigov 2025, HALMED 2025a, Roganovic 2025

## 4.3 Specific pricing, procurement and funding policies 2025

| | |
|---|---|
| Application of special pricing, procurement and reimbursement models for biosimilars (e.g., delinkage / subscription-model, management-entry agreements (MEA)) | No, not applied. |
| Enforcement of anti-trust policies | Yes, by the competition authority. No specific cases with regard to biosimilars identified. |
| Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines | Financial MEAs mainly. |

Source: PPRI 2025, Kawalec et al. 2025

## 4.4 Supportive tools and practices for policy-makers 2025

### Horizon scanning

| | |
|---|---|
| Public authorities or public payers use a **horizon scanning** system to identify loss of exclusivity (patent expiry) of biologics | No, not in place. |
| If yes, describe the process and the tools (e.g. regular consultation of a database, horizon scanning scoping meeting with stakeholders), including who use horizon scanning | Not applicable as not in place. |

Source: PPRI 2025

### Health technology assessment

| | |
|---|---|
| **HTA** is applied for biosimilar medicines | Yes, only Budget Impact Analysis (BIA) required, in some cases a full HTA is performed. |
| If yes, in which situations and settings (outpatient and inpatient) | Outpatient and inpatient medicines figure on the same national reimbursement list (A-list) and HTA applies to both sectors. |
| Differences in criteria and processes of HTA for biosimilars compared to other medicines | None identified. |
| Any specificities | None identified. |

Source: PPRI 2025, Kawalec et al. 2025, Huic 2025

## 4.5 Demand-side measures 2025

### Doctors (and further prescribers)

Country context: Only doctors may prescribe medicines.

| | |
|---|---|
| **Prescribing and switching recommendations** | |
| **Prescribing recommendations** for doctors with regard to prescription of biosimilars exist | Yes |
| If yes, what is recommended for naïve patients? | Recommendation to prescribe biosimilars for naïve patients |
| If yes, what is recommended for patients already on biologic treatment | |
| Prescription guidelines (including switching guidelines) were issued by | |
| URL of prescription & switching guidelines | |
| **Prescribing quotas** | |
| Prescribing quotas for doctors regarding prescription of biosimilars exist | No information available |
| If yes, which quotas are defined for biosimilars | |
| Any exemptions | |
| Any sanctions in case of non-achievement | |
| Any (financial) incentives for achieving the quotas | |
| Prescribing quotas were issued by | |
| URL of prescribing quotas | |
| Prescribing quotas for other non-biosimilar medicines exists | |
| **Further gain-sharing models** | |
| Further gain-sharing models exist (beyond those mentioned above) | No information available |
| If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced) | |
| Publicly accessible information | |
| **INN prescribing** | |
| In general, prescribing by INN is in place (information not focused on biologics) | Yes, indicative |
| If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions | |

| Further measures targeted at doctors | |
|---|---|
| Information materials for doctors | Yes, websites and media campaigns. Mainly provided by authorities and biosimilars industry. |
| Information events for doctors (e.g., seminars, trainings) | Yes, seminars, conferences or workshops. Mainly organised by authorities and biosimilars industry such as a day seminar organised by biosimilar medicines industry. |
| Involvement of doctors in switching studies that evaluate clinical outcomes of a switch | Yes, see e.g., Vuijk et al. 2024 (trial Chron's disease). |

Source: PPRI 2025, Medicines for Europe 2025, Vuijk et al. 2025

## Pharmacists (and further dispensers)

Country context: Only pharmacists may dispense.

| Substitution policies | |
|---|---|
| (Automatic) substitution for biosimilars | No, not allowed. |
| If yes, for which biologic substances and under which prerequisites? | Not applicable as not allowed. |
| If yes, since when, and when was it extended? (process of implementation) | |
| Any specificities | |
| URL of underlying law | |
| Generic substitution in place | No, on a voluntary basis. |
| **Gain-sharing models** | |
| Gain-sharing models for pharmacists | No, not in place. |
| If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced) | Not applicable as not in place. |
| Publicly accessible information | |
| **Further measures targeted at pharmacists** | |
| Information materials for pharmacists | |
| Information events for pharmacists (e.g., seminars, trainings) | |

Source: PPRI 2025, Medicines for Europe 2023

## Patients

| Information and educational measures | |
|---|---|
| Information materials for patients | |
| If yes, provide URL of most common materials | |
| If yes, key producers of education measures | |
| Information events for patients (e.g., seminars, trainings) | |
| If yes, key providers of educational events | |
| **Gain-sharing models** | |
| Gain-sharing models for patients | No, not in place. |
| If yes, pls. describe | Not applicable as not in place. |
| Publicly accessible information | |

Source: PPRI 2025, Medicines for Europe 2023

# 5 Impact of biosimilar policies and practices in Croatia

The table below informs about outcome indicators on patient access (e.g., higher number of patients treated), affordability (e.g, savings for the public payers, savings for patients) and availability (presence at the reimbursement list, time between market authorisation and reimbursement / market entry) which were caused by specific biosimilar policies or practices.

## Evidence from the literature on impacts of biosimilar policies and practices in Croatia

| Outcome indicator | Caused by | Findings | Publication |
|---|---|---|---|
| Savings for the public payer | No specific policy identified. | Using infliximab biosimilars as the first treatment for paediatric Crohn's disease is cost-effective compared to traditional treatments. The study (an RCT with cost-effectiveness analysis) was not linked to a specific biosimilar policy. | Vuijk et al. 2024 |
| Increase in biosimilar prescriptions | No specific policy identified | The study aimed to determine the prescription of biologic DMARDs in rheumatology at the University Hospital of Split before and after COVID-19. Overall, prescription trends for biologic DMARDs did not vary significantly, although tocilizumab prescriptions decreased due to shortages, while ixekizumab prescriptions increased due to a rise in psoriatic arthritis patients and approval for treating AS. Biosimilar prescriptions increased significantly during the pandemic. | Radić et al. 2023 |
| Biosimilar use and reduction in overall price | No specific policy identified | A study of TNF alpha inhibitors across Europe. In Croatia, overall infliximab, etanercept and adalimumab use increased significantly after market entry of the biosimilars, but for not for all substances. Croatia was one of the few countries where the second biosimilar of adalimumab was also able to gain some market shares. | Car et al. 2023 |

Source: see last column and further details on the full citation in the bibliography at the end of this country fiche

# 6 Barriers for biosimilar uptake and policy implementation in Croatia

**Evidence and communication-related barriers**

Biosimilar are still considered not to be equivalent to the reference product by some stakeholder; the health minister urged to "remove the stigma from biosimilars" (Hina 2022).

**Policy-related barriers**

Some demand-side measures to encourage biosimilar uptake are not yet in place.

Procurement procedures are still focused on price as award criterion and the single winner tenders.

**Stakeholder-related barriers**

Originator industry published critical statements about biosimilars, procurement procedure aiming for lower prices and switching (IFI 2017, IFI 2024).

Switching was reported to have been done rather rarely which suggests reluctance of the prescribers.

# 7 Facilitators and good practice examples in Croatia

While procurement procedures are still price- and single-winner focused, they appear to encourage biosimilar competition. It was reported that an existing contract for biological medicines is requested to be put on hold and a new tender be launched when a new biosimilar comes to the market.

# 8 Bibliography


AAZ 2011 — Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment. The Croatian Guideline for Health Technology Assessment Process and Reporting, 2011. Available from: HTA Hrvatske smjernice Guidelines draft 13 07 2010 izmjene nakon recenzija MH 13 05 2011 final.doc (accessed 20 December 2024)

Car et al. 2023 — Car E, Vulto AG, Houdenhoven MV, Huys I , Simoens S. Biosimilar competition in European markets of TNF-alpha inhibitors: a comparative analysis of pricing, market share and utilization trends. Frontiers in Pharmacology, Volume 14, 2023. https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2023.1151764

Gigov 2021 — Gigov A. Access to Biosimilars in Central and Eastern Europe. Writing Assignment. BSc Program: Drug Innovation Graduate School of Life Sciences. Utrecht University, 2021. Available from: Microsoft Word - Access to Biosimilars in CEE Writing Assingment Aleksandar Gigov.docx (accessed 20 December 2024)

HALMED 2024a — HALMED. Pharmaceutical pricing and reimbursement policies. Poster prepared for PPRI, 2024. Available from: Croatia_Pharmaceutical_pricing_and_reimbursement_policies_2024_0.pdf (accessed 20 December 2024)

HALMED 2024b — HALMED. Medicinal Products Database, 2024. Available from: Medicinal Products Database | Medicinal Products.: HALMED (accessed 20 December 2024)

HALMED 2024c — HALMED. Biological and Biosimilar Medicinal Products, 2024. Available from: Biological and Biosimilar Medicinal Products - Information On Medicinal Products | Medicinal Products .: HALMED (accessed 20 December 2024)

Hina 2022 — Hina. Croatia below EU average in use of biosimilar drugs. 23.10.2022. N1 Available from: https://n1info.hr/english/news/croatia-below-eu-average-in-use-of-biosimilar-drugs/ (accessed 16 April 2025)

Huic 2020 — Huic M. HTA in Croatia: Past, present and the future, 2020. Available from: Microsoft PowerPoint - HuicM_HTA in Croatia_01092022 [Read-Only] (accessed 20 December 2024)

IFI 2017 — Innovative Pharmaceutical Initiative (IFI. POSITION OF INNOVATIVE PHARMACEUTICAL INITIATIVE ORIGINAL BIOLOGICAL MEDICINES AND BIOSIMILAR MEDICINES about tenders and decision of substitution addressed to governing bodies, physicians and patients, 2024. Available from: iFi-position-paper_-ORIGINAL-BIOLOGICAL-MEDICINES-AND-BIOSIMILAR-MEDICINES.pdf (accessed 20 December 2024)

IFI 2024 — Innovative Pharmaceutical Initiative (IFI). Original biological medicines and biosimilar medicines, 2024. Available from: Original biological medicines and biosimilar medicines — iF! - Inovativna farmaceutska inicijativa % (accessed 20 December 2024)

Kawalec et al. 2017 — Kawalec P, Stawowczyk E, Tesar T, Skoupa J, Turcu-Stiolica A, Dimitrova M, et al. Pricing and reimbursement of biosimilars in central and eastern European countries. Front Pharmacol. (2017) 8:288. doi: 10.3389/fphar.2017.00288

Medicines for Europe 2023 — Medicines for Europe. MARKET REVIEW – EUROPEAN BIOSIMILAR MEDICINE MARKETS POLICY OVERVIEW, 2023. Available from: Biosimilars-Market Review-2023-final-06-09-2023.cdr (accessed 20 December 2024)

Mestre-Ferrandiz et al. 2024 — Mestre-Ferrandiz, J., Czech, M., Smolen, J. S., Cornes, P., Aapro, M. S., Danese, S., … Vulto, A. G. (2024). Capturing the holistic value of biosimilars in Europe – part 1: a historical perspective. *Expert Review of Pharmacoeconomics & Outcomes Research*, *24*(2), 237–250. https://doi.org/10.1080/14737167.2023.2297926

PPRI 2025 — Austrian National Public Health Institute (GÖG). PPRI Indicators, 2023. Available from: https://ppriindicators.goeg.at/ (accessed 20 December 2024)

Radić et al. 2023 — Radić M, Đogaš H, Vrkić K, Gelemanović A, Marinović I, Perković D, Nazlić J, Radić J, Krstulović DM, Meštrović J. Prescription Trends of Biologic DMARDs in Treating Rheumatologic Diseases: Changes of Medication Availability in COVID-19. *Journal of Personalized Medicine*. 2023; 13(8):1199. https://doi.org/10.3390/jpm13081199

Roganovic 2017 — Roganovic J. Drug Reimbursement – Croatia. Presentation, 2017. Available from: https://cddf.org/files/2017/09/1740-Croatia-CDDF-Madrid-Roganovic.pdf (accessed 20 December 2024)

Vuijk et al. 2024 — Vuijk SA, Jongsma MME, Hoeven BM, Cozijnsen MA, van Pieterson M, de Meij TGJ, et al. Randomised clinical trial: First-line infliximab biosimilar is cost-effective compared to conventional treatment in paediatric Crohn's disease. *Aliment Pharmacol Ther*. 2024; 59: 1510–1520. https://doi.org/10.1111/apt.18000



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