

MEDICINES FOR EUROPE COUNTRY SPECIFIC MARKET ACCESS POLICIES

2018

Follow us on



@medicinesforEU

Rue d'Arlon 50 - 1000 Brussels – Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

Executive Summary

Generic and biosimilar medicines provide an outstanding opportunity to increase access to essential, safe and effective medicines while ensuring the sustainability of healthcare systems. Therefore, Medicines for Europe encourages governments to focus on measures to support the use of generic and biosimilar medicines by implementing long-term sustainable policies that enable the generation of sustained benefits for all stakeholders.

Due to an ageing population, an increased demand for healthcare and an increase in the cost of new innovative medicines, healthcare systems are faced with a significant burden, especially in times of budgetary constraints due to the financial crisis. To cope with this burden, governments are implementing short-sighted and radical cost-containment measures aimed at rebalancing pharmaceutical expenditure (such as External Reference Pricing (ERP), tendering, payback/clawback policies and mandatory discounts) which ultimately endanger patients' health by risking medicines supply reliability.

At the same time, the EU is committed to ensuring equal access to appropriate and high-quality healthcare for all European citizens¹. In order to support the European Institutions in improving access to medicines for patients, while guaranteeing a stable healthcare budget and securing a sustainable future market, more must be done to increase the use of generic and biosimilar medicines and increase the efficiency of healthcare systems. The OECD², the European Commission^{3,4} and the European Council⁵ have highlighted the importance of the timely availability of generic and biosimilar medicines for healthcare systems.

To fully accomplish the potential of generic and biosimilar medicines, European governments should encourage investment in the competitive off-patent pharmaceutical market. Therefore, Medicines for Europe, along with its member associations, would like to support the sustainability of the healthcare budget by providing the following key recommendations:

- **Ensure predictable market environments** by avoiding short-term cost-containment measures and focusing on long-term sustainable policies;
- **Implement clear incentives to stimulate the use of generic and biosimilar medicines** by providing necessary information and creating compelling incentives for all stakeholders involved;
- **Increase regulatory efficiency** by optimizing the use of existing IT systems and reducing work duplication;

¹ The Parliament Magazine - <https://www.theparliamentmagazine.eu/articles/opinion/many-patients-europe-have-limited-or-no-access-treatment>

² OECD, Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives, 2015

³ Investing in Health, 2013, DG SANCO, European Commission, http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf

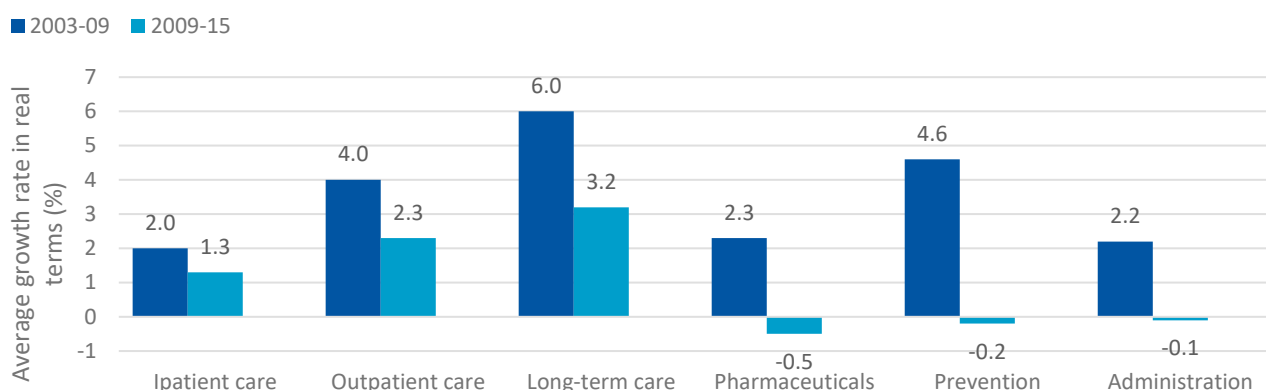
⁴ DG ECFIN and Economic Policy Committee (Ageing Working Group), Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, 2016, http://ec.europa.eu/economy_finance/publications/eeip/ip037_en.htm

⁵ Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States - <http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/>

Introduction

Due to the financial and economic crisis, many European Member States have introduced several austerity measures to balance national budgets, with some particularly focusing on healthcare spending. Data from the Organisation for Economic Co-operation and Development (OECD) show that, since 2009, average annual growth rates of health spending per capita in the different fields of healthcare (inpatient care, outpatient care, long-term care, pharmaceuticals, prevention and administration) have dropped. In particular, expenditure for pharmaceuticals in the European Union contracted annually by 0.5% (see Figure 1) contrary to the increased demand for healthcare due to an **ageing population**.

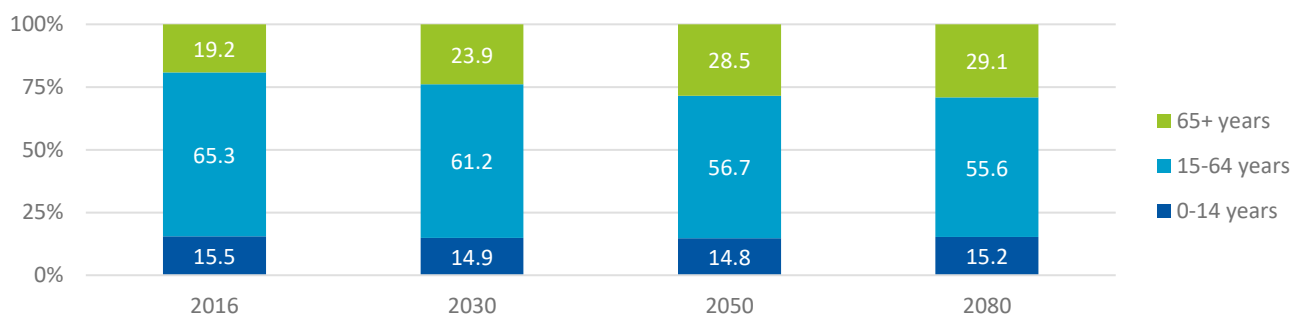
Figure 1 - Growth rates of health expenditure per capita for selected services, OECD average, 2003-15



Source: OECD Health at a Glance 2017⁶

In 2016, the population aged over 65 years was 98 million and is expected to increase to 151 million in 2050, representing a 54% increase in this age group. This means that around 28.5% of the entire population will be aged over 65 years by 2050 (Figure 2). Currently, around 50 million EU citizens are estimated to suffer from two or more chronic conditions and as most of them are 65 years and over, this number is expected to increase in coming years. It should however be expected that with the recovery from the financial crisis and an increase in GDP, the expenditure in health would take the same upwards slope and a healthy population may be considered as an engine for further economic growth⁷.

Figure 2 - Population structure by major age groups, EU-28, 2016-80 (% of total population)



Source: Eurostat Population Statistics⁸

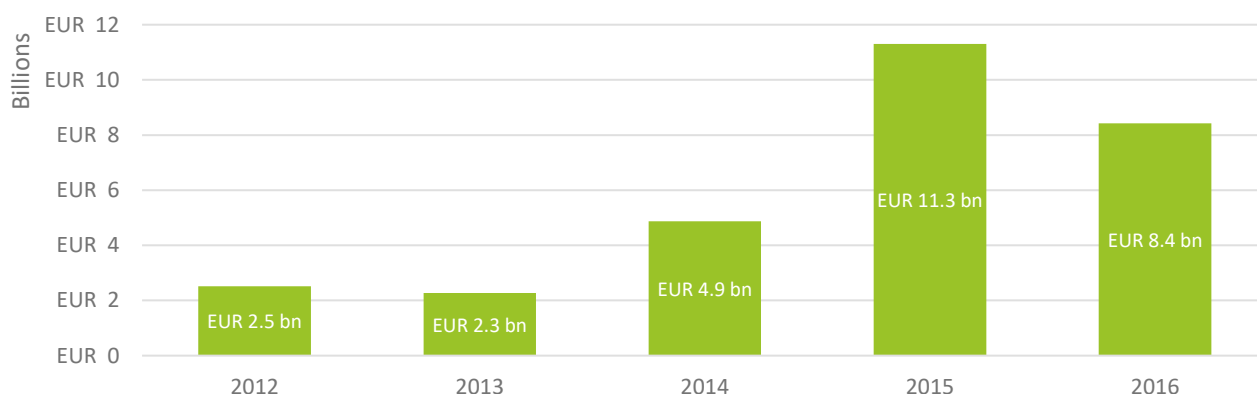
⁶ OECD. Health at a Glance 2017

⁷ Sammut, A. Assessing the Relationship between Health and Economic Growth: Malta's Case. Univ. Malta Libr. – Electron. Theses Diss. Repos. (2013).

⁸ Eurostat Population Statistic

The growth in the elderly population is also accompanied by another challenge – the **high prices of new branded medicines coming to the market**. IMS data shows that Europe spending on new brand medicines has more than doubled in 2014 to almost EUR 5 billion and peaked in 2015, surpassing EUR 11 billion. Both Europe's ageing population and the increased cost of new branded medicines pose a **major social and economic challenge for Europe and open up the debate of healthcare sustainability**.

Figure 3 - Europe new brand spending



Source: IQVIA MIDAS MATQ3 2017.

Note: Spending with branded products launched in the last two years.

Due to the unpreparedness of pharmaceutical budgets across Europe to deal with the rising cost of new brand medicines, many governments have implemented short-term cost-containment measures, such as clawback, payback, rebates, External Reference Pricing (ERP) and public procurement/tendering. These policies have especially hit the generic and biosimilar medicines industries, which already supply highly cost-efficient medicines. Due to these unsustainable policies, the prices of generic and biosimilar medicines have dropped so deeply that manufacturers struggle to have these medicines available in the national markets, leading often to withdrawals of medicines which ultimately affects patients' health. There is evidence that tendering is leading to medicine shortages in the Netherlands⁹, Spain¹⁰ and Germany¹¹. Furthermore, in Romania, the extreme pressure on price set by the combination of the clawback mechanism and external reference pricing has led to the withdrawal of medicines including many generic medicines^{4,12}. It is relevant to underline as well that according to fundamental principles of microeconomics, price ceilings create shortages by setting the price below the equilibrium. At the ceiling price, the quantity demanded exceeds the quantity supplied¹³. It is clear that these short-term cost-containment measures come at the detriment of patients' access to medicines.

Recently, the WHO acknowledged the importance of competition by generic and biosimilar medicines in the lifecycle of a medicine on its price and availability. Figure 4 shows that competition by generic and biosimilar medicines typically reduce the prices (stage 4). However, when prices are pressured due to short-term cost-containment measures to an unsustainable level, suppliers withdraw from the markets and supply reliability is endangered (stage 5). This can eventually evolve to a situation where either the patients don't have access to medicines or the establishment of a de-facto monopoly, leading to increased prices (stage 6). To avoid this supply risk which might endanger patients' health in case of medicines shortages, it is necessary to achieve a sustainable

⁹ SFK (Foundation for Pharmaceutical Statistics), Pharmaceutisch Weekblad. 2014.

¹⁰ Belen Diego, <http://www.apmhealthurope.com/home.php.2015>.

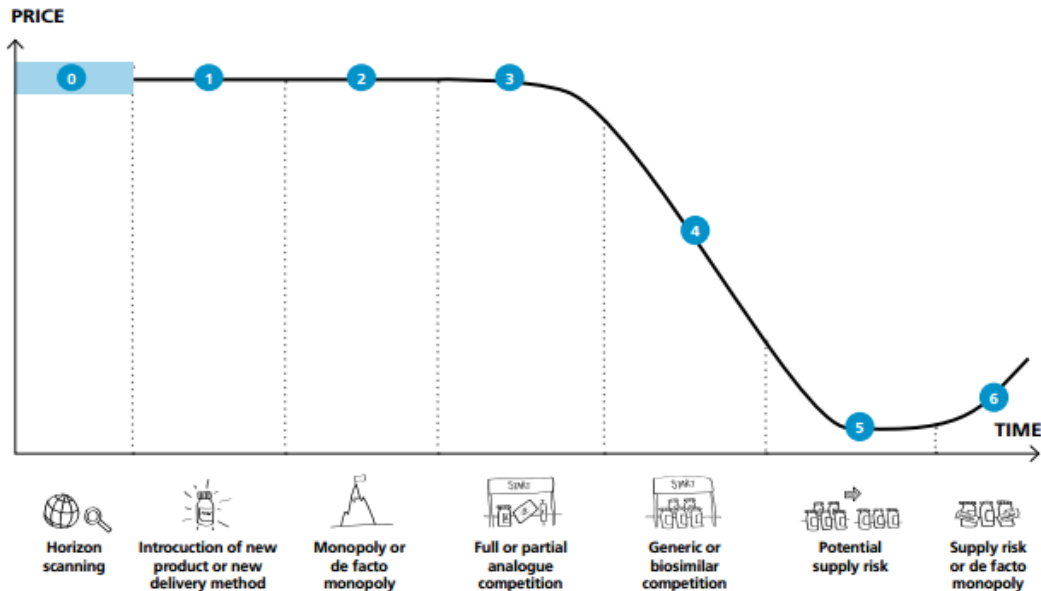
¹¹ QuintilesIMS Health. An International Comparison of Best Practice Approaches to Drug Shortages. 2015.

¹² APMGR internal data.

¹³ [Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region. \(World Health Organization Regional Office for Europe, 2016\).](#)

market which considers long term objectives. Governments must re-think and review the current cost-containment measures applied to generic and biosimilar medicines.

Figure 4 - Pharmaceutical lifecycle stages and generalised price development for a specific disease area or condition



Source: WHO report 2016¹³

In order to forecast healthcare budgeting, it is crucial for governments to include future generic and biosimilar medicines in their horizon scanning similarly to what is being done in the UK by the UK Medicines Information Service - UKMi¹⁴. This was recently underlined by the Council of the European Union which highlighted *‘the importance of timely availability of generics and biosimilars in order to facilitate patients’ access to pharmaceutical therapies and to improve the sustainability of national health systems’*.

The role of generic medicines in the sustainability of healthcare systems

The generic medicines industry is the main provider of medicines in the EU, accounting for 62% of dispensed medicines at only 29% of pharmaceutical expenditure. By 2020, generic medicines are even expected to make up 70-80% of the medicines used in Europe¹⁵.

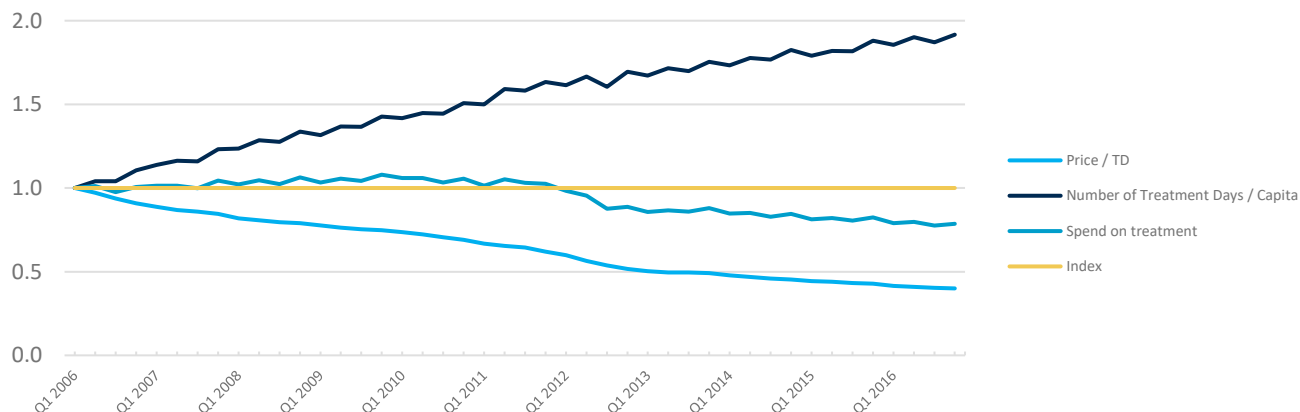
Without competition from generic medicines, payers in Europe would have had to pay €100BN more in 2014. Generic medicines provide an incredible opportunity for European governments to achieve efficiency gains which can be invested in increasing patient access to essential medicines, reducing health inequalities between European countries¹⁶. Between 2005 and 2014, generic medicines enabled twice as many patients to be treated across seven key therapy areas without any impact on overall treatment cost, as shown in Figure 5.

¹⁴ [UK Medicines Information Service - Horizon Scanning & Medicines Evaluations](#)

¹⁵ [Sheppard, A. Global Healthcare Trends and Outlook. \(2017\).](#)

¹⁶ [Elek, P., Harsányi, A., Zelei, T., Csetneki, K. & Kaló, Z. Policy objective of generic medicines from the investment perspective: The case of clopidogrel. Health Policy \(New York\). 121, 558–565 \(2017\).](#)

Figure 5 - Evolution of volume, price and treatment cost in seven therapy areas



Source: IMS MIDAS, MAT Dec 2016.

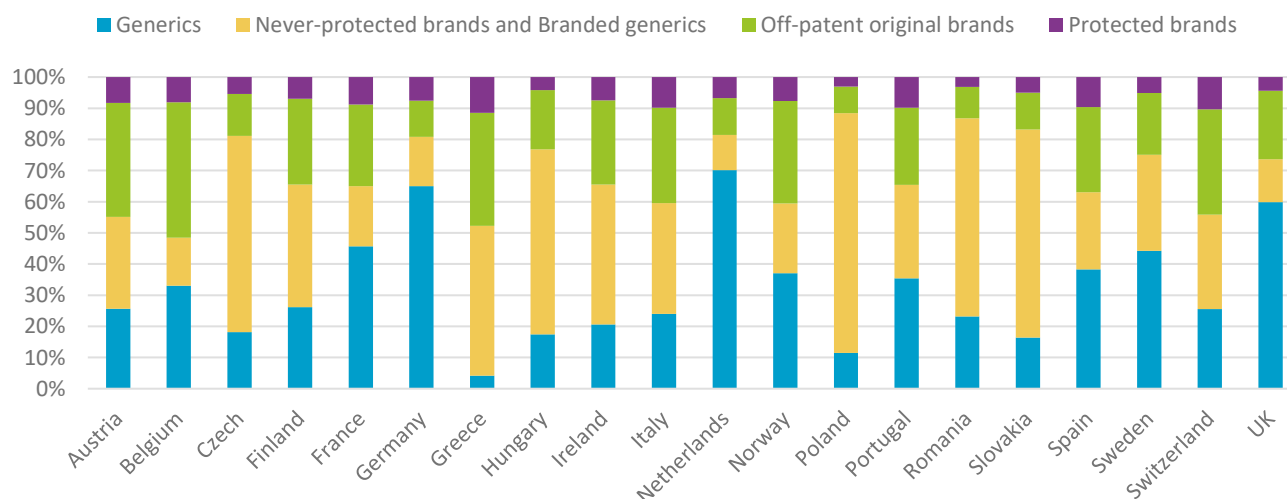
Population statistics: WorldBank, Rx, retail, oral molecules ONLY, combinations excluded; 26 European countries

The availability of generic medicines can also improve health outcomes and reduce unnecessary costs for healthcare systems by increasing patient access to more effective therapies earlier in the disease progression and improving patient adherence due to lower co-payments¹⁷

According to OECD, generic medicines are important to promote greater sustainability of healthcare spending without compromising access and quality of healthcare. "All EU countries see the development of generic markets as a good opportunity to increase efficiency in pharmaceutical spending, but many do not fully exploit the potential of generics"⁶. Indeed,

Figure 6 shows that there are still considerable opportunities in many European countries to increase the use of generic medicines and achieve efficiency gains.

Figure 6 - Protected and off-patent market shares (volume) by country, 2016



Source: QuintilesIMS Health, MIDAS, Q1 2017, retail and hospital channel.

Note: Non-original brands and branded generics include copy products in some countries; Generics include INN branded and company branded.

¹⁷ [Albrecht, Martin, Höer, Ariane, Zimmermann, A. Value of generic medicines. \(2015\).](#)

The role of biosimilar medicines in the sustainability of healthcare systems

Pharmaceutical science, regulation and policy are rapidly changing areas, particularly in relation to biotechnology, and perhaps most particularly to biologic medicines, including biosimilar medicines. Biologic medicines currently represent around 30% of pharmaceutical sales in Europe and their importance is growing. Over the last 10 years, the growth rate of the biologic market has continuously outstripped the growth rate of the total pharmaceutical market.

However, the high cost of biologic medicines, coupled with constrained resources means that they are not accessible for all patients and create financial challenges for healthcare systems. Biosimilar medicines provide an incredible opportunity for governments to address this problem. A biosimilar is a biological medicinal product that contains a version of the active substance of an already authorised original biological medicinal product (reference medicinal product) in the EEA. Similarity to the reference medicinal product in terms of quality characteristics, biological activity, safety and efficacy based on a comprehensive comparability exercise needs to be established¹⁸. Real world data have clearly shown that reference products and biosimilar medicines have no clinically meaningful differences and biosimilar medicines are interchangeable with their reference products under the supervision of a physician^{19,20}.

Since the introduction of the first biosimilar medicine the EU in 2006, biosimilar medicines have already generated more the 700 million patient days of clinical experience worldwide and generated savings of about EUR 1.5 billion in the EU-5 alone. Nevertheless, the future opportunity is even bigger with an expected cumulative spending of EUR 47 billion (2016-2020) on 8 biological medicines that are expected to lose exclusivity in EU-5 only. The potential is therefore clear: a 30% reduction in price per treatment day across these 8-key originator biologic medicines, driven by biosimilar competition in the marketplace, could yield cumulative savings for European healthcare systems of about EUR 15 billion over the next five years²¹.

At the same time, biosimilar medicines also increase patient access to state-of-the-art treatments: the availability of biosimilar filgrastim has ensured 122% more patients in EU gaining earlier access to gold standard medicines between 2006-2016²². The EU is also a leading industrial base for the research and development of biologic, including biosimilar, medicines, thanks to the robust regulatory framework. This EU know-how is something we can be proud of and we should eagerly defend our leading role in this key area: 16 countries in Europe have manufacturing sites of EU approved biosimilar medicines or products under development or evaluation.

Biosimilar medicines bring competition to the market and create access to treatment. At the moment, the opportunity of biosimilar medicines is not grasped by all European countries and this is demonstrated by the significant variation in the use of biosimilar medicines across Europe (see Figure 7). It is clear that the European governments must increase their efforts to support the medical use of biosimilar medicines to make sure they will continually benefit. Benefit sharing models, where the advantages from the use of biosimilar medicines are well understood and shared between different stakeholders (i.e. patients, physicians, hospitals, payers and manufacturers) have demonstrated to be the most successful policies to increase the use of biosimilar medicines.

¹⁸ [Committee for Medicinal Products for Human Use \(CHMP\). Guideline on similar biological medicinal products. \(2014\).](#)

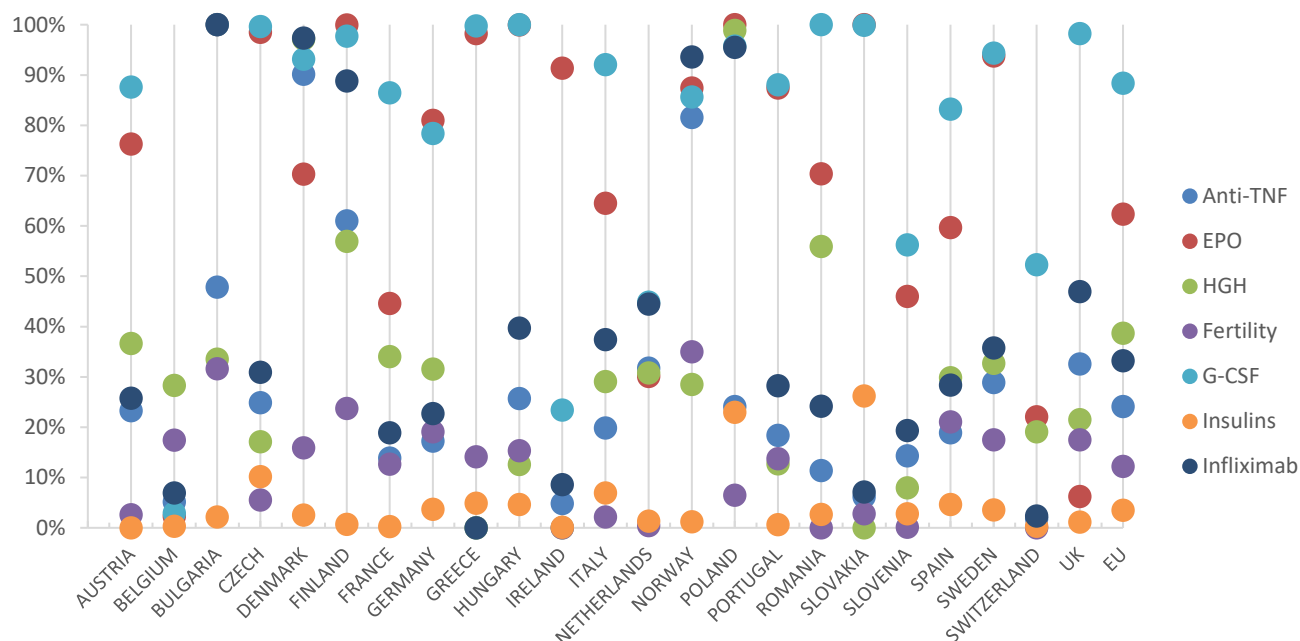
¹⁹ [Cohen, H. P. et al. Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes. *Drugs* 78, 463–478 \(2018\).](#)

²⁰ [Inotai, A. et al. Is there a reason for concern or is it just hype? - A systematic literature review of the clinical consequences of switching from originator biologics to biosimilars. *Expert Opin. Biol. Ther.* 17, 915–926 \(2017\).](#)

²¹ [Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets. IMS Institute for Healthcare Informatics \(2016\).](#)

²² IQVIA. Medicines for Europe - Generics and Biosimilars Report. (2017).

Figure 7 - Biosimilar medicines penetration in accessible market (Dec 2016)



Source: IQVIA. Medicines for Europe - Generics and Biosimilars Report. (2017).

Key market access policies

To fully realise the potential of generic and biosimilar medicines, European governments should encourage investment in the competitive off-patent pharmaceutical market. Therefore, we strongly recommend:

Predictable market environments

Over the past years, many European governments have implemented ad-hoc measures affecting generic and biosimilar medicines prices to balance pharmaceutical budgets (e.g. hospital payback in Germany, direct price cuts in France, etc.). This kind of ad-hoc measure entails significant uncertainty for the operational business environment and jeopardizes the long-term sustainability of these industries.

The generic and biosimilar medicines industries are willing to support governments in their quest for sustainable healthcare budgets but this can only be achieved through cooperation in a predictable and trustworthy environment. The 'Belgian pact for the future' is an excellent example of this kind of cooperation and we strongly encourage other European governments to do the same.

Belgian pact for the future (2016-2018)

In 2015, the Belgian Ministry of Health together with the originator and generic medicines industries signed a pact for the future (2016-2018) that would bring predictability for both sides.

In the future pact, the generic medicines industry agreed with an immediate and significant price-cut for new generic medicines entering the market in exchange of predictability of pricing, i.e. no extra-ordinary measures in case the pharmaceutical budget is exceeded. In addition, the future pact also included clear intentions to stimulate the medical use of generic and biosimilar medicines.

Clear incentives to stimulate the use of generic and biosimilar medicines

Although many European governments have already made efforts to stimulate the use of generic and biosimilar medicines, it is clear that there are still opportunities to do more. Increasing the use of generic and biosimilar medicines will not only provide additional savings, it is also the only way to ensure long-term sustainable generic and biosimilar medicines industries, necessary for continued benefits of competition in the pharmaceutical market.

- Educating and informing healthcare professionals and patients about the quality, safety and efficacy of generic medicines and biosimilar medicines;
- Supporting prescribing of generic and biosimilar medicines by introducing clinical guidelines and/or electronic prescribing systems that are properly enforced and positively incentivised;
- Supporting prescribing of biosimilar medicines by implementing benefit sharing agreements, i.e. where the advantages of the use of biosimilar medicines are understood and shared among stakeholders
- Reducing timelines and uncertainties in patent opposition procedures at the European Patent Office (EPO);
- Accelerating the timelines for pricing and reimbursement of generic and biosimilar medicines;
- Avoiding extreme pricing models such as tendering that lead to supply disruptions and may harm patients' health (acknowledged by the German government in Pharma Dialogue);
- Allowing price differentiation between generic medicines and reference products in the retail market to ensure sustainable competition;
- Prohibiting the linkage of intellectual property rights to marketing authorisations and price and reimbursement procedures;
- Eliminating pharmacy remuneration models that influence the decision to dispense the most cost-effective medicine (e.g. pharmacy remuneration based on percentage of the price of the medicine).

Regulatory efficiency

The regulatory framework for medicines has continuously evolved over time. This has enabled faster access to new medicines, both those for unmet medical conditions and high quality affordable generic and biosimilar alternatives. An efficient regulatory system is critical for timely access to medicines and there are opportunities for taking an ambitious approach to identify future improvements to benefit all stakeholders.

Medicines for Europe supports high regulatory standards and a stringent marketing authorisation process but does not support the administrative burden on authorities and industries deviating resources from activities contributing to public health to an administrative workload without added value to public health protection. This drive for efficiency would be a win-win opportunity for both the pharmaceutical industry and regulators: lower costs and less burden. The Regulatory Efficiency Report (available [here](#)) is a source of proposals to optimise efficiency (short and long term).

Priorities:

- Optimisation of the regulatory processes (particularly Variations) by linking to the IT infrastructure and IT tools to avoid redundancies in the system;
- Overcome R&D duplication by moving towards single development of generic/ biosimilar/ value added medicines;
 - Elimination of unethical repetition of the same clinical studies for each jurisdiction;
- Further improvement of the DCP and CP through more flexibility and work sharing.

MEDICINES FOR EUROPE COUNTRY SPECIFIC MARKET ACCESS POLICIES

2018

1. France

Pharmaceutical expenditure makes up 15.1% of total healthcare expenditure in France²³, and generic medicines have contributed to a reduction of 2.0% per year since 2011²⁴. Furthermore in 2017, the use of generic medicines led to cost-efficiency gains of €2.9 billion²⁵.

Generic medicines are an asset to the sustainability of the French healthcare system²⁶, however their use across France remains low. Due to cultural resistance, French physicians prescribe only 46% of generic medicines from the *Répertoire** compared to over 70% in Germany and the UK²⁷.

The low use of generic medicines in France means that there is a real opportunity to increase patients' access to medicines and control healthcare expenditure. The uptake of Generic medicines is a priority of the National Health Strategy published by the Government in December 2017. Nevertheless, while the 2018 *Loi de Financement de la Sécurité Sociale* (LFSS 2018) expects €340 million of savings from the promotion and use of generic medicines, only €110 million of the total amount result from the development of volumes and €230 million from price cuts and price convergence²⁸. Furthermore, in December 2017, the *Comité Economique des Produits de Santé* (CEPS) requested additional price cuts on generic medicines (€160 million), undermining the sustainability of the generic pharmaceutical industry.

Several positive developments have occurred in the French market: positive results following the first wave of the Public Campaign regarding generic medicines, '*Dévenir générique, ça se mérite*' launched by the government in September 2016 were achieved and the campaign was renewed in 2017 for another year. The LFSS 2018 also introduced a new opportunity to launch experimentations for a period of 5 years maximum of new arrangements/methods for the delivery of medical care which are derogatory to the existing ones. It is necessary to improve efficiency through the development of the generic medicines market and the creation of savings though increased volumes rather than additional price cuts²⁹.

Furthermore, it should be noted that more than 66% of generic medicines sold in France are produced in Europe, and 40% of which in France³⁰. This should be upheld as maintaining a dynamic industry in Europe as it is a positive factor for growth and should incentivise the implementation of measures that not only promote patient access to generic medicines, but also ensure the maintenance of manufacturing sites and consequent jobs in Europe.

Regarding biosimilar medicines, France has created a biosimilar medicines market that is still moderate (e.g. the use of biosimilar infliximab in France is the lowest across the EU)³¹. In addition, high volume sales of originator biologic medicines versus other EU countries and the future patent loss of many of those provide a future opportunity for payers to efficiently improve sustainability of the healthcare system.³² Through the National Health Strategy published in December 2017, the Government has set a very ambitious objective of 80% of

²³ OECD Health Statistics, 2013

²⁴ OECD Health Statistics, 2015

²⁵ GEMME data, 2017

²⁶ OECD Health Statistics 2015, 2015

²⁷ GEMME data, 2016

²⁸ Press kit – PLFSS 2018

²⁹ GEMME – Jalma study 2017

³⁰ Roland Berger/LEEM study 2016

³¹ IMS Midas Health, July 2016

³² Gabi Online, Biosimilar competition in Europe, 2013, available here: <http://gabionline.net/Reports/Biosimilar-competition-in-Europe>

**Répertoire* - Represents part of the official information on medicinal products which have been granted marketing authorization (MA), independently of its commercialisation status.

penetration for biosimilars in 2022³³. Incentives need to be implemented in order to reach this objective. The Minister of Health also published an instruction, sent to Hospital directors and Regional Health Agencies, which includes quotas for Hospital and retail prescriptions of biosimilars. It is also important to emphasise that the French Medicines Agency has recently published the first version of the list of reference of biosimilar medicines groups which will be updated regularly.

1.1 Country Specific Recommendations: Proposal for France 2018

Following the assessment by Medicines for Europe together with the *Association des Professionnels du Medicament Générique* (GEMME), both Associations would like to propose the following recommendations for France:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of generic medicines, through:

Retail level

- a. The adoption and implementation of measures to increase the prescription of generic medicines which are in the *Répertoire* and an increase in the number of active substances in the *Répertoire*.
 - i. Development of incentives for physicians for increased prescription within the *Répertoire*
- b. The prevention of External Reference Pricing and price cuts for generic medicines

Hospital level

- a. Increasing the existing target agreements to prescribe generic medicines at hospital level and dispensed at retail level
- b. Ensure supply reliability of tender winners to prevent medicines shortages

2. Increase the cost-effectiveness of the healthcare sector, by promoting the use of biosimilar medicines, through:

- a. The adoption and implementation of information and education campaigns on biosimilar medicines, emphasising the benefits of gainsharing models involving different stakeholders (e.g. patients, healthcare professionals, etc.)
- b. The establishment of pricing and reimbursement rules for biosimilar medicines distinct from those for generic medicines, which foster their development
- c. Defining annual target agreements to prescribe biosimilar medicines at both hospital and retail levels.
- d. Introducing incentives for physicians to increase the prescription of biosimilar medicines.

³³ Stratégie Nationale de Santé – December 2017

1.2 Measures to increase the use of generic medicines in France

Retail level

The adoption and implementation of measures that increase the prescription of medicines listed in the *Répertoire* and increase the number of active substances in the *Répertoire*

The *French Cour des Comptes* report from 2014 has recommended fostering generics development by empowering the physicians' role.³⁴ Physicians' prescriptions in the *Répertoire* should therefore be increased with measures such as prescription assistance programmes that follow prescription guidelines, target agreements to prescribe, prescription budgets and strict prescription by International Non-proprietary Name. Furthermore, a new law in France is creating a new opportunity to launch experimentations for a period of 5 years maximum of new arrangements/methods for the delivery of medical care which are derogatory to the existing ones. A study that GEMME developed together with Jalma positioned France as a market with sub-utilisation of generic medicines compared with other European markets (the medicines that are in the repertoire represent only 44% of the reimbursed medicines and only 57% of prescriptions are based on INN). The study also puts forward 5 proposals for improvement of efficiency and savings through a reasonable scenario of growth in volume while preserving the value of the generic market.

Prevention of External Reference Pricing and price cuts for generic medicines

According to the World Health Organisation (WHO) and Health Action International (HAI) working paper, efficient medicines prices can be achieved by promoting competition through the introduction of competitive policies, instead of using pricing mechanisms such as External Reference Pricing³⁵. Therefore, French authorities should review the application of External Reference Pricing (ERP) to generic medicines as the resulting price levels do not reflect national market dynamics.

Regarding pricing cuts, a new generic medicine receives 60% of the pre-patent expiry price of the respective originator medicine³⁶. There should be a revision of this price policy, namely for generic medicines that have a high manufacturing investment and/or have an extremely low price as this policy threatens the sustainability of the generic pharmaceutical industry.

Hospital level

Increase the existing target agreements to prescribe generic medicines at hospital level but dispensed at retail level

Patient access to generic medicines should be increased at retail level after patient discharge from hospital. Therefore, the existing prescription objectives for generic medicines prescribed at hospital level but dispensed at retail level should be increased.

³⁴ Cours des comptes ; La diffusion des médicaments génériques : des résultats trop modestes, des coûts élevés ; 2014 ; available here : <https://www.ccomptes.fr/Publications/Publications/La-securite-sociale2>

³⁵ WHO/HAI, Project on Medicines Prices and Availability, External Reference Pricing, May 2011

³⁶ QuintilesIMS Analytics, Q2 2015.

1.3 Measures to increase the use of biosimilar medicines in France

Adoption and implementation of information and education campaigns on biosimilar medicines

The scientific concept of biosimilarity is not yet fully understood by all stakeholders. Indeed, one of the aims of the European Commission consensus paper on biosimilar medicines³⁷, elaborated and agreed by all EU stakeholders, is to inform stakeholders about biosimilar medicines.

Due to the responsibility and unbiased status of the European and the national regulatory bodies, it is crucial that European and national authorities work together to create awareness of the important role of biosimilar medicines in patients' health and sustainability of healthcare systems. The implementation of information campaigns, the active participation in scientific meetings and conferences, are key steps to develop education on biosimilar medicines and emphasise the benefits of these medicines among the different stakeholders, in particular patients and physicians³⁸.

Establish distinct pricing and reimbursement rules for biosimilar medicines

Biosimilar medicines should fall under specific pricing rules. Biosimilar medicines must complete extensive clinical comparability studies and their development can take up to 9 years or more, with associated costs in the range of between €150 and €250 million, depending on the molecule¹³. Therefore, the paradigm of generic medicines cannot be applicable to biosimilar medicines. These distinct pricing and reimbursement rules should generate enabling conditions for the development of this market.

Defining annual target agreements to prescribe biosimilar medicines at both hospital and retail levels

Currently there are no target agreements to prescribe biosimilar medicines and it is of utmost importance to establish the right framework to incentivise physicians to increase patient access to biosimilar medicines. Therefore, target agreements to prescribe biosimilar medicines should be defined annually at both hospital and retail levels.

³⁷ EC Consensus Paper, "What you need to know about biosimilars" Medicinal Products, Process on Corporate Responsibility in the Field of Pharmaceuticals Access to Medicines in Europe, 2013, available here:

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf

³⁸ SKP. Policy Requirements for a Sustainable Biosimilar Market.2016, available here: <http://www.medicinesforeurope.com/2016/09/19/policy-requirements-for-a-sustainable-biosimilar-market-simon-kucher-2016/>

2. Italy

In Italy, the public pharmaceutical spend of the total healthcare expenditure for Italy is 7.2 % (2016)³⁹. Between 2015 and 2016 it was significantly reduced by 2%⁴⁰. In Italy, the generic medicines use on the reimbursed pharmaceutical market is only 24% by volume⁴¹. In particular, exclusively for reimbursed medicines at retail level, where 86% of generic medicines are concentrated, the use of generic medicines reaches 28.5%⁴². Although the patient use of generic medicines has increased, it remains still lower compared with other European countries. It is important to underline that Italian out-of-pocket costs for preferring originator medicines instead of generic medicines is around €1BN. Therefore, generic medicines can provide a real opportunity not only to gain healthcare efficiencies but also to increase patient access to medicines. The generic medicines sector contributes to €120 Million⁴³ in cost-efficiencies on average every year in Italy. Furthermore, the generic medicines industry plays a significant role in maintaining more than 10.000⁴⁴ direct and indirect jobs and fosters economic growth in Italy.

Regarding biosimilar medicines, Italy suffers from cultural resistance which has been changing over the years. There are key regional differences in biosimilar medicines use across Italy due to the implementation of differentiated policies. Incentives to use the lowest-cost biological medicine and rules to promote the prescription of biosimilar medicines to naïve patients are examples of policies that contribute to higher patient access to biosimilar medicines, which should be harmonised throughout Italy.

³⁹ Italian Ministry of Finance. Il monitoraggio della spesa sanitaria, p. 36, 2016. Available on: <http://www.rgs.mef.gov.it/Documenti/VERSIONE-I/Attivit--i/Spesa-soci/Attivit-monitoraggio-RGS/2017/IMDSS-RS2017.pdf>

⁴⁰ Italian Ministry of Finance. Il monitoraggio della spesa sanitaria, p. 36, 2016. Available on: <http://www.rgs.mef.gov.it/Documenti/VERSIONE-I/Attivit--i/Spesa-soci/Attivit-monitoraggio-RGS/2017/IMDSS-RS2017.pdf>

⁴¹ IQVIA Data, MIDAS, Q4 2016, retail and hospital channel.

⁴² IQVIA Data, YTD 12/2016, retail channel, class A (100% reimbursed and prescription bound)

⁴³ Average public budget retail and hospital spending 2013-2016 (Italian Medicines Agency-AIFA)

⁴⁴ Assogenerici Internal Data

2.1 Country Specific Recommendations: Proposal for Italy 2018

Following the assessment by Medicines for Europe together with the Italian Generic Medicines Association, Assogenerici, both Associations would like to propose the following recommendations for Italy:

1. Increase the cost-effectiveness of the healthcare sector, by promoting the use of generic medicines through the:

Retail level

- a. Adoption and implementation of measures that incentivise physicians' prescription and pharmacists' dispensing of generic medicines
 - i. Incentives to physicians' prescription through e-prescription systems and therapeutic guidelines
 - ii. Linking pharmacist remuneration to generic medicines dispensation targets
- b. Reform of the payback mechanisms considering the specificities of generic medicines manufacturers
- c. Prevention of patent linkage.
- d. Assurance of predictability and stability for the industry
- e. Removal of barriers for pricing & reimbursement approval to promote faster patient access to generic medicines
- f. Removal of generic medicines from regional tendering at retail level

Hospital level

- a. Exclusion of the generic medicines sector from the payment of payback
 - b. Adjustment of tendering design to increase patient access to generic medicines by
 - a. Determining a fair price base tender
 - b. Introducing the 'Pure' renegotiation provision in the specifications of all contracts to immediately open the tender at the time of patent expiry
 - c. Establishing minimum order quantity
 - d. Ensuring the certainty of all phases of the tendering procedure
 - e. Implementing a new system to determine bidding prices for procurement authorities
 - f. Simplification of tender procedures with an intense process of digitalisation
2. Increase the cost-effectiveness of the healthcare sector by promoting the use of biosimilar medicines through the:
 - a. Provision of a level playing field for biosimilar medicines
 - a. After the publication of AIFA position paper⁴⁵ in March 2018, continue to educate all stakeholders by means of an information campaign, on the safety, quality and effectiveness of biosimilar medicines
 - b. Establishment of pricing and reimbursement rules for biosimilar medicines distinct from those for generic medicines, which foster their development.

⁴⁵ AIFA - Secondo Position Paper AIFA sui Farmaci Biosimilari. Available here: http://www.aifa.gov.it/sites/default/files/pp_biosimilari_27.03.2018.pdf

2.2 Measures to increase the use of generic medicines in Italy

Retail level

Adopt and implement incentives for physicians to prescribe, pharmacists to dispense and patients to choose generic medicines

There is room to increase the use of generic medicines in Italy, as the current patient use of these medicines is still lower compared with other European countries. It is of utmost importance to establish the right framework to incentivise physicians to prescribe generic medicines through e-prescription systems and therapeutic guidelines with the adequate enforcement tools.

Pharmacists can also be incentivised to increase the use of generic medicines, for example through measures such as linking pharmacist remuneration to generic medicines dispensation targets. Informing citizens of the benefits of generic medicines by implementing communication and education campaigns is also an effective tool to increase awareness and patient access to generic medicines.

Abolish the payback mechanism applied to generic medicines companies

Since 2013 the pharmaceutical industry promoted strong legal action against the payback in court which ruled in favor of the pharmaceutical industry.

On 23 December 2017 the Senate Assembly approved the last Budget Law of the parliamentary term. Some partial provisions on payback on pharmaceutical spending have been introduced while the long-awaited reform of the pharmaceutical Governance has not been approved. Among these measures the most important are: the payback due for products marketed for the first time in the year of the overspending (with no revenues data records in the previous year) is limited to a maximum of 10% of the turnover's positive change between the year of overspending and the previous year (except for orphan and innovative medicines); the conclusion of settlement agreements related to legal disputes promoted by companies – which have duly paid the 2016 payback – against the payback for 2013, 2014 and 2015.

The application of a payback mechanism to generic medicines companies should be reviewed and abolished. In other European Member States, the payback system is mainly applied to originator medicines that contribute to the increase of pharmaceutical expenditure and not generic medicines that contribute to increase health system efficiency gains. If full exclusion of generic medicines from the payback system is not possible, adjustments should be made to meet the specificities of the generic medicines market. Among optimal solutions there are indexing the payback only to the real value market share of the companies on public pharmaceutical expenditure and the compensation between budgetary silos. The existence of the payment of payback puts local small and medium-sized enterprises at risk and can lead to the withdrawal of multinational companies from the country.

Prevent patent linkage and tendering at retail level, and reduce litigation costs

Removing barriers which prevent sustainable competition must be tackled. Patent linkage slows down generic medicines entry in the Italian market and increases litigation costs for manufacturers, which result in inefficiencies for the healthcare system. Medicines for Europe calls for your support to advance the legislative

process and take part in a constructive dialogue with the authorities to promote competition, healthcare efficiency gains and better access to treatment for patients⁴⁶.

In addition, it is relevant to be aware of the risks and consequences of introducing a tendering system at retail level. Experience in other EU Member States has shown that tendering results in medicines shortages^{47,48}, that ultimately affect patients' health. This situation also leads to major market access hurdles for Small and Medium-sized Enterprises (SMEs).

Ensure predictability and stability for the industry

The measures adopted by the Italian government to contain pharmaceutical expenditure in Italy are of great concern for the industry. The unforeseen decision, the unusual process of price policy discussions with individual companies and the lack of predictability of the recent measures were unfortunate.

Generic medicines play an essential role in treating patients by increasing the accessibility and value of pharmaceuticals and by contributing considerably to the sustainability of public and private healthcare budgets in Italy. The sustainability of the generic medicines sector is vital to ensure that the industry can continue to bring new competition to the pharmaceutical sector – including in complex medicines.

The long-term sustainability of the generic medicines sector relies on predictable pricing policies and a pro-competitive pharmaceutical market. Government mandated price cuts which aim to drive prices to the lowest possible level are unsustainable for the generic medicines industries in Italy.

The industry acknowledges the major healthcare challenges faced by the Italian government due to the high price of new medicines. The industry is fully prepared to engage in a constructive partnership to strengthen the sustainability of healthcare and in particular the pharmaceutical market in the future, but what is crucial is the predictability of the rules in light of the long-term sustainability for the Italian generic medicines industries, where short term policies challenge the strong manufacturing base present in Italy and the contribution in terms of jobs.

Remove barriers for pricing & reimbursement approval for a faster patient access to generic medicines

In Italy, for medicinal products subject to the Centralised Procedure (CP), applications for pricing & reimbursement can be submitted only after the marketing authorisation (MA) has been granted (publication on EMA website of the EC decision) while its evaluation starts after the publication in the European Official Journal. Waiting for the publication therefore means that there is an unnecessary time lag for pricing & reimbursement decisions, thereby delaying access to medicines for patients.

After the publication of the Marketing Authorisation in the European Official Journal, theoretically within 60 days, the *Ufficio Valutazione & Autorizzazione of Agenzia Italiana del Farmaco* (AIFA) should publish the implementation of the Community MA including the MA numbers in the Italian OJ. This includes a separate MA number specific to Italy, which is required for the sole purpose of the classification of the product for P&R. If AIFA released these national numbers immediately after the notification to the MA Holder of the EC decision

⁴⁶ Pharmaceutical Sector Inquiry, Final Report, July 2009,

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

⁴⁷ SFK (Foundation for Pharmaceutical Statistics), *Pharmaceutisch Weekblad*, 9 May 2014

⁴⁸ An International Comparison of Best Practice Approaches to Drug Shortages, IMS Health, 21 January 2015

(according to NTA Volume 2A Chapter 6 November 2005), this would further simplify and shorten the process of P&R approval, ensuring a faster patient access to generic medicines and generating more savings for the healthcare systems.

In addition, though the decree states that the publication in the Italian OJ and P&R decision should take place within 60 days, this usually lasts about 5-6 months. This can be attributed to the fact that the adoption of the Community decision is approved by the National Technical Commission (CTS), while the P&R decision is taken by the Commission on Price and Reimbursement (CPR). Both these commissions' approvals are necessary for AIFA to finalise the decree and publish it in the Italian Official Journal. However, these commissions meet once a month but on separate occasions, contributing to delays in P&R approval.

The process could be significantly improved if:

- Pricing & Reimbursement applications submitted immediately after the EC decision, are immediately evaluated without waiting for the publication in the European OJ
- Italian Marketing Authorisation numbers were released immediately after the EC decision

Removal of generic medicines from regional tendering at retail level

In recent years numerous regional authorities have developed alternative form of medicines distribution, different from the traditional retail pharmacy one. Such forms of alternative distribution are normally led by hospital pharmacy, which have the duty to distribute directly to patients medicines previously purchased via tenders. Such form of distribution was originally introduced for medicines under particular conditions:

- Necessity of recurrent checks
- Treatment of patients in home care
- Hospital Discharge

Regional authorities have now disproportionately extended such tenders to large chronic use medicines, normally off patent ones, forcing patients to long route to hospitals and regional health authorities offices around the country. Direct and indirect costs of such kind of approach have never been considered by the local health authorities, leading the system to extreme cases where hospital pharmacies have been forced to dispense till 6 months of medicines supply to a single chronic patient that during the same period changed completely the pharmaceutical therapy wasting a great deal of medicines and public money.

There is a clear need to reform the rules governing the so called “direct distribution by hospital pharmacies”, limiting its use to the cases where originally was meant for and introducing a rule implying that once the medicine goes off patent it must be out of this tender driven distribution system.

Hospital level

Exclude generic and biosimilar medicines sector from the payment of payback

Since 2013 the pharmaceutical industry promoted strong legal action against the payback in court which ruled in favor of the pharmaceutical industry.

On 23 December 2017 the Senate Assembly approved the last Budget Law of the parliamentary term. Some partial provisions on payback on pharmaceutical spending have been introduced while the long-awaited reform of the pharmaceutical Governance has not been approved. Among these measures the most important are: the payback due for products marketed for the first time in the year of the overspending (with no revenues data records in the previous year) is limited to a maximum of 10% of the turnover's positive change between the year of overspending and the previous year (except for orphan and innovative medicines); the conclusion of settlement agreements related to legal disputes promoted by companies – which have duly paid the 2016 payback – against the payback for 2013, 2014 and 2015.

The application of a payback mechanism at the hospital level to generic medicines companies should be abolished. In other European Member States, the payback system is mainly applied to originator medicines that contribute to increasing pharmaceutical expenditure and not generic medicines that contribute to increased health system efficiency gains.

The existence of the payment of payback puts local SMEs at risk and can lead to the withdrawal of multinationals from the country.

Adjust the tendering design to increase patient access to generic medicines

- *Determine a fair price base tender*

In order to create competition while avoiding medicines shortages, it would be relevant that tenders consider not only the lowest price of medicines but also qualitative criteria that do not create barriers to patients' access to generic medicines.

- *Introduce the 'Pure' renegotiation provision in the specifications of the tender in order to immediately open the tender at the time of patent expiry*

The 'pure' renegotiation provision is a clause that, in the case of a medicine patent expiry, compels the procurement authority to immediately start a competitive procedure to identify a new supplier. Therefore, generic medicines would be able to participate in the respective tender and greater competition and savings for healthcare systems would be ensured. However, generally, in the absence of this specific clause in the tender specifications, contracting authorities only open the tender to originator medicines and require them to lower their prices to the level of the lowest price of generic medicines. Therefore, the introduction of the 'pure' renegotiation provision in the tender specifications should be always ensured.

- *Establish a minimum order quantity*

All tenders should define a minimum order quantity, to avoid the proliferation of micro-orders that increase the risk of a supply interruption, as the manufacturer might not have the capacity to address the additional demands, increasing the risk of medicines shortages.

- *Ensure the certainty of all phases of the tendering procedure*

The lack of clear clauses in all phases of the tendering procedure makes business planning difficult which may lead to retraction of manufactures and ultimately medicines shortages.

- *New system to determine bidding prices for procurement authorities*

A new tendering system is necessary to reduce the percentage of unawarded lots and to promote a more sustainable competition among manufacturers.

- *Simplification of tender procedures with an intense process of digitalisation*

Promoting competition also requires a simplification of procedures for manufacturers who are willing to participate in tenders: an intense process of digitalisation of the process is necessary.

2.3 Measures to increase the use of biosimilar medicines in Italy

Provide a level playing field for biosimilar medicines

Regarding the use of biosimilar medicines in Italy, different levels of utilisation can be identified at regional level. We therefore urge the Italian authorities to implement measures which:

- Establish clear and transparent guidelines, based on scientific evidence, supporting the interchangeability between the reference product and biosimilar, while allowing the prescribing physician the 'right-to-refuse', if justified for medical reasons.
- Educate all stakeholders by means of an information campaign, on the safety, quality and effectiveness of biosimilar medicines and on the gainsharing model among the different stakeholders: with biosimilar medicines more patients are treated, there is more care through expansion of the clinical team while generating sustainability for healthcare systems.

Establish distinct pricing and reimbursement rules for biosimilar medicines

Biosimilar medicines should fall under specific pricing and reimbursement rules where an automatic price reduction is not applied. Biosimilar medicines must complete extensive clinical comparability studies and their development can take up to 9 years or more, with costs associated in the range of between €150 and €250 million⁴⁹, depending on the molecule. Therefore, the paradigm of generic medicines cannot be applicable to biosimilar medicines. These distinct pricing and reimbursement rules should create enabling conditions for the development of this market.

⁴⁹ SKP. Policy Requirements for a Sustainable Biosimilar Market.2016, available here: <http://www.medicinesforeurope.com/2016/09/19/policy-requirements-for-a-sustainable-biosimilar-market-simon-kucher-2016/>

3. The Netherlands

Generic medicines in the Netherlands account for 75% of the reimbursed market in volume⁵⁰. Nevertheless, the Dutch market faces some challenges, namely the ‘preference policy’ used by healthcare insurance companies.

Healthcare insurers will only reimburse one of a few medicines within a certain medicine cluster and often only the most inexpensive medicines are reimbursed, including low price off-patent medicines already established and stable for a long period. There is no mandatory price differential between generic and originator medicines and generic medicines are generally priced at least 50% below the price of the respective originator medicine. The fierce price competition when new generic medicines enter the market and when manufacturers compete to be a preferred supplier pushes generic prices down much further, with not uncommon reductions of up to 95%⁵¹. This extreme pressure on prices has been forcing out generic medicines suppliers from the market whose products have not been selected for reimbursement, thereby reducing generic competition and often generating periodic medicines shortages. Recently a working group with different stakeholders was set up under the responsibility of the Ministry of Health with the aim of proposing suitable measures to prevent medicines shortages. Bogin together with the Dutch pharmacist organisation and the Dutch innovative medicines organisation commissioned Berenschot for a study into the effects of health insurance companies preference policies on the availability of medicines in the Netherlands. This study was published in March 2018⁵².

At the hospital level, the *Biosimilars en generieke geneesmiddelenindustrie Nederland* (BOGIN) has concluded an agreement with the hospital pharmacists’ association (NVZA) on good contracting practices: to tender for a contract period of medicines for more than 1 year, to spread tenders throughout the year (not all to start/end at the same date: usually 1 January) and to purchase the agreed ordered quantities.

Regarding biosimilar medicines, it is important to underline that there is no common awareness and understanding regarding the quality and safety of biosimilar medicines: specialists have to be informed individually after every new biosimilar medicines entry in a new therapeutic area. Bogin has launched recently a website for patients with independent information about biosimilar medicines (www.uwbiosimilars.nl)

⁵⁰ QuintilesIMS Health, MIDAS, Q2 2015, retail and hospital channel.

⁵¹ QuintilesIMS Analytics, Q22015

⁵² https://www.berenschot.nl/publish/pages/6054/effects_preference_policy-berenschot.pdf

3.1 Country Specific Recommendations: Proposal for the Netherlands 2018

Following the assessment by Medicines for Europe together with *Biosimilars en generieke geneesmiddelenindustrie Nederland* (BOGIN), both Associations would like to propose the following recommendations for the Netherlands:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of generic medicines, through:

Retail level

- a. Reimbursement of multiple medicines in the same medicine cluster in order to create a sustainable market and increase patient access to generic medicines
- b. Avoid the application of the 'preference policy' in medicines that can no longer drive price competition, (i.e. generic medicines that are off patent for a long period) and allow free choice within the reimbursement limits
- c. The encouragement of stakeholders, namely health insurers, to revise the 'preference policy' and propose measures to avoid medicines shortages

Hospital level

- a. Guarantee that the hospital groups follow the recent agreement on good contracting practices

2. Increase the cost-effectiveness of the healthcare sector by promoting the use of biosimilar medicines, through:

- a. The adoption and implementation of information and education campaigns on biosimilar medicines, emphasising the benefits of gainsharing models among different stakeholders
- b. Avoid the implementation of national tendering on biosimilar medicines

3.2 Measures to increase the use of generic medicines in the Netherlands

Retail level

Reimburse multiple medicines in the same medicine cluster in order to create a sustainable market and increase patient access to generic medicines

Currently, healthcare insurers only reimburse one of a few medicines within a certain medicine cluster and often only the most inexpensive medicines are reimbursed. This preference policy has driven prices down and forced out generic medicines suppliers whose products have not been selected for reimbursement, thereby reducing generic competition that ultimately can lead to medicines shortages. The reimbursement of multiple medicines within the same medicine cluster creates a sustainable market for participation of generic medicines suppliers, stimulating generic competition while avoiding medicines shortages.

Avoid the application of the ‘preference policy’ to medicines that can no longer drive price competition, (i.e. established generic medicines that are off patent for a long period) and allow free choice within the reimbursement limits

Healthcare insurers have been applying the ‘preference policy’ to generic medicines that are already off patent for a long period. As these medicines are already priced as low as possible, the ‘preference policy’ should not be applied to these medicines and free choice of the medicines to be reimbursed should be implemented. Extreme pressure on prices has been forcing out generic medicines suppliers from the market, thereby reducing generic competition and often generating medicines shortages.

Encourage stakeholders, namely health insurers, to revise the ‘preference policy’ and propose measures to avoid medicines shortages

Recently a working group with different stakeholders was set up under the responsibility of the Ministry of Health and health insurers with the aim of proposing more suitable measures than the ‘preference policy’. It is important to encourage stakeholders, especially health insurers, to revise this policy as its consequences may impact patients’ health due to an increased risk of medicines shortages.

Hospital level

Guarantee that the hospital groups follow the recent agreement on good contracting practices

Biosimilars en generieke geneesmiddelenindustrie Nederland (BOGIN) has concluded an agreement with the hospital association (NVZA) on good contracting practices: the period of contract for more than 1 year, tenders spread throughout the year (not all to start/end at the same date: usually 1 January) and to purchase the agreed ordered quantities. Guaranteeing the effective implementation of this agreement is crucial, as these practices allow business predictability and create a sustainable market attractive for generic medicines manufacturers to compete and increase patient access to generic medicines while avoiding medicines shortages.

3.3 Measures to increase the use of biosimilar medicines in the Netherlands

Implement information and education campaigns on biosimilar medicines, emphasising the benefits of gainsharing models among different stakeholders

The scientific concept of biosimilarity is not yet fully understood by all stakeholders in the Netherlands. Indeed, one of the aims of the European Commission consensus paper on biosimilar medicines⁵³, elaborated and agreed by all EU stakeholders, is to inform stakeholders about biosimilar medicines.

Due to the responsibility and unbiased status of the European and the national regulatory bodies, it is crucial that European and national authorities work together to create awareness of the important role of biosimilar medicines in patients' health and sustainability of healthcare systems. The implementation of unbiased information campaigns, the active participation in scientific meetings and conferences, are key steps to develop education on biosimilar medicines and emphasise the benefits of these medicines among the different stakeholders, in particular patients and physicians⁵⁴.

Avoid the implementation of national tendering on biosimilar medicines

The long-term sustainability of the biosimilar medicines sector relies on predictability and a pro-competitive pharmaceutical market. Experience has proven that tender systems' design puts extreme pressure on medicines prices, leading to an unsustainable market that forces medicines manufacturers out of the market. The lack of competition not only creates a monopolistic market for the respective originator, but also increases the risk of medicines shortages affecting patients' health.

- In case tendering would be implemented for biosimilar medicines, it would be crucial to agree on good contracting practices (spreading tenders throughout the year, accurate volumes, etc.) to create sustainability and guarantee biosimilar competition in the market.

⁵³ EC Consensus Paper, "What you need to know about biosimilars" Medicinal Products, Process on Corporate Responsibility in the Field of Pharmaceuticals Access to Medicines in Europe, 2013, available here:

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf

⁵⁴ SKP. Policy Requirements for a Sustainable Biosimilar Market.2016, available here: <http://www.medicinesforeurope.com/2016/09/19/policy-requirements-for-a-sustainable-biosimilar-market-simon-kucher-2016/>

4. Spain

The pharmaceutical share of the total health expenditure for Spain is 16.7%.⁵⁵ Spain has had a large reduction in pharmaceutical expenditure, which decreased by 9% between 2008 and 2011. The generic medicines penetration is 40% by volume in the reimbursed market⁵⁶.

The use of generic medicines in Spain has traditionally been low compared to the average use in Europe, both in volume and value. The main focus of the Spanish government has been on decreasing the prices of generic medicines drastically. Additionally, the current reimbursement regulation imposes that there is no price difference between originator and generic medicines in most references groups, and has therefore eliminated the main advantage of generic medicines. Nevertheless, incentives that positively distinguished the dispense of generic medicines, such as the Spanish normative (2012-2015) applied to INN prescription medicines at the same price level, are no longer in place. Furthermore, the differing market shares between the autonomous communities within Spain show the importance of demand-side policies on the use of generic medicines. Policies are needed to increase both the efficiency of the healthcare system with regard to pharmaceuticals and to increase the sustainability of the Spanish generic medicines retail market.

⁵⁵ OECD, 2013, Health at a Glance, available here: <http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf>

⁵⁶ QuintilesIMS Health, MIDAS, Q2 2015, retail and hospital channel.

4.1 Country Specific Recommendations: Proposal for Spain 2018

Following the assessment by Medicines for Europe together with *Asociacion Española de Medicamentos Genéricos* (AESEG), both Associations would like to propose the following recommendations for Spain:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of generic medicines through the creation of a 'National Plan for Generic medicines' that ensures a stable and predictable market. In particular, the National Plan should include the:
 - a. Adoption and implementation of measures such as price differentiation between generic and originator medicines.
 - b. Adoption and implementation of measures to increase the prescription of generic medicines
 - c. Implementation of prescription by International Non-proprietary Name, homogeneously, in all Spanish Autonomous Communities
 - d. Prevention of tendering on active substances and active ingredients at regional level.

Medicines for Europe would like to propose the following recommendations for Spain:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of biosimilar medicines through the:
 - a. Establishment of pricing and reimbursement rules for biosimilar medicines distinct from those for generic medicines, which foster their development

4.2 Measures to increase the use of generic medicines in Spain

Adopt and implement price differentiation between generic and originator medicines

The price differentiation between generic and originator medicines has to be sustained for a period of time after patent expiry, in order for generic medicines to be on a level playing field with other medicines already on the market. Failing to establish a price difference means that generic medicine manufacturers will have no incentive to enter the market. This situation will eventually remove generic medicines from the market and will eliminate competition for the originator medicines, thereby compromising patient access to medicines.

The adoption and implementation of measures to increase the prescription of generic medicines

The use of generic medicines in Spain has traditionally been low compared to other European countries, both in volume and value and the focus of the Spanish government has been on decreasing the prices of generic medicines drastically and not on implementing incentives to increase patient access to generic medicines. An agreement on policies to increase the prescription of generic medicines resembling that of Portugal and France would contribute to the increased use of generic medicines in Spain.

Increase prescription by International Non-proprietary Name (INN), homogeneously, in all Spanish Autonomous Communities

In September 2011, a Royal Decree was enacted to implement the prescription by INN nationwide, after successful policies mandating prescription by INN in some regions such as Andalusia. Nevertheless, the prescription by INN has historically varied widely across regions. The increase of prescription by INN homogeneously across all Spanish Autonomous Communities is expected to result in increased patient access to generic medicines and an increased contribution to savings for Spanish healthcare systems.

Prevent tendering systems on active substances and active ingredients at national level

The tendering system in Andalusia still remains a threat to patient access to medicines and for the sustainability of the generic medicines industry in Spain. Evidence from the Netherlands⁵⁷ and Germany⁵⁸ has shown that the application of a tendering system increases market concentration at company, active substance and active ingredient levels. This eventually leads to less competition in the generic medicines market and consequent medicines shortages.⁵⁹ Furthermore, the pharmaceutical companies joining the tender system in Andalusia often have less than 1% of the market share leading to uncertainty of supply and eventually posing a serious risk of medicines shortages.

In addition, as 7 out of 10 generic medicines are manufactured locally in Spain, the application of a tender system will have significant negative implications in terms of jobs, economic growth and cost-efficiencies.

⁵⁷ SFK (Foundation for Pharmaceutical Statistics), Pharmaceutisch Weekblad, 9 May 2014

⁵⁸ An International Comparison of Best Practice Approaches to Drug Shortages, IMS Health, 21 January 2015

⁵⁹ Panos Kanavos Report, Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands and Germany, 2012

4.3 Measures to increase the use of biosimilar medicines in Spain

Establish pricing and reimbursement rules for biosimilar medicines distinct from those for generic medicines, which foster their development

Biosimilar medicines should fall under specific pricing and reimbursement rules where an automatic price reduction is not applied. Biosimilar medicines must complete extensive clinical comparability studies and their development can take up to 9 years or more, with associated costs in the range of between €150 and €250 million⁶⁰, depending on the molecule. Therefore, the paradigm of generic medicines cannot be applicable to biosimilar medicines. These distinct pricing and reimbursement rules should create enabling conditions for the development of this market.

⁶⁰ SKP. Policy Requirements for a Sustainable Biosimilar Market.2016, available here: <http://www.medicinesforeurope.com/2016/09/19/policy-requirements-for-a-sustainable-biosimilar-market-simon-kucher-2016/>

5. Portugal

In Portugal, the pharmaceutical share accounts for 15.5% of the total health expenditure (2015)⁶¹ which is below the OECD average that in 2015 was 16.2%.

Some of the more recent reforms in the health sector were linked to the Portugal's Economic Adjustment Programme in place between 2011 and 2014.

The government has asserted its commitment to encouraging more rational prescribing and, more fundamentally, significantly boosting the consumption of generic medicines. A significant step was to enforce compliance with international non-proprietary name (INN) prescribing, although an important caveat allows doctors to continue prescribing by brand name in certain circumstances. In 2017, the implementation of a pharmacists' remuneration (0.35€ per box) for the dispensing of generic medicines promoted an increase in generics market share. Generic medicines currently account for 47.5% of dispensed medicines and nearly 24% of pharmaceutical expenditure⁶². A great effort has been made so far to allow an increased use of generic medicines. However pharmaceutical reform measures that threaten the sustainability of the generic medicines industry need to be addressed. These include the law of referrals which increase the costs of patent litigation, price cuts and the payback mechanism. Only by tackling these barriers can a secure and continuous supply of medicines to patients be ensured.

Prescribing controls in the hospital sector are relatively well established and doctors tend to prescribe by generic name. The government has implemented a compulsory national hospital formulary with which all NHS institutions are obliged to comply. The National Pharmacy and Therapeutics Commission (CNFT) is responsible for determining which medicines are included in the formulary. In January 2018 were published the Terms of Reference for contracting health care in the NHS for 2018 which define the targets and penalties for over or less prescribing in specific areas.

Concerning biosimilar medicines, the publication of CNFT guidelines state for the drugs infliximab, etanercept and rituximab, there is sufficient evidence to consider that switching patients on treatment with the reference biological drug to a biosimilar drug will not result in loss of efficacy or increased risk of adverse reactions. This publication was a positive step to promote biosimilar medicines uptake.

However, in order to achieve the full potential of biosimilar medicines and to create efficiency gains and increase patients' access to medicines, it is crucial to include more incentives for physicians to prescribe, pharmacists to dispense and patients to prefer biosimilar medicines.

⁶¹ OECD Health Statistics, 2017

⁶² Infarmed data, 2017

5.1 Country Specific Recommendations: Proposal for Portugal 2018

Following the assessment by Medicines for Europe together with the *Associação Portuguesa de Medicamentos Genéricos e Biossimilares* (APOGEN), both Associations would like to propose the following recommendations for Portugal:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of generic medicines through the:

Retail level

- a. Adoption and implementation of measures that incentivise physicians' prescription and patients' preference for generic medicines
- b. Abolishment of payback rates for the generic medicines industry
- c. Abolishment of the annual price revision for generic medicines
- d. Limitation of the price reduction of new generic medicines to 65% of the originator price
- e. Introduction of an amendment of the "Law of Referral"

Hospital level

- a. Abolishment of payback rates for the generic medicines industry
- b. Abolishment of the annual price revision for the generic medicines industry
- c. Revision of the actual model of central hospital tenders
- d. Introduction of an amendment of the "Law of Referral"

2. Increase the cost-effectiveness of the healthcare sector by promoting the use of biosimilar medicines through the:

- a. Abolishment of the payback rates for the generic medicines industry
- b. Abolishment of the annual price revision of biosimilar medicines
- c. Revision of the minimum market shares of use of biosimilar medicines
- d. Adoption and implementation of incentives for physicians to prescribe and patients to prefer biosimilar medicines
- e. Establishment of a national list procedure

5.2 Generic medicines measures for Portugal

Retail level

Adopt and implement incentives for physicians to prescribe and patients to prefer generic medicines

Physicians should be incentivised through reward mechanisms, such as target agreements, to prescribe generic medicines. The development of clinical guidelines supported by the e-prescription system would additionally facilitate physicians' prescribing of generic medicines. Information and education campaigns for patients must be re-launched to increase the use of generic medicines.

Abolish the payback mechanism for the generic medicines industry

In view of the contribution already given by generic medicines to the sustainability of the Portuguese NHS, payback rates should not be applied to generic medicines.

Abolish the annual price revision for generic medicines

The price of generic medicines is linked to the price of the main market competitor and should be reviewed annually. This aspect should, be legally abolished, since any change in the originator medicine price will affect the respective generic medicine. The actual regulation compromises free competition between economic operators and, if applied, will undermine the sustainability of the generic medicines sector.

Limit price reduction of new generic medicines to 65% of the originator price

The price reduction of generic medicines in Portugal should be limited to 65% of the originator price. This will prevent the lowering of the price below marginal cost, thereby guaranteeing a constant medicines supply.

Amend the law of 'Referral'

As a result of the referrals regulation, '*Lei das Arbitragens*' (law of 'Referral'), originator companies can start arbitration proceedings within 30 days of the publication of the generic Market Authorisation application in order to defend their patent in case of infringement. Originator companies, therefore, start proceedings to protect their legal rights even when there is no likelihood of an infringement preventing the generic medicine company from launching the product after patent expiry. In the National Strategy for Medicines and Health Products 2016-2020, the need was recognised to identify generic medicines under 'arbitration procedure' and to expedite its procedure, nevertheless no measures were implemented. In order to limit the initiation of unnecessary arbitration proceedings, it is crucial to amend the 'law of referral' to apply penalties in case the originator companies have used the law to 'pay for delay'.

Hospital level

Abolish the payback rates for the generic medicines industry

As generic medicines are not the driver of healthcare costs but of healthcare efficiency, payback rates should not be applied to generic medicines. A payback rate of 14.3% for medicines on restricted prescription to hospitals/clinics puts in place a barrier for the introduction of generic medicines in the hospital sector and as such threatens the sustainability and efficiency of the healthcare system. Such payback rates must urgently be reconsidered.

Abolish the annual price revision for generic medicines

The price of generic medicines is linked to the price of the main market competitor and should be reviewed annually. This aspect should, in any case, be legally abolished, since any change in the originator medicine price will affect the respective generic medicine and eventually will undermine the sustainability of the generic medicines sector.

Revise the current model of central hospital tenders

The current model of CPAs (Contrato Público de Aprovisionamento)⁶³ leads to a decrease of 91% on the average price of medicines. In addition to this price decrease, generic manufacturers can still be subject to hospital tenders leading to a further price decrease. This extreme price erosion undermines the sustainability of generic manufacturers, and may force generic manufacturers out of the market increasing the risk of medicines shortages.

Amend the law of ‘Referral’

As a result of the referrals regulation, ‘*Lei das Arbitragens*’ (law of ‘Referral’), originator companies can start arbitration proceedings within 30 days of the publication of the generic Market Authorisation application in order to defend their patent in case of infringement. Originator companies, therefore, start proceedings to protect their legal rights even when there is no likelihood of an infringement preventing the generic medicine company from launching the product after patent expiry. In the National Strategy for Medicines and Health Products 2016-2020 the need was recognised to identify generic medicines under ‘arbitration procedure’ and to expedite its procedure, nevertheless no measures were implemented. In order to limit the initiation of unnecessary arbitration proceedings, it is crucial to amend the ‘law of referral’ to apply penalties in case the originator companies have used the law to ‘pay for delay’.

⁶³ CPAs/Contrato Público de Aprovisionamento is composed by the centralized purchasing and the national hospital tenders managed by the SPMS (Ministry of Health shared services – purchasing; logistics etc).

5.3 Biosimilar medicines measures for Portugal

Abolish the payback rates for the biosimilar medicines industry

In view of the current and potential contribution of biosimilar medicines to the sustainability of the Portuguese NHS, payback rates should not be applied to biosimilar medicines. A payback rate of 14.3% for biosimilar medicines threatens the sustainability of the biosimilar medicines industry, and therefore access of patients to these medicines. Such payback rates must urgently be reconsidered.

Abolish the annual price revision for biosimilar medicines

The price of generic medicines is linked to the price of the main market competitor and should be reviewed annually. This aspect should, in any case, be abolished, since any change in the originator medicine price will affect the respective generic medicine and eventually will undermine the sustainability of the generic medicines sector.

Revision of the minimum target agreements for the use of biosimilar medicines

Hospitals should be rewarded if a pre-established target agreement of a certain biosimilar medicines is attained respectively during the first, second and third year of marketing of that biosimilar medicine. Taking into consideration the new scientific evidence and the last CNFT guidelines, the actual target of 20% of market share in the first year should be revised.

6. Bulgaria

Bulgaria's pharmaceutical expenditure is above other European countries and makes up a disproportionate amount of the healthcare budget, at 38% of total health expenditure⁶⁴. It is also growing rapidly due to the entry of high-cost innovative medicines, but without considerable improvements in health outcomes⁶⁵. Greater use of generic and biosimilar medicines with rationalised spending related to new high cost medicines would lead to health system efficiency gains and better access to medicines for patients.

The introduction of new medicines to the Bulgarian market along with high VAT rates on medicines has resulted in high out-of-pocket payments for patients, at about 81% of total pharmaceutical expenditure⁶⁶, which causes decreased access to medicines and problems with treatment adherence. These out-of-pocket payments must urgently be tackled through the implementation of flat co-payments for patients.

The current pricing mechanism for generic medicines in Bulgaria is External Reference Pricing (ERP) to the lowest price of a basket of countries, and benchmarking to 30% below the cost of the reference originator medicine. ERP leads to the establishment of prices that are not sustainable for the Bulgarian generic medicines industry. In addition, benchmarking without any incentives to use generic medicines discourages competition. Pricing policies therefore need to be supplemented by measures that stimulate the use of these medicines.

Regarding biosimilar medicines, as more biological medicines lose patent protection in the coming years, it is important for Bulgaria to recognise the significant access and efficiency gains that biosimilar medicines will bring to the health system. Incentives for biosimilar medicines use, aimed at physicians, pharmacists and patients, should run parallel to the establishment of pricing and reimbursement rules distinct from those for generic medicines - a requirement to enable the sustainability of this sector.

⁶⁴ Ministry of Health of the Republic of Bulgaria & International Bank for Reconstruction and Development, Final Report with Recommendations for Reforming Bulgaria's Pharmaceutical Sector, May 2015

⁶⁵ Ibid.

⁶⁶ Ibid.

6.1 Country Specific Recommendations: Proposal for Bulgaria 2017

Following the assessment by Medicines for Europe and the Bulgarian Pharmaceutical Association (BGPharma), we would like to propose the following recommendations for Bulgaria:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of generic medicines, through the:
 - Retail level**
 - I. Introduction of a flat co-payment policy for patients and a higher level of reimbursement for essential medicines
 - II. Prevention/optimisation of External Reference Pricing or price linkage for generic medicines
 - III. Implementation of a national information and education campaign, and prescribing guidelines, on generic medicines
 - Hospital level**
 - a. Introduction of a flat co-payment policy for patients and a higher level of reimbursement for essential medicines
 - b. Optimisation of the tendering system
 - c. Implementation of a national information and education campaign, and prescribing guidelines, on generic medicines
2. Increase the cost-effectiveness of the healthcare sector, by promoting the use of biosimilar medicines, through the:
 - a. Adoption and implementation of incentives for physicians to prescribe and patients to prefer biosimilar medicines
 - b. Establishment of distinct pricing and reimbursement rules for biosimilar medicines, which foster their development
 - c. The adoption and implementation of information and education campaigns on biosimilar medicines, emphasising the benefits of gainsharing models among different stakeholders

6.2 Measures to increase the use of generic medicines in Bulgaria

Retail level

Introduction of a flat co-payment policy for patients and a higher level of reimbursement for generic medicines

The entrance of expensive innovative medicines onto the Bulgarian market, along with high VAT rates for medicines, have resulted in high OPPs. This contributes to reduced access to medicines and decreased adherence to treatment, which can have a negative impact on health outcomes. Flat co-payments for Bulgarian patients, along with a reduction in VAT and an increased use of cost-effective generic medicines, would ensure sustainable access to medicines and better health outcomes for Bulgarian patients. In addition, at present there are certain generic medicines that are reimbursed only at 25% for the lowest price in an INN group. Increasing this reimbursement to a minimum of 75%, especially in generic essential medicines, would significantly reduce the OPP burden on patients.

Prevention/optimisation of External Reference Pricing or price linkage for generic medicines

External Reference Pricing (ERP) is the key price-setting mechanism in Bulgaria. However, these prices do not always reflect national market dynamics. Reference is made to countries with medicines prices which bring value for money in that context, but are not suitable for the country making the reference. In order to ensure that Bulgarian patients have access to essential medicines, Bulgarian authorities should instead examine if there are alternative pricing mechanisms to establish medicine prices – this point is emphasised by the World Health Organisation (WHO) and Health Action International (HAI)⁶⁷. If not prevented, it would be important to optimise the price estimation: the price should be the average of the prices of the country basket instead of the lowest price.

Currently, the price linkage with the originator is 30%. This percentage should be reduced, as the extreme pressure on prices is unsustainable for the generic medicines industry forcing out the supply of certain generic medicines from the market, leading to medicines shortages. It is important to consider the balance between the price and the availability of generic medicines.

Implement a national information and education campaign and prescribing guidelines, on generic medicines

A national information and education campaign which informs patients of the quality, safety and efficacy of generic medicines should be implemented to strengthen their trust. This should be supported by messages on the value that generic medicines bring through improved patient adherence to medication, better health outcomes and increased access to medicines⁶⁸.

⁶⁷ WHO/HAI, Project on Medicines Prices and Availability, External Reference Pricing, May 2011

⁶⁸ IGES Institut GmbH, Value of Generic Medicines, October 2015

Hospital level

Optimise the tendering system

The current tendering system in Bulgaria should be optimised to face its challenges:

2. Improvement of the electronic tendering platform where requirements such as discounts according to the percentage of the remaining shelf-life, undermine the sustainability of generic medicines manufacturers, preventing generic manufacturers from participating in the tenders.
3. Avoid the delays and consequent medicines shortages due to legal disputes

Implementation of a national information and education campaign on generic medicines

A national information and education campaign which informs patients of the quality, safety and efficacy of generic medicines should be implemented to strengthen their trust. This should be supported by messages on the value that generic medicines bring through improved patient adherence to medication, better health outcomes and increased access to medicines⁶⁹.

⁶⁹ IGES Institut GmbH, Value of Generic Medicines, October 2015

6.3 Measures to increase the use of biosimilar medicines in Bulgaria

Adopt and implement incentives for physicians to prescribe and patients to prefer biosimilar medicines

Physicians should be incentivised to prescribe biosimilar medicines through continuous education. This should be supported by information and education campaigns which reassure physicians, pharmacists and patients about the quality, safety and efficacy of biosimilar medicines and emphasise their benefits among all the stakeholders.

Establish distinct pricing and reimbursement rules for biosimilar medicines

Biosimilar medicines should fall under specific pricing and reimbursement rules where an automatic price reduction is not applied. Biosimilar medicines must complete extensive clinical comparability studies and their development can take up to 9 years or more, with associated costs in the range of between €150 and €250 million⁷⁰, depending on the molecule. Therefore, the paradigm of generic medicines cannot be applicable to biosimilar medicines. These distinct pricing and reimbursement rules should create enabling conditions for the development of this market.

Adopt and implement information and education campaigns on biosimilar medicines, emphasising the benefits of gainsharing models among different stakeholders

The scientific concept of biosimilarity is not yet fully understood by all stakeholders and needs to be further explained and widely communicated. Indeed, one of the aims of the European Commission consensus paper on biosimilar medicines⁷¹, elaborated and agreed by all EU stakeholders, is to educate stakeholders about the differences between generic and biosimilar medicines.

Due to the responsibility and unbiased status of the European and the national regulatory bodies, it is their role to implement information campaigns, with officials taking a more active part in scientific meetings and conferences, giving a regulatory and scientific overview on biosimilar issues.

Patients and physicians in particular should be provided with information, as they have a pivotal role in the increased use of biosimilar products. Measures that can contribute to increasing patients and physicians' knowledge on biosimilar medicines, such as information campaigns, are crucial⁷².

⁷⁰ SKP. Policy Requirements for a Sustainable Biosimilar Market.2016, available here: <http://www.medicinesforeurope.com/2016/09/19/policy-requirements-for-a-sustainable-biosimilar-market-simon-kucher-2016/>

⁷¹ EC Consensus Paper, "What you need to know about biosimilars" Medicinal Products, Process on Corporate Responsibility in the Field of Pharmaceuticals Access to Medicines in Europe, 2013, available here: http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf

⁷² GfK, Factors Supporting a Sustainable European Biosimilars Market, https://www.medicinesforeurope.com/wp-content/uploads/2016/03/GfK_Final_Report- Factors Supporting a Sustainable European Biosimilar Medicines Market.pdf

7. Ireland

The Irish healthcare system is the second largest budget expenditure item at €13.1 billion for 2015, and pharmaceutical expenditure made up 15% of total health expenditure in 2014⁷³.

Over the coming years, Ireland's healthcare budget and treatment needs will increase as the population ages and the incidence of chronic disease rises. The Irish Longitudinal Study on Ageing (TILDA) states that the *“combination of population growth and ageing will increase demands for treatments by between a quarter and a third by 2026 if current approaches to treatment continue”*⁷⁴. It is therefore essential that Ireland plans how to meet these challenges in the most effective and cost efficient way.

Generic medicines account for 64% of dispensed medicines and 24% of pharmaceutical expenditure⁷⁵, and there is still room to increase the use of generic medicines. Physicians do not currently prioritise treating new patients with generic medicines, resulting in increased costs for the healthcare system and decreased access to medicines. Cost-containment policies have also led to reduced access, with prices in Ireland lowered by the State by up to 90% in recent years⁷⁶. For example, external reference pricing has resulted in very low prices, forcing some companies to withdraw their products. With a small population size of 4.5 million people in Ireland, any additional price cuts could lead to major drug availability problems for Irish patients.

There is a need for reforms also in the biosimilar medicines arena. Mechanisms to promote the use of biosimilar medicines will become especially important in the coming years, as many biological products become off-patent. There is room to increase health system efficiency and increase access to patients through the establishment of interchangeability guidelines, as already done in Finland⁷⁷, the Netherlands⁷⁸ and Germany⁷⁹. This would ensure that patients on costly originator medicines are prescribed equally safe and effective biosimilar medicines. These guidelines should be supported by incentives directed at physicians and patients, to shift their preference to biosimilar medicines.

Ireland is a manufacturing hotspot for generic medicines - it is the largest net exporter of pharmaceuticals in the European Union, making up 50% of all Irish exports⁸⁰, and contributes significantly to economic growth.

⁷³ Health Enterprise Alliance, Medicine Reform: Ensuring Access and Affordability, September 2015

⁷⁴ Irish Longitudinal Study on Ageing (TILDA), <http://tilda.tcd.ie/>

⁷⁵ IMS Health Midas Database Q2 2015

⁷⁶ Health Enterprise Alliance, Medicine Reform: Ensuring Access and Affordability, September 2015

⁷⁷ Are biosimilar medicines interchangeable? MEB position (2015).

Position of Paul-Ehrlich-Institute on interchangeability of biosimilar medicines (2015).

⁷⁸ Interchangeability of biosimilars – Position of Finnish Medicines Agency Fimea (22/2/2015).

⁷⁹ Position of Paul-Ehrlich-Institute on interchangeability of biosimilar medicines (2015).

⁸⁰ Health Enterprise Alliance internal data, 2015

7.1 Country Specific Recommendations: Proposal for Ireland 2018

Following the assessment by Medicines for Europe and the Health Enterprise Alliance (HEA), we would like to propose the following recommendations for Ireland:

1. Increase the cost-effectiveness of the healthcare sector by promoting the use of generic medicines, through:
 - a) Treating all new patients with generic medicines
 - b) Facilitating generic competition and avoiding unsustainable prices
 - c) Preventing the application of External Reference Pricing (ERP) to generic medicines
 - d) Incentivising the prescription of cost-effective medicines
2. Increase the cost-effectiveness of the healthcare sector, by promoting the use of biosimilar medicines, through the:
 - a) Removal of the 'biosimilar medicines blocker' clause
 - b) Definition of target agreements to prescribe biosimilar medicines
 - c) Adoption and implementation of incentives for physicians to prescribe and patients to prefer biosimilar medicines

7.2 Measures to increase the use of generic medicines in Ireland

Treat all new patients with generic medicines

In Ireland, since the 2013 Act, generic substitution is legally permitted. Though, for some conditions like epilepsy, or transplant patients, clinicians do not advise that patients already being treated with originator medicines change their medication to generic medicines. Nevertheless, it is important to emphasise that when new patients are starting treatment, there is no clinical reason why these patients cannot use generic medicines. They should therefore be prescribed generic medicines which have the same quality, safety and efficacy as the originator medicines. By allowing pharmacists to dispense generic medicines to these new patients, €15 million⁸¹ of cost-efficiencies can be achieved.

Stimulate generic competition and avoid unsustainable prices

Currently, some generic medicines prices are set at unsustainable levels due to short-term cost-containment measures such as External Reference Pricing, Clawback mechanisms, etc. The subsequent extreme pressure on prices leads to the reduction of suppliers in the market and consequently increases the risk of medicines shortages. For instance, Eltroxin®, a medicine which treats patients with thyroid problems has been out of stock for several months resulting in the need for the Health Service Executive (HSE) to resort to high cost unlicensed alternatives. The lack of competition is leading to reduced patient access to medicines, unnecessary spending on alternative treatments and a missed opportunity to generate cost-efficiencies. It is therefore essential that competition is stimulated within the generic medicines industry and to avoid unsustainable prices.

Prevent External Reference Pricing (ERP)

External Reference Pricing (ERP) should not apply to generic medicines as the set price levels do not reflect national market dynamics. This is especially the case for Ireland, where references are made to high volume, low price markets. As Ireland is a low volume market, the low prices that are referenced threaten the sustainability of the generic and biosimilar medicines industries. Irish authorities should instead examine if there are alternative pricing mechanisms to establish medicine prices – this is also a point emphasised by the World Health Organisation (WHO) and Health Action International (HAI)⁸².

Incentivising the prescription of cost-effective medicines

Currently there are some device-based medicines, mainly inhalers, which contain the same active ingredient, however are deemed ‘non-interchangeable’ under the terms of the 2013 Act, due to the device itself. Inclusion of these device-based medicines in an interchangeable list and incentivising their prescribing will result in cost-efficiency gains of €18 million⁸³, which currently cost the State more than €72 million a year.

⁸¹ Health Enterprise Alliance internal data, 2015

⁸² WHO/HAI, Project on Medicines Prices and Availability, External Reference Pricing, May 2011

⁸³ Ibid.

7.3 Measures to increase the use of biosimilar medicines in Ireland

Remove the 'biosimilar medicines blocker' clause

Recently it was agreed that when a biosimilar medicine enters the market, the respective originator medicine would have a reduction of 30% of their reimbursement. This new clause prevents biosimilar manufacturers from participating in the market as the price reduction to compete with the respective originator would be unsustainable. Removing the 'biosimilar medicines blocker' would increase price competition and lead to savings/sustainability of the healthcare systems.

Implementing target agreements for prescribing on biosimilar medicines

Currently there are no target agreements to prescribe biosimilar medicines and it is of utmost importance to establish the right framework to incentivise physicians to increase patient access to biosimilar medicines. Therefore, target agreements of approximately 40% to prescribe biosimilar medicines should be implemented at both hospital and retail levels.

