European Commission

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

## AUGMENT Biosimilars
## Country fiche MALTA

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augment biosimilars

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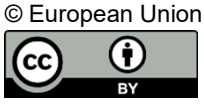

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Annex 7.21

# AUGMENT Biosimilars country fiche: Malta 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.

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# 1 Summary of biosimilar policies and practice in Malta in 2025

### Key stakeholders

The Malta Medicines Authority ensures biosimilar safety, quality, and effectiveness. It is responsible for implementing the regulatory provisions for biosimilars and conducting pharmacovigilance.

The Ministry for Health and Active Ageing is the payer for all reimbursed medicines in Malta. The Directorate for Pharmaceutical Affairs (DPA) coordinates the pricing and reimbursement process of biosimilars. It influences their accessibility within the public healthcare system by making recommendations with regards to reference prices and policies related to their inclusion in the Government Formulary List to the decision-making bodies.

Central Procurement and Supplies Unit (CSPU) is responsible for the procurement of biosimilars in the public sector.

### Major biosimilar policies and practices

In Malta, there is no biosimilar price link in place. Biosimilars are procured through tendering processes in both the inpatient and outpatient sectors. The Central Procurement and Supplies Unit (CPSU) at the Ministry for Health centrally manages the procurement of all medicines used in the public sector, including biological medicines. The tendering process follows an award system based on the Best Price Quality Ratio.

All medicines for outpatient use, including biosimilars, included in the Government Formulary List (positive list) are fully reimbursed at 100% to eligible patients, with no co-payments required. Their inclusion in the Government Formulary List follows the same process as other medicines, based on the list of chronic disease conditions outlined in Part II of the Fifth Schedule of the Social Security Act. There is no separate or specific procedure for biosimilars in inpatient and outpatient reimbursement. Doctors are recommended to switch to biosimilars when available. As per legislation, specifically Subsidiary Legislation 458.49: Prescription and Dispensing Requirements Rules, INN prescribing is mandatory, however, it is not allowed for biologicals as the legislation specifies that the brand name must be specified on a prescription if the prescribed product is a biological medicinal product, and hence, biosimilar substitution is not allowed at the pharmacist/dispensing level.

### Barriers, facilitators and good practice examples

Malta's biosimilar market remains small. Price reductions by originator suppliers and a tendering system based on INN make it less attractive for biosimilars to enter the market. It is probable that the one winner tender system used in procurement results in other competitors, possibly those proposing biosimilars, to lose interest in remaining on the local market. It should also be noted that biosimilars are for the most part provided by the National Health Service and consequently, the private market is probably not a profitable option for them.

# 2 Key data regarding biosimilars in Malta

**First biosimilar medicine** launched (i.e. brought on the market):
The first biosimilar monoclonal antibody was infliximab in 2016. There were however a number of biosimilars such as those for filgrastim and erythropoietin that were introduced before this.

*Source*: https://pharmaceuticalaffairs.gov.mt/wp-content/uploads/documents/circular_428_2016.pdf

Number of the **biosimilars marketed**:
14 molecules with biosimilars available, as of 2024

*Source*: Medicines for Europe 2023

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

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Legislator | Ministry for Health and Active Ageing (MHA) | **Sets legislation and policies. Determines which medicines are listed on the Government Formulary List** | |
| National regulatory authority | Malta Medicines Authority | Implements regulatory provision regarding biosimilars, safety, quality assurance, efficacy and pharmacovigilance<br><br>Organizes information-sharing events such as the Seminar on Biosimilar Medicines held in 2021 which was aimed at providing an interactive forum for the sharing of knowledge on the biosimilar landscape, including regulatory requirements in the development of biosimilars, pharmacovigilance aspects, prescribing and switching, economic considerations, purchasing mechanisms, the impact on healthcare and the future of the biosimilar medicines market. Barriers to uptake, in conjunction with factors that may contribute to the long-term sustainability of biosimilars, were also addressed. | Malta Medicines Authority: Biological Medicinal Products.<br><br>https://medicinesauthority.gov.mt/file.aspx?f=5989 |
| Pharmaceutical pricing authority | Directorate for Pharmaceutical Affairs (DPA)<br>Ministry for Health and Active Ageing (MHA) | DPA:<br>Calculates reference prices based on External Price Referencing for use in the procurement process.<br><br>Prepares HTA reports for decision | |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| | | making regarding the inclusion of new medicines on the government formulary and follow up decisions.<br><br>Reports on Horizon Scanning of pipeline biosimilars for early insight and better decision-making.<br><br>Ensures that procurement specifications are in line with GFL policies and ensure a competitive procurement process.<br><br>MHA:<br>Makes final decision on inclusion based on HTA & price information. | |
| Pharmaceutical reimbursement authority | Directorate for Pharmaceutical Affairs (DPA)<br><br>Ministry for Health and Active Ageing (MHA)<br>- Government Formulary List Advisory Committee (GFLAC)<br>- Advisory Committee for Health Care Benefits (ACHCB) | As per previous section.<br>If necessary, circulars are published which may include prescribing guidelines for biosimilars that will be available through the National Health Service.<br><br>MHA:<br>As the payer, the MHA decides following the Government Formulary List Advisory Committee (GFLAC) and the Advisory Committee for Health Care Benefits (ACHCB), makes recommendations for inclusion of a medicine on the reimbursement list (GFLAC based on HTA & ACHCB based on financial data as prepared by DPA) to the Minister who takes the final decision. | Directorate for Pharmaceutical Affairs (DPA):Hospital formulary list and Outpatients' formulary list |
| Procurement agency | Central Procurement and Supplies Unit (CSPU) | Manage the procurement & supply of materials, works and/or services across the Government Healthcare Services in line with Public Procurement Regulations. | |
| HTA agency / body | Directorate for Pharmaceutical Affairs - Ministry for Health-Government of Malta | Consideration of pipeline/already available biosimilars during the production of HTAs if not already on the GFL. | |
| National competition authority | Malta Competition and Consumer Affairs Authority (MCCAA) | Enforcement of the competition law, anti-trust cases<br><br>MCCAA:<br>Oversees the prices related to medicines in the private market, by guaranteeing that medicines are priced in such a way as to be affordable by the public at large. The process involves following pricing performance when compared to prices of medicines in other EU countries. In collaboration with the Medicines Authority, the MCCAA engages in dialogue with importers aimed at achieving reduction of prices. This process is co-operative in nature | MCCAA: New Generic Medicines /Biosimilars<br><br>MCCAA: List of medicine price reductions. |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| | | and not mandatory. | |
| National patent office | Id-Direttorat tar-Reġistrazzjonijiet tal-Proprjetà Industrijali / Industrial Property Registrations Directorate | Granting and managing patents on biologic medicines | |
| Doctors | *Represented by:*<br><br>*Medical societies*:<br>Medical Association Malta (MAM) | Prescribe biosimilars. Inform patients<br>Medical societies in disease areas with biologics use | |
| Nurses | *Represented by:*<br><br>Malta Union of Midwives and Nurses (MUMN) / Malta Union of Midwives and Nurses | Patient education<br>Assist in switchover processes.<br>Assist in administration of biosimilars | |
| Community pharmacists | *Represented by:*<br>Kamra ta`l-Ispiżjara ta` Malta / Malta Chamber of Pharmacists | Dispense medicines, inform patients | |
| Hospital pharmacists | *Represented by:*<br>Malta Association of Hospital Pharmacists (MAHP) | Dispensing/administration, inform patients / health professionals / procurers<br>Assist in switchover processes.<br>Assist in administration of biosimilars | |
| Patient organisations | *Represented by:*<br>Malta Health Network (MHN) | Arthritis and Rheumatism Association of Malta<br>Malta Association of Crohn's and Colitis<br>Malta Health Network | |
| Consumer organisations | Consumers' Association Malta, Association of Consumer Rights | | |
| Biosimilar industry | *Represented by:*)<br><br>Malta Chamber of Commerce Healthcare Executive Committee and Market Access Taskforce<br><br>Malta Enterprise | Note specific to biosimilars but may be involved in the local introduction and supply of biosimilars. | |
| Generic industry | *Represented by:*)<br><br>Malta Chamber of Commerce Healthcare Executive Committee and Market Access Taskforce<br><br>Malta Enterprise | | |
| Pharmaceutical industry in general | *Represented by:*<br><br>Malta Chamber of Commerce Healthcare Executive Committee and Market Access Taskforce | | |

| Stakeholder | Name in local language and English translation & URL | Role with regard to biosimilars | Publications by this stakeholder group |
|---|---|---|---|
| Pharmaceutical industry for new biological medicines | *Represented by:*<br><br>Malta Chamber of Commerce Healthcare Executive Committee and Market Access Taskforce | | |

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

# 4 Biosimilar policies and practices in Malta 2025

Note that the information relates to the year 2025, to the national level and to outpatient and inpatient sectors, unless specified differently.

## 4.1 Pricing and procurement policies

### Biosimilar price link

| | |
|---|---|
| A **biosimilar price link** is in place. | No |
| It applies for the following situations: | |
| Price reduction of the first biosimilar compared to the reference product | |
| Price reduction of the second, third and further biosimilars | |
| Price reduction for the reference product | |
| Any further specificities | In the public sector, for new medicines added to the Government Formulary List (GFL) a Maximum Reference Price calculated by the Pharmaceutical Pricing Unit at the Directorate for Pharmaceutical Affairs is used to guide the procurement process. This is the same for other medicines already on the GFL, although price control is also achieved by procuring through a tendering system.<br>Malta's private pharmaceutical market operates under a free-market pricing policy with no statutory price controls and no price regulations, allowing licensed market players (pharmacies, wholesale dealers, manufacturers, or Marketing Authorization Holders) to determine retail prices. While there are no pricing authorities regulating medicine prices, retail pharmacies commonly apply a 20% mark-up on wholesale prices recommended by distributors. Prices are monitored by the MCCAA through a referencing mechanism that benchmarks consumer prices against EU Member States.<br><br>Cost-plus pricing, generic price link, and biosimilar price link policies are not in place in Malta. |
| Generic price link | No |

*Source*: PPRI 2025, Vogler et al. 2024

### External price referencing

| | |
|---|---|
| External price referencing is applied for biosimilars. | Yes, both in inpatient and outpatient sectors, with average/median price of countries in the reference basket for Malta. External Price Referencing is applied to all reimbursed medicines, including biosimilars. |

| | |
|---|---|
| If yes, it is applied for the following situations: | HTA used in the budget impact analysis, negotiations and tenders for procurement. |
| Any specificities | |
| External price referencing is in place for other medicines than biosimilars. | External Price Referencing is applied to all reimbursed medicines, including biosimilars. All medicines supplied through the inpatient and outpatient sectors of the public health service are procured centrally through tendering. |

*Source*: PPRI 2025, Medicines for Europe 2023

### 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 and outpatient sectors within the NHS |
| **Tendering biosimilars in the inpatient sector** | |
| Scope of biological medicines tendered | All biological medicines |
| Institutional framework | Managed centrally by the Central Procurement and Supplies Unit (CPSU) at the Ministry for Health and Active Ageing |
| Information available on procurement procedures and practices | Award criteria is based on Best Price Quality Ratio |
| **Tendering biosimilars in the outpatient sector (or tendering-like policies)** | |
| Scope of biological medicines tendered | All biological medicines |
| Institutional framework | Managed centrally by the Central Procurement and Supplies Unit (CPSU) at the Ministry for Health and Active Ageing |
| Information available on procurement procedures and practices | Award criteria is based on Best Price Quality Ratio |
| Generics are tendered (or procured through competitive tendering-like policies). | Inpatient: Yes<br>Outpatient: Yes<br>Same tender covers both inpatients and outpatients |

*Source*: PPRI 2025; Vogler, Salcher-Konrad and Habimana 2022, Vogler et al. 2024

## 4.2 Reimbursement policies

### Reference price system

| | |
|---|---|
| Biosimilars are included into the reference price system (RPS) applied in the outpatient sector. | Not applicable |
| If yes, how many and under which specifications | Not applicable |
| If publicly accessible, indicate URL of RPS list | Not applicable |
| When were first biosimilars included in the reference price system? | Not applicable |
| Any further specificities | Not applicable |
| In general, a reference price system is in place (for other medicines than biosimilars), and how those medicines are clustered? | No |

*Source*: PPRI 2025

## 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<br>The same tender which covers inpatients covers outpatient supply |
| If yes, how many and date of inclusion into reimbursement, if known) | If the active ingredient is included on the Outpatient Formulary List or Hospital Formulary List, there is potential of biosimilar availability depending on the tender cycle. |
| Extent of reimbursement rates applicable for biosimilars included in the outpatient positive list | 100% |
| Any specificities regarding the process of inclusion into outpatient reimbursement compared to other medicines for outpatient use | There is no specific process for biosimilars. The process of inclusion of biosimilars into outpatient reimbursement is like that of other medicines. It is based on disease specific of the list of conditions as outlined in The Fifth Schedule of the Social Security Act. |
| Indicate URL of outpatient positive list | https://pharmaceuticalaffairs.gov.mt/wp-content/uploads/2024/11/outpatients_gfl_oct_2024.pdf |
| Co-payments for biosimilars for outpatient use | No |
| For medicines for outpatient use in general (other medicines than biosimilars)<br>Positive list for medicines in general<br>Percentage reimbursement rates are in place<br>Co-payments for reimbursable outpatient medicines | For medicines in general for outpatient use:<br>- Positive list<br>- Full (100%) reimbursement for all procured medicines in the reimbursement list<br>- No co-payments |
| **Reimbursement in the inpatient sector** | |
| Biosimilars are included in hospital pharmaceutical formularies (at national, regional and/or facility level) | Clinicians prescribe in accordance to what is available within the Hospital Formulary List and the current product being procured by CPSU by tender is used. |
| Any specificities regarding the process of inclusion into hospital pharmaceutical formularies compared to other medicines for inpatient use | No. The inclusion of medicines on the Hospital Formulary list for inpatient use follows the same procedure as described for outpatient medicines. |
| Indicate URLs of hospital pharmaceutical formularies, if publicly accessible | URL of national hospital pharmaceutical formulary:<br>https://pharmaceuticalaffairs.gov.mt/en/resources/the-government-formulary-list/ |
| Co-payments for biosimilars for inpatient use | Not applicable |
| For medicines for inpatient use in general (other medicines than biosimilars):<br>Hospital pharmaceutical formularies<br>Co-payments for medicines for inpatient use | Hospital Formulary List<br>No co-payments for medicines for inpatient use |

*Source*: PPRI 2025, Vogler et al. 2024, Machado et al. 2024

## 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.<br>There is no official policy specifically for the procurement of biosimilars. The procurement is by INN, allowing originator product and biosimilar to compete in the same procurement procedure. |
| Enforcement of anti-trust policies | |
| Specific pricing and funding (e.g., subscription models, MEAs, …) for other medicines | Mainly financial MEAs |

*Source*: PPRI 2025, Moorkens et al. 2017

## 4.4 Supportive tools and practices for policy-makers

### Horizon scanning

| | |
|---|---|
| Public authorities or public payers use a horizon scanning system to identify loss of exclusivity (patent expiry) of biologics | Yes. DPA performs an annual biosimilar Horizon Scanning exercise to identify biosimilars currently in the pipeline. |
| 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 | The process involves gathering information from free and publicly available sources such as information published by other Horizon Scanning Systems, databases, investor reports and grey literature. Horizon Scanning is primarily used internally within DPA to enable early insight, ultimately helping achieve better decision making. |

*Source*: PPRI 2025, Vogler 2022

### Health technology assessment

| | |
|---|---|
| HTA is applied for biosimilar medicines | HTA is not specifically applied for biosimilars but biosimilars may be included in HTA for active ingredients that are not already included on the Government Formulary List. |
| If yes, in which situations and settings (outpatient and inpatient) | Any |
| Differences in criteria and processes of HTA for biosimilars compared to other medicines | None |
| Any specificities | |

*Source*: PPRI 2025

## 4.5 Demand-side measures

### Doctors (and further prescribers)

Country context: Only doctors may prescribe.

| **Prescribing and switching recommendations** | |
|---|---|
| Prescribing recommendations for doctors with regard to prescription of biosimilars exist | Yes. Circulars issued with regards to this are publicly available on the DPA website. |
| 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 | When biosimilars were first introduced on the National Health Service, recommendations to switch patients for economic reasons were in place, with corresponding guiding circulars. Currently for both naïve and switching, biologics/biosimilars are prescribed according to what is procured and available within the NHS. |
| Prescription guidelines (including switching guidelines) were issued by | Circulars issued by the Chief Medical Officer |
| URL of prescription & switching guidelines | https://pharmaceuticalaffairs.gov.mt/en/resources/circulars-and-memos |
| **Prescribing quota** | |
| Prescribing quota for doctors with regard to prescription of biosimilars exist | No |
| If yes, which quota are defined for biosimilars | |
| Any exemptions | |
| Any sanctions in case of non-achievement | No |
| Any (financial) incentives for achieving the quota | No |
| Prescribing quota were issued by | |
| URL of prescribing quota | |
| Prescribing quota for other non-biosimilar medicines exists | No |
| **Further gain-sharing models** | |
| Further gain-sharing models exist (beyond those mentioned above) | No |
| 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 place (information not focused on biologics) | INN prescribing is in place but not for biological medicines. Refer to below section. |
| If INN prescribing is allowed, there are some exemptions, and biologics are among the exemptions | Biological medicines are to be prescribed by brand name:<br><br>https://pharmaceuticalaffairs.gov.mt/wp-content/uploads/documents/circular_428_2016.pdf<br>"Doctors are to prescribe according to brand name."<br><br>https://legislation.mt/eli/sl/458.49/eng/pdf<br>"Every prescription shall:<br>Bear the name, date of birth, age and locality of current residence of the patient and the 'Common name' as defined in article 2 of the Medicines Act; the brand name if (i) the prescribed product is a biological medicinal product, as defined in Part I, point 3.2.1.1. of the Schedule to the Medicines (Marketing Authorisation) Regulations, or,..."<br>"if the product prescribed qualifies under the criteria for prescribing a brand name as specified in paragraph (c), the pharmacist dispensing the product shall dispense the product with the brand name as prescribed." |

| **Further measures targeted at doctors** | |
|---|---|
| Information materials for doctors | Ad hoc meetings and circulars as per below: https://pharmaceuticalaffairs.gov.mt/wp-content/uploads/documents/circular_428_2016.pdf |
| Information events for doctors (e.g., seminars, trainings) | As above |
| Involvement of doctors in switching studies that evaluate clinical outcomes of a switch | |

*Source*: PPRI 2025, Machado et al. 2024, Barbier et al. 2022

### Pharmacists (and further dispensers)

Country context: Pharmacists may permit medicinal products to be prepared or dispensed by a pharmacy technician under their personal supervision as regulated by or under the Medicines Act.

| **Substitution policies** | |
|---|---|
| (Automatic) substitution for biosimilars | Not permitted |
| If yes, for which biologic substances and under which prerequisites? | |
| If yes, since when, and when was it extended? (process of implementation) | |
| Any specificities | |
| URL of underlying law | |
| Generic substitution in place | Yes but not for biologics/biosimilars (as above). |
| **Gain-sharing models** | |
| Gain-sharing models for pharmacists | Not applicable |
| If yes, pls. describe (care setting: outpatient / inpatient, contract parties, content and incentives of gain-sharing, when was it introduced) | |
| Publicly accessible information | Not applicable |
| **Further measures targeted at pharmacists** | |
| Information materials for pharmacists | Yes |
| Information events for pharmacists (e.g., seminars, trainings) | Ad hoc meetings and circulars as per below: https://pharmaceuticalaffairs.gov.mt/wp-content/uploads/documents/circular_428_2016.pdf |

*Source*: PPRI 2025, Machado et al. (2024), Barbier et al. (2022)

### Patients

| **Information and educational measures** | |
|---|---|
| Information materials for patients | Yes |
| If yes, provide URL of most common materials | Annex 2 https://pharmaceuticalaffairs.gov.mt/wp-content/uploads/documents/circular_428_2016.pdf<br><br>https://pharmaceuticalaffairs.gov.mt/en/resources/circulars-and-memos/ |
| If yes, key producers of education measures | Issued by Office of the Chief Medical Officer and published on the DPA website. |
| Information events for patients (e.g., seminars, trainings) | Yes |
| If yes, key providers of educational events | MMA Seminar on Biosimilar Medicines 2021 |

| Gain-sharing models | |
|---|---|
| Gain-sharing models for patients | Not applicable |
| If yes, pls. describe | |
| Publicly accessible information | Not applicable |

*Source*: PPRI 2025, Barbier et al. (2022)

# 5 Impact of biosimilar policies and practices in Malta

No information available in the literature.

# 6 Barriers for biosimilar uptake and policy implementation in Malta

### Legal barriers

Legislation currently prevents biosimilar switching at the pharmacist-level since Subsidiary Legislation 458.49: Prescription and Dispensing Requirements Rules specifies that biological medicines need to be prescribed and dispensed by Trade Name.

### Organisational barriers (health-systems or health institutions-related)

e.g., fragmented health systems; different competences and funding responsibilities for outpatient and inpatient sectors; different policy frameworks for private and public settings; lack of implementation plans; lack of accountability of stakeholders; small markets, parallel exports

A relatively small market for biosimilars. For instance, the price reductions by originator suppliers make the market unattractive for biosimilar manufacturers since the tendering is by INN. Since the current tendering system allows for one winning bid, uptake may seem low due to the limited number of options for the same active ingredient. The feasibility and sustainability of procuring originator biologic and several biosimilars of the same active molecule in a small market is questionable.

### Financial barriers

Incentives are not required in the Maltese scenario to support biosimilar switching by physicians and substitution practices of pharmacists (e.g. no gainsharing, no prescription quotas), especially as evidence has evolved further in recent years further supporting this stance.

### Evidence and communication-related barriers

Communication on biosimilars is relatively limited. There are no documented National Policies targeting patients or healthcare professionals but specific circulars to guide healthcare professionals in cases of biosimilar switching and substitution were issued by the CMO's office for each biosimilar added to the reimbursed list.

In several cases, scientific evidence to support biosimilar switching practice (e.g., switching studies from Malta) are not available.

# 7 Facilitators and good practice examples in Malta

Significant efforts by the Maltese National Health Authority have enabled the entry of biosimilars into the market (e.g. inclusion of biosimilars in the reimbursement list, introduction of switching and substitution of biosimilars). Biosimilar penetration is likely to foster competition (e.g. reduced pricing), as they can affect the price of the entire therapeutic class, including the reference product.

# 8 Developments in Malta

### Recent changes

Recent changes include:

- The annual internal Horizon Scanning reports on biosimilars which are used internally to gain early insight on biosimilars that are in the pipeline.
- The use of Horizon Scanning for biosimilars in specific cases for example to aid in HTA production or on an ad hoc basis for example to provide information for appeals to tenders.

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