



# Filling the gap

How off-patent medicines  
can **improve the equity  
and quality** of cancer care





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As Chairperson of Medicines for Ireland, I am very pleased to present this hugely important policy paper published by Medicines for Europe.

It is recognised that smarter use of generic, biosimilar and value added medicines will ensure equitable access to cancer care. This is especially the case in Ireland, where increased competition for resources within the Health Service Executive, means that smarter use of off-patent medicines can improve the equity and quality of cancer care for patients.

Europe's Beating Cancer plan is a welcome milestone to drive focused policy frameworks for cancer care in Europe. To achieve its mission, the cancer plan must support sustainable policies that improve access to generic, biosimilar and value-added medicines.

An important checklist of key policies that must be implemented to ensure equity and quality of cancer care is achieved has been established by Medicines for Europe.

They are:

- Finding synergies and sharing best practices
- Comprehensive uptake policies for off-patent medicines
- EU and national cancer strategies promoting the use of off-patent medicines
- Removing barriers after expiry of Intellectual Property (IP)
- Adapting EU framework to develop value added medicines

This policy paper is an important overview for key policy makers in this area. In Ireland, the Covid-19 pandemic has caused delays in cancer care that have been articulated by leading organisations such as the Irish Cancer Society. We all know that Cancer is one of the most burdensome health challenges of our time and while we have made incredible scientific advances in our understanding and treatment of cancer, there are gaps in equity of access to existing treatments.

In addition, it was recognised in November by the National Director of the HSE's National Cancer Control Programme that up to 2,000 cancers may be undetected due to pandemic disruption. Therefore, all stakeholders need to work together to ensure we can create agile policies for off-patent medicines in the Ireland and throughout the EU to support greater patient access to cancer care.

**David Delaney**  
**Chairperson**  
**Medicines for Ireland**



## **Availability of affordable off-patent cancer treatment is one of the greatest assets to efficient cancer care in Europe. They offer an opportunity for Member States to deliver on equitable patient access to the pharmaceutical standards of care and to better cancer care pathways.**

By including comprehensive policies to support the uptake of off-patent medicines, the Beating Cancer Plan can encourage the redeployment of freed-up budget resources to support patients more effectively.

The generic, biosimilar and value added medicines industries directly and indirectly contribute to tackling uneven access to preventive measures, screening & diagnostics, treatment and life-long care.

### **Key messages:**

1

**Access to oncology treatment and care** across Europe is not equitable – among countries, and even across regions and hospitals within countries. More action is needed to find **synergies and to share best practices for countries to achieve equitable access to cancer care.**

2

**Comprehensive policies** which **support the uptake of generic and biosimilar medicines** are required to broaden patient access to oncology therapies. **Incentives and utilisation support measures** would allow reliable supply as well as efficiency gains for pharmaceutical budgets, **greater access and care equity, and more patients to be treated.**

3

**EU and National cancer strategies** should actively **promote the use of off-patent medicines** and **redeploy the freed up budget.** Reinvestment would improve the quality of cancer care by involving all actors in the benefit sharing.

4

**The removal of access restrictions and anti-competitive marketing strategies after expiry of Intellectual Property (IP)** and other protections is essential to leverage the opportunity with off-patent oncology treatment.

5

For a more **holistic and patient-centred approach** towards disease prevention and treatment, value added medicines development should be supported by **adaptation of EU framework to better support innovation on off-patent medicines by repurposing, reformulating or combining therapies to optimise oncology treatments.**





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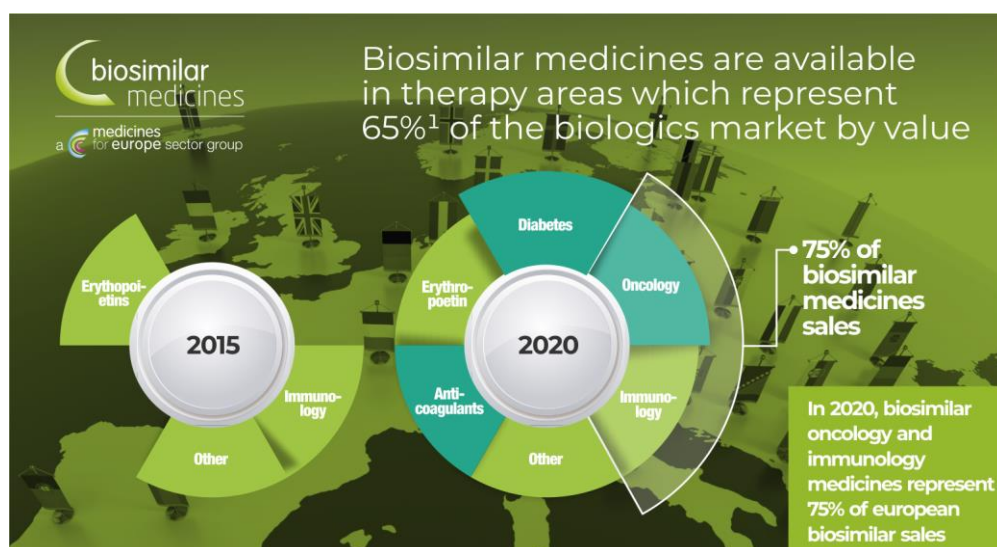
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## > Biosimilar medicines and cancer care

A growing number of new cancer therapies are biological molecules. Treatments such as rituximab, the first monoclonal antibody approved in the EU for a cancer indication, presented an important improvement of leukaemia prognosis, that is considered “standard of care” today. Biosimilar medicine versions of rituximab and other agents, such as trastuzumab and bevacizumab are contributing to **extended treatment options** for the healthcare community.

The cost of cancer therapy is increasing as more targeted therapies come to market, putting pressure on healthcare budgets and in some countries impacting equitable access. Over the next 10 years many more biological “standards of care” are set to lose market exclusivity<sup>1</sup>, opening up to off-patent competition from biosimilar medicines in the field of oncology. More use of biosimilar medicines can improve patient access to oncology medicines and other healthcare products and services via better and more informed use and improve healthcare budget sustainability.



### Source:

1. IQVIA MIDAS MAT Q2 2020; Country cohort includes 30 countries within Europe Economic Area - Biologics market by value

2. 2015: Hematopoietic Growth Hormones, Growth hormones, Sex Hormones; 2020: + osteoporosis

The medical oncology community in Europe largely embraced the biosimilar medicines opportunity to enhance overall cancer care. For instance, the European Society for Medical Oncology (ESMO) released their position paper on biosimilar medicines ([link](#)) before the first biosimilar approval for use, already acknowledging the prominent role these therapeutic options could play as a “must-have weaponry” and a “catalyst for equal access” in cancer care<sup>2</sup>.

The value of biosimilar medicines for patients and healthcare systems is well recognised. Since the first approval of biosimilar medicine in 2006, we have accumulated over **2 billion patient treatment days**<sup>3</sup> in Europe alone, testifying to the safety and efficacy and the robust regulatory framework designed by European regulators.

1- <https://www.medicinesforeurope.com/wp-content/uploads/2020/12/BIOS2.pdf>

2- Tabernero J. – Biosimilars create opportunity for sustainable cancer care; European Pharmaceutical Review, 22 Feb 2017

3- <https://www.medicinesforeurope.com/wp-content/uploads/2020/12/BIOS5.pdf>



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Today, the existing biosimilar competition in cancer care has led to an increase in the number of patients that healthcare systems can treat while reducing significant equity gaps across Europe. There are well-identified barriers for patients' access to oncology treatment in Europe and worldwide<sup>4</sup>, especially concerning availability and out-of-pocket payments. In the European Union, differences in access to trastuzumab pertaining to the delays with reimbursement approvals, healthcare spending levels and trastuzumab usage in Member States, were shown to be related to discrepancies in breast cancer patients' outcomes in the Union, particularly when comparing Eastern and Western European Countries.<sup>5</sup> With the first biosimilar trastuzumab being launched in late 2017, the uptake of this life-saving medicine has increased, and more patients have been granted access. The use of biosimilar medicines for oncology has been increasing ever since with a large opportunity remaining for European countries to expand access and achieve cost optimisation<sup>6</sup>.

**In 2020, 3 molecules used to treat cancer patients are available in the EU. It has been estimated that these three medicines account for 15% of all cancer medicines sales and that the biosimilar options could bring a cost reduction of EUR 2.4 billion in Europe per year.<sup>7</sup>**

With more oncologic biological therapies set to lose their market exclusivities in the next 5 years, countries will enjoy even greater opportunities to increase patient access to cancer treatment.



<sup>4</sup>- Cherny, N. I., Sullivan, R., Torode, J., Saar, M. & Eniu, A. ESMO International Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in countries outside of Europe. Ann. Oncol. 28, 2633-2647 (2017)

<sup>5</sup>- Cherny, N. I., Sullivan, R., Torode, J., Saar, M. & Eniu, A. ESMO International Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in countries outside of Europe. Ann. Oncol. 28, 2633-2647 (2017)

<sup>6</sup>- IQVIA – The impact of Biosimilar competition in Europe 2020

<sup>7</sup>- [Chapman, S., Paris, V., & Lopert, R. \(2020\). Challenges in access to oncology medicines. 123.](#)



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**Beyond access to medicines, biosimilar use has created opportunities for re-investment of savings into other cancer care products or services. Biosimilar medicines have been instrumental in increasing access to biologics and cancer care across Europe.**

Moreover, the use of these medicines can be key in improving the quality of treatment for a broader number of patients. Through **benefit-sharing**, savings derived from the use of cost-effective biosimilar medicines can be re-deployed and re-invested beyond medicines (including newer, personalised therapies), in healthcare services, e.g. in better infrastructure and hiring more staff to take care of patients.



## REINVEST TO IMPROVE CANCER CARE: Creating Off-site nurse clinics

In Cardiff, rituximab intravenous formulation biosimilars were predicted to save one hospital £300,000 -335,000 a year over the subcutaneous reference biologic, however there was another aspect to consider for patients. Patients need to travel across town, through large urban areas to get lymphoma chemotherapy and the time-savings of subcutaneous drugs could be lost in overall travel times. **Hence, the financial savings from biosimilars were used to work with patients and advocates to develop and staff infusion clinics closer to patients' homes.** Feedback from patients was overwhelmingly positive: patients reported that they were pleased with their reduced travel times, the ease of parking at offsite units, and the prompt attention they received when arriving for their appointments. For Cardiff the initial benefit to haematology patients can now be expanded for other patients needing intravenous therapies – such as those with inflammatory disease as well.



## WIDER ACCESS TO CANCER TREATMENT: Update of treatment guidelines after biosimilar launch

Update of NICE guideline for Pertuzumab for adjuvant treatment of HER2-positive early stage breast cancer.

After the biosimilar launch in 2018, NICE guidelines were updated to reflect the improved cost-effectiveness of biosimilar trastuzumab. As a result, adjuvant pertuzumab is recommended for HER2-positive early stage breast cancer in people with lymph node-positive disease. The introduction of biosimilar has increased treatment options and resulted in broader access to medication.



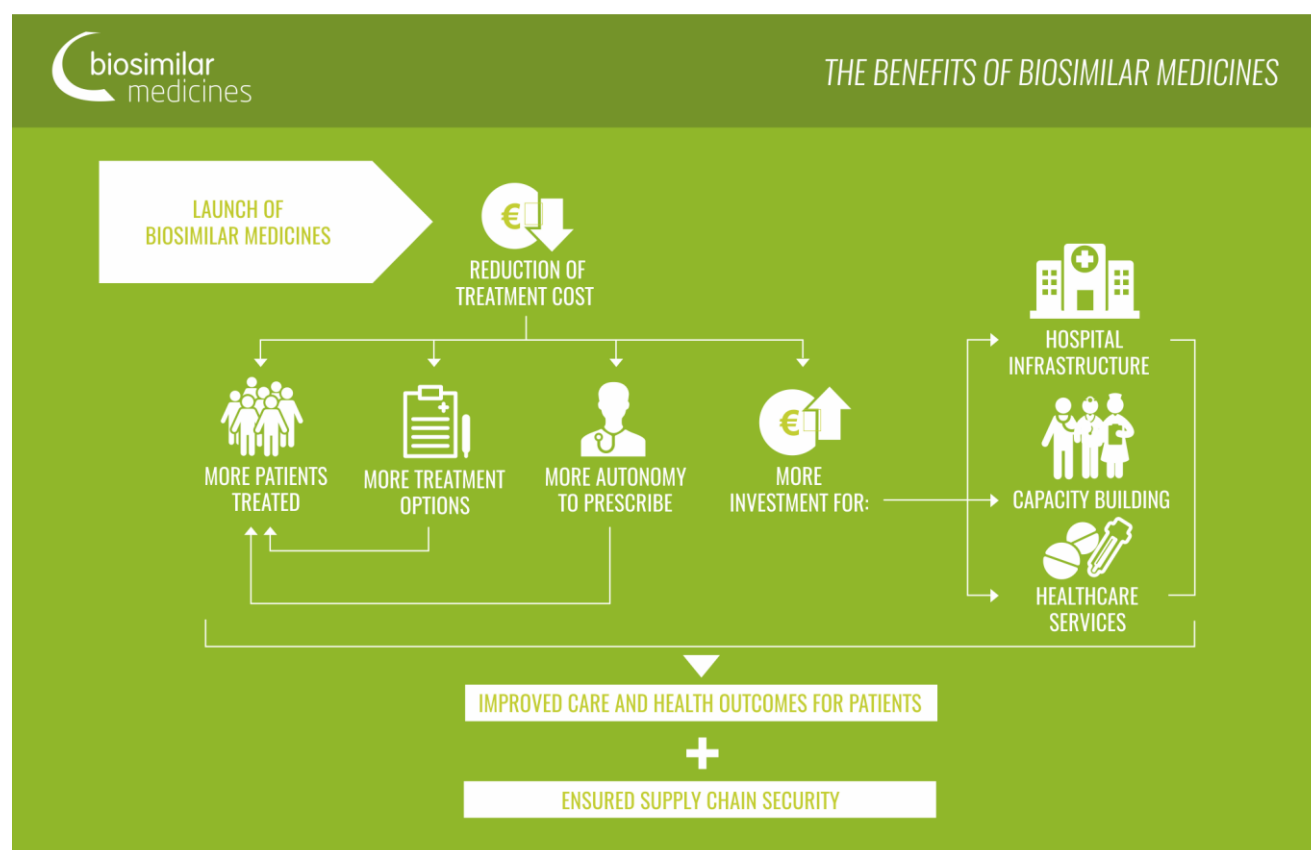


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Biosimilar medicines undoubtedly contribute to the reduction of treatment costs which can be reinvested into better care for patients. **A recent IQVIA report on Biosimilar competition in Europe 2020 underlines<sup>8</sup>** - Biosimilar medicines have an **unambiguously positive and prominent impact on pharmaceutical budgets** – since their availability, they have contributed to the sustainability of pharmaceutical budgets by decreasing the overall cost of biologic expenditure by almost a third (where biosimilar competition has been enabled), contributing to 5% of savings on the total European pharmaceutical budget. This budget relief should be invested into more patients treated where availability is not optimal or reinvested into other areas in healthcare, both ultimately resulting in improved care and health outcomes for oncology patients.



There are many strategies and policy framework designs to achieve these benefits. Good biosimilar medicine policies balance the benefits of multi-source competition, volume uptake which increases patient access, and price discounts that generate savings. They all share key components as they were defined by IQVIA biosimilar sustainability scorecard, evaluating, and comparing policy measures across several EU countries<sup>9</sup>

<sup>8</sup>-[IQVIA-The impact of Biosimilar competition in Europe 2020](#)

<sup>9</sup>-[IQVIA Institute, & Medicines for Europe, \(2020\). Country Scorecards for Biosimilar Sustainability.](#)



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POLICY AREA	SUSTAINABLE MARKET
 <b>Regulatory environment and clinical guidelines</b>	<ul style="list-style-type: none"> <li>• <b>Instant or very short market entry</b> after approval</li> <li>• Publication of <b>multiple guidelines</b> on usage and protocols prior to first biosimilar entry</li> <li>• Authorisation and <b>guidance of physician-led ability to switch to a biosimilar medicine</b> at entry of first biosimilar on the market</li> <li>• <b>No biologic pharmacy substitution</b> allowed</li> </ul>
 <b>Awareness and education</b>	<ul style="list-style-type: none"> <li>• Access to <b>comprehensive and unbiased training or education</b> prior to first biosimilar entry</li> </ul>
 <b>Incentives</b>	<ul style="list-style-type: none"> <li>• <b>Incentives in place to encourage use</b> of most economically advantageous product upon introduction of competition</li> <li>• <b>An incentive or quota that does not restrict physician choice</b></li> </ul>
 <b>Pricing rules and dynamics</b>	<ul style="list-style-type: none"> <li>• <u>No forced originator price cuts</u> by central authorities required, <b>market forces to determine price</b></li> <li>• <b>No reference price</b> determined by central authorities, <b>market forces to determine price</b></li> </ul>
 <b>Purchasing mechanisms</b>	<ul style="list-style-type: none"> <li>• <b>12- to 24-month contracts</b> ensure market competitiveness and avoid patients being switched often</li> <li>• <b>Tender opens upon introduction of competition</b></li> <li>• <b>4-6 months lead time</b> to allow necessary preparations and stock build-up</li> <li>• Consistently <b>award multi-winner tenders</b> to allow market sustainability</li> <li>• Decision based on the <b>most economically advantageous tender offers</b> (e.g. incorporating sustainability, price, product characteristics, continuity of supply)</li> </ul>

**Source:**

IQVIA Institute – [TheIdealsustainablemarketscorecard](https://www.iqvia.com/insights/country-scorecards-for-biosimilar-sustainability). Country Scorecards for Biosimilar Sustainability for [Denmark](#), [France](#), [Germany](#), [Hungary](#), [Italy](#), the [Netherlands](#), [Norway](#), [Poland](#), [Romania](#), [Spain](#), [Sweden](#) and the [UK](#) can be accessed on the [Institutewebsite](https://www.iqvia.com/insights/country-scorecards-for-biosimilar-sustainability).





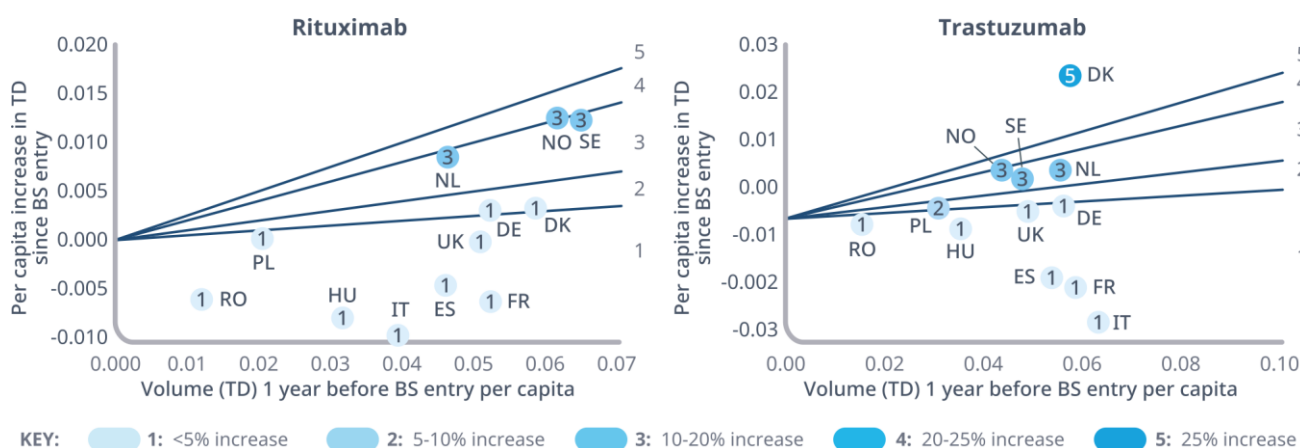
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## Many European countries can do better at increasing access for all cancer patients by using existing biosimilar medicines..

Access to biological therapy for cancer patients differs in European countries, meaning that once the biosimilar versions become available, countries depart from various levels of use and access. Such is the case for rituximab and trastuzumab (chart below) where the differences become clear between access levels before the biosimilar introduction (horizontal axis) and the level of access increase after the introduction of biosimilar medicines (vertical axis)<sup>10</sup>.



Source: Country Scorecards for Biosimilar Sustainability IQVIA, June 2020: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/country-scorecards-for-biosimilar-sustainability/iqvia-institute-scorecards-appendix-orb2520.pdf?la=en>

Despite biosimilar versions being available in several European markets and substantially lowering the cost of treatment, not all countries are using this opportunity to increase access to medicines for patients. Frequently, biological therapies are subject to prescription control, based on disease progression factors. Patients need to meet specific restrictive clinical criteria set out to rationalise the use due to the initial high cost of therapy. In some countries the criteria, set before biosimilar competition when costs were high, have remained unchanged and continue to limit the actual access to biological treatment, despite sizable decreases in the cost of this treatment. In certain cases, patients still need to meet strict qualifications to be entitled to receive biological treatment and even then, after a certain time or if their disease is in remission and drops below the qualification criteria, their biological treatment can be suspended until a relapse or progression of the disease is observed<sup>11</sup>. These access restrictions should be lifted in conjunction with uptake policies for biosimilar medicines.

10- IQVIAInstitute.&MedicinesforEurope.(2020).CountryScorecardsforBiosimilarSustainability.

11- <https://www.producencilekow.pl/wp-content/uploads/2019/10/raport-calosc-v2.pdf>



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## Main recommendations to deliver on benefits of biosimilar medicines in cancer care:

### Promote biosimilar medicines use in the EU and National Cancer Strategies to ignite competition and improve access to medicines and care.

Benefits derived from the use of biosimilar medicines should be made tangible for all stakeholders in the healthcare system. Good practice examples include prescribers' incentives and benefit-sharing schemes, that include reinvestment into other health care areas (diagnostic, screening).

### Remove barriers to uptake and foster biosimilar medicines competition.

Dedicated biosimilar uptake policies should be designed in a way to foster healthy long-term competition. Competition only exists if biosimilar medicines are used. Supportive uptake policies that foster smart purchasing practices and create conducive biosimilar competition include: Tendering schemes allowing for multiple winners, timely opening of tenders once biosimilar medicines are available on the market, criteria beyond price and a defined level of predictability by appropriate length of tender contracts. Policies to increase competition and uptake of these medicines should be accompanied by measures to prevent the misuse of intellectual property (IP) processes and other regulatory protections to delay market entry – see section Barriers to competition.

### Continuous stakeholder engagement and education on biosimilars and the growing clinical experience.

Availability of information resources by trusted EU and national authorities is crucial in building trust and understanding. Beyond basic information, continuous engagement with healthcare community stakeholders is needed to share the growing experience (e.g. pharmacovigilance), explain the evolution and advances of the regulatory science framework but also to ensure all communities, including those for which biosimilar medicines are yet to become available, are given access to important resources and contribute with their unique perspective.

### Share experience and best practices among Member States.

The last 15 years have shown that there is no 'silver bullet' or ideal formula when it comes to biosimilar policy frameworks. Nonetheless, the European Union represents a unique opportunity to share very diverse experiences from the different markets allowing for faster and smarter policy designs over time which cover for the key enablers<sup>12</sup>: regulatory and clinical guidelines, awareness and education, incentives, pricing rules & dynamics and purchasing mechanisms.

12- [IQVIAInstitute,&MedicinesforEurope,\(2020\).CountryScorecardsforBiosimilarSustainability.](#)



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## > Value added medicines and cancer care

In view of the need for a more holistic and patient-centred approach towards disease prevention and treatment, value added medicines represent an opportunity to rethink and optimise oncology treatments.

There is significant untapped potential in Europe to optimise existing therapies. Building on the previous experience and knowledge we have gained over the years of use of a medicine, Value Added Medicines present an opportunity to innovate to bring therapies to indications which have no approved therapies and reduce unmet medical need (repurposing), build on existing medicine to allow for patient-centric design or address healthcare inefficiencies (drug reformulation) and combine medicine and different services that can substantially improve treatment outcomes (complex combinations).



**DRUG REPOSITIONING**  
Finding new indications



**DRUG REFORMULATION**  
New delivery system



**COMPLEX COMBINATION**  
New regimens  
or adding technology

Value Added Medicines can bring important benefits to patients, healthcare professionals, payers and healthcare systems in a sustainable and affordable way. To foster innovation, we need to consider some fundamental changes to the way innovation is fostered and evaluated. Even in areas of clear unmet need, such as paediatric indications, the PUMA off-patent incentive framework has not delivered sufficient results for children. In contrast, the United States has a flourishing value added medicines pharmaceutical segment through framework legislation to stimulate innovation in off-patent molecules. Continuous innovation, throughout the lifecycle of the medicine, is needed to improve treatments for larger patient populations with chronic and non-communicable diseases, such as cancer, to deliver on unmet medical need (e.g. repurposing for Covid-19 treatments) at sustainable cost for healthcare systems. There is a need to adapt the EU framework to encourage innovation and stimulate R&D investment on well-established substances.





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## Meeting the unmet medical need - repurposing

Non-availability of appropriate treatment options is unfortunately a reality in many oncology indications. The repurposing of existing medicines, building on the substantial knowledge with known targets and established safety of the medical substance, presents a largely untapped, affordable and safe treatment approach to address unmet medical needs. To secure more developments in the area, it is crucial that national authorities commit to prioritising the use of such approved medicines over off-label use of unapproved products.



## Value Added Medicines: reformulation – improving standard of care<sup>14</sup>

Albumin-bound paclitaxel (Abraxane), a reformulation of paclitaxel, a metastatic breast cancer medicine targeted delivery significantly reduces administration time, has higher efficacy and there is no requirement for pre-medication with steroids and antihistamines. Guidelines, introduced to enable better patient care in the COVID-19 pandemic, recommended Abraxane over regular paclitaxel or docetaxel to reduce toxicity and potential for admission to hospital. This value added innovation supported most vulnerable patients and minimised risk.

Guidelines can be accessed:  
<https://www.nice.org.uk/guidance/ng161/resources/interim-treatment-change-options-during-the-covid19-pandemic-endorsed-by-nhs-england-pdf-8715724381>

## Moving to patient-centric care models

Covid-19 has also changed patient needs in a number of ways and dramatically reduced accessibility of hospital cancer care. Some of the consequences of treatment delays caused by the pandemic are already apparent, with evidence pointing to increased mortality of cancer patients<sup>13</sup>. The rapid transition to digital consultations and remote monitoring paves the way for the shift towards more primary or out-of-hospital care. We have to leverage the lessons from pandemic and utilize them in healthcare reforms that will support greater quality and equity of care. To reduce the increased risk for oncology patients, the care models will need to change, to allow the move from hospital-centred to patient-centred approach. To be able to deliver treatment at a distance, we will have to support the move by reformulating medicines to enable new care models. It is crucial that whole healthcare community works together and align ways to overcome shortcoming of the current paradigm and identify benefits that can be achieved

<sup>13</sup>- Hanna et al., Mortality due to cancer treatment delay: systematic review and meta-analysis, BMJ 2020;371:m4087

<sup>14</sup>- <https://www.nice.org.uk/guidance/ng161/resources/interim-treatment-change-options-during-the-covid19-pandemic-endorsed-by-nhs-england-pdf-8715724381> accessed 15/12/2020



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## Main recommendations to encourage investment and improve access to Value Added Medicines innovation:

### Ensure clarity in early development.

Continuous innovation, being based on well-established substances, needs a specific approach and incentivising environment to enable accessible innovation. Early dialogue between regulators and pricing and reimbursement authorities, involving all healthcare stakeholders and finding approaches to pragmatic evidence generation are key for marketing authorisation holders to gain clarity and invest in a medicine that will best benefit society and patients.

### Creation of a fit-for-purpose legal framework.

The EU has a unique opportunity to improve access to Value added medicines for patients with some key initiatives outlined in the Pharmaceutical Strategy for Europe. By tailoring the system of incentives provided by the EU pharmaceuticals framework to support innovation throughout the molecule lifecycle, we can achieve a competitive and resource-efficient framework, while delivering on the unmet need and ultimately improve lives of patients in Europe. Value Added Medicines should be established as a separate group of medicines defined in EU legislation. Having a clear definition of a Value Added Medicine and added healthcare benefits are critical to provide direction to the industry and agree on the key improvements that will result in better and more efficient care.

### Coordinate benefit recognition and share best practises among EU Member States.

Member States should recognise Value Added Medicines as a separate class of medicines. Therefore, pricing and reimbursement rules should be shaped to adequately assess continuous innovation and adjusted to the specificity of Value Added Medicines: a different rule and assessment process should be established, as the current pathways for generic medicines (e.g. internal price referencing, mandatory discounts) or innovative medicines (e.g. clinical benefit, cost-effectiveness) are not appropriate for such products.



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## > Generic medicines and cancer care

The majority of cancer agents and supportive care prescriptions (e.g. anti-nausea and antibiotics) are generic medicines. Generic medicines represent close to 70% of prescription medicines in Europe.

The societal value of existing medicines in the treatment of cancer should encourage a careful and strategic consideration of procurement and purchasing policies, conducive to ensuring availability.

- **Oncology treatment: The majority of chemotherapeutics, hormone therapy and more targeted treatments are available in off-patent generic versions.**
- **Supportive treatment: Effective cancer treatment is often conditioned to the availability of supportive care to manage disease symptoms, the side-effects of cancer therapy, including of the newest innovative therapies and optimally adhere to therapy cycles such as with anti-nausea medicines, pain treatment, depression/anxiety and antibiotics.**

The benefits of generic medicines in cancer treatment are threefold: overall economic value, patient-related value and patient access<sup>15</sup>



### Overall economic value

Generic medicines contribute with the majority of the medicines supply, while their cost is much lower than on-patent options.

Additionally, generic medicines manufacturers invest between 7.3% and 17.5% of their turnover in research and development to increase treatment options in the future.



### Patient-related value

Lower treatment adherence is associated with poorer health outcomes and comorbidities. High(er) co-payments for branded medicines and education measures in case of generic substitution support a positive impact of generic medicines on patient adherence and therefore on health outcomes.



### Patient access

Rapid generic market penetration is a precondition for achieving cost-reductions for healthcare systems and patients and improvement of health outcomes.

<sup>15</sup> - [Albrecht M, Chen X, Höer A, de Millas C, Ochmann R, Seidlitz C, et al. Value of generic medicines. 2015; \(October\).](#)





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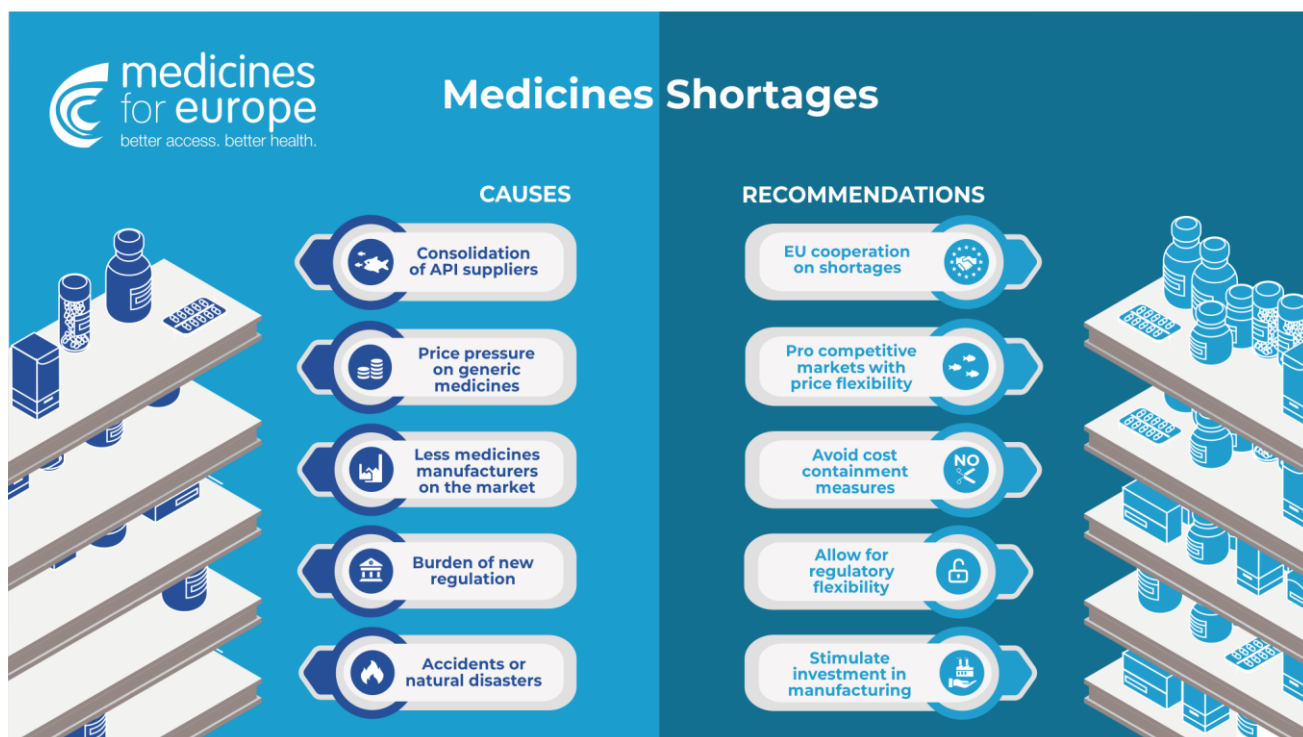


Generic medicines contribute to improving healthcare, either by **providing access** for substantially more patients at the same spending level (higher cost-effectiveness) or by **decreasing expenditure** at equal treatment rates.

*“The inexpensive, essential cancer medicines are good, off-patent, and very effective, and their availability should be a given - what is the excuse for not addressing shortages of inexpensive, essential medicines?”<sup>16</sup>*

The Pharmaceutical Strategy directly calls for **procurement reform to secure the supply of medicines** across the EU to prevent shortages. Additionally, the societal value of existing medicines in the treatment of cancer should encourage the careful and strategic consideration of procurement and purchasing policies, to encourage availability. Cancer treatment is based on very strict therapeutic programmes where any disruption in medicines availability can have serious consequences for patient health.

Procurers must ensure they contribute to diversification of supply and incentivise supply reliability by reforming tender processes to include multiple winners and consider other factors than price, such as supply reliability, when awarding winners. There are considerable challenges in terms of complex production processes for oncology medicines and meagre rewards for manufacturers supplying Europe with these products.



<sup>16</sup>- Vyas M, de Vries EGE, Casali PG, Tabernero J. Shortages of inexpensive essential medicines. Lancet Oncol. 2019 May;20(5):e224-e225. doi: 10.1016/S1470-2045(19)30248-7. Epub 2019 Apr 18. PMID: 31006527.



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The continuous availability of cancer medicines is a patient-centric shared concern and responsibility of payers, regulators and supply chain actors. Generic medicines in cancer care should be considered as an opportunity to increase patient access and prevent medicines shortages through increased choice and availability of treatments.

To tackle medicines shortages in a multi-source context, policies should tackle the root causes of medicines shortages (preventing medicines shortages) and mitigate them once they occur (mitigating medicines shortages).

**Addressing root causes of medicines shortages:** Ensure market predictability and sustainability.

- Reduce the administrative and cost burden of maintaining medicines in the market by improving regulatory efficiency.
- Incentivise investment in manufacturing supply-chain resilience.
- Reform the procurement process to ensure stable supply by:
  - Adjusting the number of procurement winners according to market, product and country characteristics. Using selection criteria that consider other factors than price and ensure fair competition (MEAT criteria) Guaranteeing that procurement contracts are reopened after the entry of the first multisource medicine to ensure a competitive and predictable supply to patients.
  - Preventing disproportionate penalties for supply disruptions as this encourages manufacturers to withdraw products from the market, thus undermining the very aim of the policy. Using extended lead times and predictable volumes that guarantee a predictable supply of medicines to patients.

**Mitigating medicines shortages:**

- Allow regulatory flexibility to accept multi-language packs, different pack sizes and e-leaflets to facilitate the movement of medicines across the EU from regions with over-supply to regions with under-supply.

## Barriers to off-patent medicines competition

To increase access to cancer treatments across Europe, it is fundamental to make the best use of generic and biosimilar medicines. Policies to increase competition and uptake of these medicines should be accompanied by measures to prevent the misuse of intellectual property (IP) processes and other regulatory protections to delay generic and biosimilar medicines market entry. To this end, it is vital to **ensure the highest quality of the patent system in Europe, including removing the possibilities to abuse granting procedures** (e.g. through abuse of divisional patents), as well as ensuring a **consistent**



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## **EU application of the IP Enforcement Directive on damages for generic/biosimilar companies in cases of unduly delayed off-patent competition.**

To increase access and tackle budgetary sustainability challenges, it is equally important to remove any obstacle to immediate generic and biosimilar launch as soon as protections expire and competition is supposed to take place, in line with the objective for which the Bolar exemption was introduced. Therefore, the EC now has a chance to proceed with the **harmonisation & enlargement of the EU Bolar by clarifying all the actions allowed under Bolar for generic and biosimilar medicines (incl. API supply & administrative actions - e.g. Marketing Authorisations, P&R listing, tender bids, etc.)**

At the same time, an actual day-1 launch for generic and biosimilar medicines should be ensured by **1) banning patent linkage in EU law**, as it still exists in many Member States despite the European Commission<sup>17</sup> considering it “unlawful” and committing to “act against” it due to the fact that it actually delays access unnecessarily to generic medicines for patients; and, **2) prolonging, in the SPC manufacturing waiver, the 6-month period for production and stockpiling for day-1 launch in Europe as it is inadequate for biosimilars whose production time is definitely longer than that.**

<sup>17</sup>- [https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)





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**Main recommendations to deliver benefits on benefits of generic medicines in cancer care:**

## **Increase the rational use of generic oncology medicines across Europe to improve access to medicines.**

In some central and eastern European countries, access to generic oncology medicines remains a challenge. Additionally, for countries with better access to therapy, increasing the rational use of generic oncology medicines enables greater medical options for physicians in case of medically appropriate earlier use.

## **The importance of life saving oncology generic medicines urges the reform of procurement and pricing policies.**

As proposed in the Pharmaceutical Strategy, smart and innovative procurement procedures should be designed to foster competition and improve access - e.g. by integrating issues such as security and continuity of supply and allowing multiple winners. There is a need for close cooperation and dialogue with the industry to design sustainable competitive framework.

## **Improve the efficiency of the EU regulation system.**

Achieving greater operational efficiency, with improvements such as digitalisation of regulatory system, implementation of electronic Product information and reform of Variations regulation, as proposed in the Pharmaceutical strategy would help with mitigation of shortages and improve availability of medicines.

## **Remove barriers to the off-patent competition.**

Ensure the highest quality of the patent system in Europe, including removing the possibilities to abuse granting procedures as well as ensuring a consistent EU application of the IP Enforcement Directive on damages for generic/biosimilar companies in cases of unduly delayed off-patent competition.

## > About Medicines for Ireland

As the supplier of the majority of medicines in Ireland to both the HSE and to patients directly, Medicines for Ireland (MFI) members are a critical and central stakeholder in the Irish health service.

The Covid-19 pandemic has brought unprecedented challenges to the pharmaceutical industry in Ireland and our members have responded to this challenge to ensure the supply of medicines to the patients who need them the most. As an organisation, MFI worked creatively in helping to find solutions to ensure the import and export of critical medicines. Solutions such as the 'Green lanes' process is one such example.

In this context, Medicines for Ireland has worked pro-actively with Government, regulators and key policy makers to ensure round the clock continuity of supply in Ireland. Medicines for Ireland continues to work directly with the Department of Health and the Health Products Regulatory Authority (HPRA) as well as the HSE, EU Commission and all relevant EU institutions to ensure a solution focused approach is taken to secure a stable supply of medicines to the Irish market.

Since 2013, the use of generic medicines and biosimilars have provided savings of €1.6bn to the Irish state. There is further potential to save much more and the members of Medicines for Ireland will continue to work with Government on behalf of patients and their families to ensure a sustained supply for patients in Ireland.

## > Medicines for Ireland Members



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