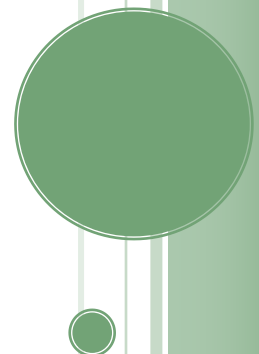




NATIONAL BIOSIMILAR MEDICINES POLICY

Consultation Paper

August 2017



Public Consultation Paper:
National Biosimilar Medicines Policy

Department of Health

August 2017

Department of Health

Hawkins House, Hawkins Street, Dublin 2

Ireland

E-mail: biosimilar_consultation@health.gov.ie

Website: <http://health.gov.ie/consultations/>

Contents

Introduction	3
The Challenge to the Health System in Ireland	3
National Biosimilar Medicines Policy	4
Biological and Biosimilar Medicines.....	7
Biological Medicines	7
Biosimilar Medicines	7
Biosimilar Uptake in Ireland	8
Prescribing and Interchangeability	9
Prescribing	9
Interchangeability.....	9
Switching in Ireland	10
Substitution in Ireland	10
Biosimilar Medicine Policies Internationally	12
Prescribing, Switching and Substitution	12
Legislation, National Guidelines and Quotas.....	12
Education and Supports.....	15
Incentives and Disincentives	18
Tendering and Pricing Policies.....	19
Tendering	19
Pricing Policies.....	22
Inappropriate Business Practices.....	24
Consultation Questions	26
The Consultation Process	30
Freedom of Information	30
What happens after this consultation?.....	30

INTRODUCTION

The Challenge to the Health System in Ireland

Medicines play a vital role in improving the overall health of Irish patients. Securing access to new and innovative medicines, in a timely manner, is a key objective of the Irish health service. However, the challenge is to deliver this objective in an affordable and sustainable way. The medicines bill for the community drugs schemes – primarily the GMS (medical card), Long Term Illness, Drugs Payment as well as the High Tech Arrangement – including fees and ingredient costs, is forecast at just over €1.7 billion in 2017. To ensure that patients receive the highest quality care, it is essential that these resources invested in medicines are used efficiently and effectively. This requires an integrated approach to reduce the price of all treatments, to deliver greater efficiencies across the supply chain and also to promote the use of the most cost-effective treatments.

While the cost of the community schemes and the High Tech Arrangement has been relatively stable at about €1.7 billion since 2012, this is due, mainly, to a successful programme of generic substitution and reference pricing. This programme is ongoing and has reduced prices for both off-patent and on-patent treatments. However, this apparent headline stability masks a change within the total. The GMS scheme has reduced from €1.2 billion in 2013 to €875 million in 2016. On the other hand, the High Tech has grown from €442 million in 2013 to €597 million in 2016.¹ Growth in spending within the High Tech Arrangement will raise significant challenges in future years, driven primarily by the increasing volume of existing medicines in addition to the high cost of the future pipeline of new medicines.

¹ Primary Care Reimbursement Service, *Statistical Analysis of Claims and Payments*, 2013

National Biosimilar Medicines Policy

To address some of these challenges, the Government is developing a National Biosimilar Medicines Policy to promote the rational use of biosimilar medicines and to create a sustainable environment for biological medicines in Ireland.²

A biosimilar is a biological medicine that is highly similar to an approved biological medicine (the reference medicine). Biosimilar medicines can only be authorised for use once the patent for the reference medicine has expired. However, they have no clinically meaningful differences compared to the reference medicine.³ Biosimilars are typically less expensive to produce than the reference medicine, due to lower research and development costs.⁴ As a result of the lower costs and competition for market share, they are generally priced at a significant discount to the reference medicine. As stated by the European Medicines Agency (EMA), '*Biosimilar competition can offer advantages to EU healthcare systems, as it is expected to improve patients' access to safe and effective biological medicines with proven quality*'.⁵

A key element of effective resource management is cost-effective prescribing. The World Health Organisation (WHO) defines rational medicine use as where 'Patients receive medications...at the lowest cost to them and their

² A biological medicine is a medicine that is developed from a living organism such as a bacterium.

³ European Medicines Agency, *Biosimilars in the EU: information guide for healthcare professionals*, 2017

⁴ Mestre-Ferrandiz et al., *Biosimilars: How Can Payers Get Long-Term Savings?*. 2016

⁵ European Medicines Agency, *Biosimilars in the EU: information guide for healthcare professionals*, 2017

community’.⁶ This practice allows for the most effective use of resources for health services, patients and the taxpayer.

Prescribing practices are at the discretion of a patient’s clinician. Biological medicines are widely prescribed across a growing range of disease areas in Ireland. Many of the most frequently prescribed medicines have lost or are due to lose patent protection. Over €200 million is currently spent, in the community and in hospitals, on biologicals that have a biosimilar available or due to become available in 2018. Despite the opportunities presented by biosimilars, uptake in Ireland remains low in comparison to many member states.

The National Biosimilar Medicines Policy is being drafted in anticipation of the expiration of a number of biological patents over the next few years. The policy will aim to increase biosimilar use in Ireland, by creating a robust framework in which biologicals and biosimilars can be safely, cost-effectively and confidently used in the health service.

The Department of Health has initiated this consultation process to ensure that a wide range of views are considered in developing this policy framework.

This consultation sets out the definitions of biological and biosimilars medicines, as well as the legal and regulatory environment surrounding their market authorisation and use, both internationally and in Ireland. It goes on to explore and consider policies in other EU countries which aim to increase

⁶ World Health Organisation. *Promoting rational use of medicines: core component*, 2002.

uptake of biosimilars. Questions are posed for the reader throughout these sections though views outside of those prompted by these questions are also welcome.

BIOLOGICAL AND BIOSIMILAR MEDICINES

Biological Medicines

Biologicals differ from chemical medicines in that they are developed from a living organism, such as a bacterium or yeast. Biologicals range in complexity and diversity, from relatively small molecules, such as human insulin, to complex molecules such as monoclonal antibodies.⁷

Because of the nature of biological production processes, not every batch of a biological medicine is identical. However, these minor differences between batches of a biological do not affect the safety and effectiveness of these medicines.⁸

Biosimilar Medicines

A biosimilar is a biological medicine that is highly similar to an already approved biological medicine. Biosimilars are approved against the same standards of pharmaceutical quality, safety and efficacy as biologicals.⁹ Because biosimilars are made from living organisms, there may be minor differences from the reference medicine. However these differences between biosimilars and the reference medicine are not clinically meaningful in terms of their safety or efficacy.¹⁰

Biosimilars can only be authorised for use once the patent for the reference biological has expired. In general, a reference medicine has been authorised for at least 10 years before a biosimilar can be made available.

⁷ Health Products Regulatory Authority, *Guide to Biosimilar for Healthcare Professionals and Patients*, 2015

⁸ European Medicines Agency, *Biosimilars in the EU: information guide for healthcare professionals*, 2017

⁹ *Ibid.*

¹⁰ *Ibid.*

Since the approval of the first biosimilar in 2006, the EMA has approved the highest number of biosimilars worldwide. None of the 28 biosimilars approved by the EMA have been withdrawn or suspended because of safety or efficacy.¹¹

The EMA states that: *‘The evidence acquired over 10 years of clinical experience shows that biosimilars approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines.’*¹²

Biosimilar Uptake in Ireland

Biosimilars have been authorised in Ireland since 2006, in line with all other Member States. Despite the EMA granting market authorisation for 28 biosimilars, uptake in Ireland has been low relative to other EU countries. Only 11 biosimilars are currently reimbursable by the State. Recognising the important role that biosimilars will play in improving the cost-effectiveness of the State’s medicine bill, the 2016 Framework Agreement on the Supply and Pricing of Medicines provides for automatic price reduction for biologicals on introduction of a biosimilar to the market.¹³ This price reduction strikes a balance between reducing the price paid by the HSE and encouraging biosimilars into the market.

¹¹ European Medicines Agency, *Biosimilars in the EU: information guide for healthcare professionals*, 2017

¹² Ibid.

¹³ <http://health.gov.ie/blog/publications/framework-agreement-on-the-supply-and-pricing-of-medicines/>

PRESCRIBING AND INTERCHANGEABILITY

Prescribing

Prescribing practice is at the discretion of a patient's clinician. Biologicals and biosimilars are typically prescribed by a clinician in a hospital. The Health Products Regulatory Authority (HPRA) published a *Guide to Biosimilar for Healthcare Professionals and Patients* in 2015. The HPRA recommends consultation between prescribers, pharmacists and procurement staff in deciding treatment preferences for using a reference or biosimilar medicine in Ireland.¹⁴

Interchangeability

The EMA defines interchangeability as “...*the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference product with a biosimilar (or vice versa) or replacing one biosimilar with another. Replacement can be done by:*

- *Switching, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent.*
- *Substitution (automatic), which is the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the prescriber.”¹⁵*

In the EU, biosimilars are given market authorisation by the EMA. However, EMA evaluations do not include recommendations on whether the biosimilar is interchangeable with the reference medicine. Prescribing practices and

¹⁴ Health Products Regulatory Authority, *Guide to Biosimilar for Healthcare Professionals and Patients*, 2015

¹⁵ European Medicines Agency, *Biosimilars in the EU: information guide for healthcare professionals*, 2017

advice to prescribers fall under the responsibility of Member States. Within this remit, decisions on the extent to which medicines are interchangeable are important, as this is a key mechanism for achieving cost efficiencies in prescribing.

Switching in Ireland

In Ireland, the relevant authority, the HPRA, supports physician-led interchangeability of biologicals and biosimilars i.e. clinicians can switch patients on a reference medicine to a biosimilar.¹⁶ However, any change should be made in consultation with the patient. While acknowledging that prescribing practices are at the discretion of clinicians, the HPRA does not recommend that patients switch back and forth between a biosimilar and a reference medicine.¹⁷

Substitution in Ireland

Physician-led interchangeability should not be confused with the HPRA list of interchangeable medicines that may be substituted in a community pharmacy, as set out in the Health (Pricing and Supply of Medical Goods) Act 2013. This practice is referred to as generic substitution. The 2013 Act specifically excludes biosimilars from the interchangeable list of small molecule chemical medicines and they cannot be substituted in pharmacies.

¹⁶ The HPRA has confirmed that the Health (Pricing and Supply of Medical Goods) Act 2013 does not prohibit physician-led interchangeability.

¹⁷ Health Products Regulatory Authority, *Guide to Biosimilar for Healthcare Professionals and Patients*, 2015

Section A - Questions to consider :

1. Before reading this consultation paper, were you aware of biosimilars medicines?
2. Before reading this consultation paper, what was your understanding of Ireland's legal and regulatory position on biosimilars? Has this understanding changed from reading this paper? Please explain your answer.
3. Before reading this consultation paper, were you aware of the low uptake of biosimilars in Ireland? What, in your view, are the primary reasons behind this?

BIOSIMILAR MEDICINE POLICIES INTERNATIONALLY

Creating a sustainable environment for biologicals and biosimilars is a key policy priority for many EU Member States. Several Member States have implemented successful policies to increase biosimilar use. This section sets out some of the policy levers that Member States have adopted and seeks views on the applicability of these to Ireland.

National policies typically use a mix of policy levers, which include promoting the launch of biosimilars in the market, supporting safe prescribing to new patients, switching existing patients and promoting competition to reduce the cost to patients and the State.

These measures can take many forms, from statutory and clinical guidelines to financial incentives and disincentives to education and promotion. This section is not an exhaustive list of measures and respondents are invited to put forward alternative policy levers that they believe are worth considering. An appropriate mix of policy levers for Ireland will be required and respondents are asked to consider the individual policy lever, the form it should take and how it would interact with other levers.

Prescribing, Switching and Substitution

Legislation, National Guidelines and Quotas

Prescribing biosimilars to new patients is permitted across the EU. Switching an existing patient to a biosimilar, under the supervision of a clinician, is also widely permitted and encouraged. A recent paper by Kurki et al. investigated studies into the interchangeability of biosimilars and concluded that

switching patients from a reference product to a biosimilar can be considered safe when the patient is clinically monitored.¹⁸

Poland encourages switching existing patients to biosimilars at every therapeutic level. Other countries encourage switching under certain circumstances. In the UK, switching is permitted by law but the decision to switch rests with the physician. In Belgium and Spain, switching is not generally recommended but the decision is also up to the physician. In France, switching is allowed as long as the patient is monitored closely by their physician and has been informed about the switch.¹⁹

Biosimilar substitution is generally not permitted in EU countries. Belgium prohibits pharmacy-led substitution of biosimilars by law. Hungary, Spain, Greece, Italy and the UK have guidelines prohibiting biosimilar substitution. In Poland, there is no regulation against biosimilar substitution and substitution may occur.²⁰ France has recently legislated for biosimilar substitution under certain conditions. However, due to legal issues, automatic substitution has not yet been implemented.²¹

National guidelines are also important sources of information for patients and healthcare professionals. Biosimilar guidelines are published in a number of countries, by national regulatory authorities, regional authorities

¹⁸ Kurki et al., *Interchangeability of Biosimilars: A European Perspective*, 2017

¹⁹ Rémuzat et al., *Supply-side and Demand-Side Policies for Biosimilar: and Overview in 10 European Member States*, 2017

²⁰ Thimmaraju et al., *Legislation on Biosimilar Interchangeability in the US and EU- Developments Far from Visibility*. 2015

²¹ The law in France cannot be implemented until the relevant decrees regarding the precise set of conditions required for biosimilar interchangeability have been adopted.

and health technology assessment bodies. Guidelines typically outline the legal framework for prescribing policies and reimbursement restrictions, but may also discuss the safety and effectiveness of biosimilars. For example, in the UK, the National Institute for Health and Care Excellence (NICE) provides guidance on options for using biosimilars, evaluation of biosimilars, licensing and comparability, pharmacovigilance, and brand name prescribing.²²

Prescription quotas, set by statute or guidelines, are used to increase biosimilar uptake. Prescription quotas set a target for the percentage of biosimilars prescribed by each physician or hospital and for the percentage of patients prescribed biosimilars on an aggregate level.²³ Germany sets regional prescription budgets and quotas for biosimilars. Italy also has a regional quota system for biosimilar prescribing.

In Belgium, as part of a new Future Pact (Pacte d'Avenir), the Government, industry representatives and physician and hospital pharmacist associations have signed a convention to encourage biosimilar use for at least 20% of new patients. If this target is not met, the Government has pledged to introduce legislation to make the target mandatory.²⁴

²² <https://www.nice.org.uk/advice/ktt15/chapter/Evidence-context>

²³ Carone et al., *Cost Containment Policies in Public Pharmaceutical Spending in the EU*, 2012

²⁴ IMS Institute, *Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets*, March 2016

Sweden and the UK have financial rewards for physicians who meet prescription quotas or targets. Italy and Germany use financial penalties where physicians do not meet quotas or targets.²⁵

Section B - Questions to consider :

1. Do you see a role for national, statutory or clinical prescribing guidelines for biosimilar medicines in Ireland? Please explain your answer.
2. Do you think that prescriber-led switching of patients to biosimilars should be encouraged in Ireland? Please explain your answer.
3. Do you think that pharmacy-led substitution of biosimilars should be implemented in Ireland? Please explain your answer.
4. Do you see a role for prescription quotas in Ireland in order to increase biosimilar uptake?
 - i. What is an appropriate prescription quota to implement?
 - ii. Should quotas only be employed for a limited duration?
 - iii. Should quotas apply at a local or national level, and should

Education and Supports

A legal framework for prescribing and switching patients to biosimilars is, on its own, not sufficient to increase biosimilar prescribing and switching. Additional measures are needed to encourage biosimilar uptake. This section will look at how education and other supports have been used to increase biosimilar uptake in EU countries.

²⁵ Rémuzat et al., *Supply-side and Demand-Side Policies for Biosimilar: and Overview in 10 European Member States*, 2017

Educational programmes, to increase knowledge and confidence in biosimilar use, are in place in a number of countries (for example Belgium, France, Germany, Italy, Spain, Sweden and the UK). Tailored educational programmes for physicians are used in the UK and Germany. Forums and discussions take place in these two countries which allow physicians to share their views and experiences of biosimilars.²⁶

In the UK, the NICE Adoption and Impact Programme provides a setting to share experiences of introducing biosimilars, giving clinicians and hospital management additional support and information when introducing biosimilars to their own patients.²⁷

An education and engagement programme to support healthcare professionals with the introduction of biosimilars has also been developed in the UK, in a joint project between industry and healthcare professionals. The aim is to improve understanding of biosimilars and help healthcare professionals to better inform patients about their use and assist in their timely introduction when appropriate.²⁸ A process timeline has been established which outlines the milestones involved in a successful adoption of biosimilars in National Health Service (NHS) trusts.²⁹

In Denmark, the Danish Medicines Agency worked with patient organisations to identify information gaps from a patient perspective on

²⁶ Rémuzat et al., *Supply-side and Demand-Side Policies for Biosimilar: and Overview in 10 European Member States*, 2017

²⁷ Rémuzat et al., *Supply-side and Demand-Side Policies for Biosimilar: and Overview in 10 European Member States*, 2017

²⁸ <http://cancervanguard.nhs.uk/biosimilars-adoption/>

²⁹ <http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/>

biosimilars.³⁰ Information booklets and videos were created to address these information gaps. Information sessions were also aimed at physicians, to inform them of legal requirements regarding biosimilars and about the concerns their patients might have.

Additional supports are provided in a number of UK hospitals to aid the transition of patients from reference drugs to biosimilars and to provide information to patients. In the University Hospital Southampton, specialist nurses were employed to ensure that the appropriate screening and assessment of patients was being conducted and to provide additional monitoring and surveillance.³¹

Section C - Questions to consider :

1. Before reading this paper, were you aware of any educational programmes and/or national guidelines in place in Ireland aimed at increasing knowledge of biosimilars?
2. Do you see a role for educational programmes and/or national guidelines in increasing biosimilar knowledge and awareness in Ireland? Please explain your answer.
 - i. If so, should these programmes and/or guidelines be tailored for specific groups i.e. patients, prescribers, pharmacists, nurses etc? If so, which groups? Please explain your answer.
 - ii. Is there a need to provide education or guidance to biosimilar suppliers on entering the Irish pharmaceutical market? Please explain your answer.

³⁰ Benedicte Lunddahl. *Pharmacovigilance on biologics and biosimilars: A Danish perspective*. 2016

³¹ NICE, *Technology Appraisal Adoption Support*, 2015

Incentives and Disincentives

Incentives and disincentives have been used to increase biosimilar uptake. Despite legislation allowing biosimilar use and educational programmes encouraging use, uptake may remain low. Financial incentives and disincentives can be used to stimulate biosimilar uptake by changing physicians' and patients' behaviours.

One example of a financial incentive is a gain-share agreement, where those in charge of implementing a change in practice benefit from the savings generated by that change, incentivising them to generate more savings. In the UK, a gain-share agreement was established between the University Hospital Southampton NHS Foundation Trust and local clinical commissioning groups. Savings from switching patients to biosimilars were used to fund the additional staff needed to implement and monitor the safe switching of patients to biosimilars.³²

Patient co-payments are an example of a financial disincentive used to increase the uptake of biosimilars. Germany, Hungary, Poland, Spain and Sweden have patient co-payment systems which favour cheaper medicines. For example, Spain requires patients to pay 100% of the drug price if the preferred medicine is not prescribed.³³

³² NICE, *Technology Appraisal Adoption Support*, 2015

³³ Rémuzat et al., *Supply-side and Demand-Side Policies for Biosimilar: and Overview in 10 European Member States*, 2017

Section D - Questions to consider :

1. Considering what has been seen in other countries, should incentives and/or disincentives be used in Ireland to increase the uptake of biosimilars?
 - i. If so, should there be different incentives and/or disincentives for prescribing biosimilars to new patients and for switching existing patients?
2. Do you see a role for gain-sharing agreements in promoting the uptake of biosimilars in Ireland? How might this be structured in an Irish setting?
3. Do you see a role for patient incentives, such as patient co-payment systems, in promoting the uptake of biosimilars in Ireland? How might this be structured in an Irish setting?

Tendering and Pricing Policies

Tendering and pricing policies are used across the EU to achieve lower prices for medicines in a safe, cost-effective and sustainable way. Different tendering policies involve varying levels of engagement and collaboration between key stakeholders such as prescribers, patients, pharmacists, other healthcare professionals and procurers. Beyond achieving lower prices, tendering can allow for a wide range of views and experiences from key stakeholders to be taken into account in the procurement process. This information sharing can also lead to greater confidence in, and uptake of, biosimilars.

Tendering

Pharmaceutical procurement may be undertaken through tendering at national, regional and/or hospital level. Countries which tender at higher

levels tend to achieve the largest reductions in price. For example, Norway uses national level tenders for certain drug classes and has gained up to 72% price reductions for certain biosimilars.³⁴ Regional level tenders in Italy have reduced prices by up to 60%.³⁵ Hospital level tenders are also widespread, for example in France, Spain and Belgium.

Tender assessment panels often include patient representatives, specialists from different clinical areas, pharmacists and procurers. In evaluating tenders, multiple criteria can be taken into account to achieve the best value in terms of safety, sustainability and cost-effectiveness.

The Norwegian Drug Procurement Cooperation provides the basis and specification for purchase and delivery agreements for pharmaceutical manufacturers. This group is made up of patient representatives, pharmacoeconomic specialists, and experts in rheumatology, gastroenterology and dermatology.³⁶

Many EU countries use non-exclusive or multi-winner tenders (for example France, Germany, Portugal and Spain). These tenders can result in the inclusion of the reference drug and a biosimilar on the list of prescribable medicines.

³⁴ Asbjorn Mack, *Norway, biosimilars in different funding systems. What works?*, 2015

³⁵ Curto et al., *Regional Tenders on Biosimilars in Italy: An empirical analysis of awarded prices*. 2013

³⁶ Asbjorn Mack, *Norway, biosimilars in different funding systems. What works?*, 2015

Poland uses exclusive tenders and only the most cost-effective product, in terms of price, safety, effectiveness, sustainability and other factors, goes on the list of prescribable medicines.³⁷

Norway and the UK use tenders where, for each drug class, the highest ranked medicine, in terms of cost-effectiveness, is the preferred drug to prescribe. Prescribers are advised to prescribe this drug, but they may prescribe the drug they feel is most appropriate on a patient-by-patient basis.³⁸

Section E - Questions to consider :

1. To what extent, if any, are you aware of tendering processes for pharmaceutical procurement in Ireland currently? Please explain your answer.
2. Do you see a role for tendering in biosimilar procurement in Ireland? Please explain your answer.
3. What role, if any, should healthcare providers play in a tendering process?
4. If tendering is used in biosimilar procurement, what level should the tender be conducted at i.e. national tender, hospital group tender, hospital tender? Please explain your answer.
5. Should exclusive tenders (i.e. single winner tenders) be used for biosimilar procurement? Please explain your answer.

³⁷ Precision For Value. *Impact of Market Access Factors in the Adoption of Biosimilar Anti-TNFs across Europe*. 2016

³⁸ Asbjorn Mack, *Norway, biosimilars in different funding systems. What works?*, 2015

Pricing Policies

Internal and external reference pricing is used in many countries to set prices of medicines. Internal reference pricing refers to the practice of setting the price by comparing prices of equivalent or similar products in a chemical, pharmacological or therapeutic group in the same country.³⁹ External reference pricing is defined as ‘the practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country’.⁴⁰

Germany uses internal reference pricing for biosimilars. Greece uses external reference pricing, with biosimilars priced at the average of the three lowest prices across the EU.⁴¹

Price linkage policies link the price of a biosimilar to the reference product in a market. Many EU countries use this policy, but the relationship between biosimilar and reference prices varies. In Austria, generic pricing policy is applied to biosimilars, which means the first biosimilar on the market is priced at 52% of the reference product, the second biosimilar at 44% and the third at 40%.⁴²

³⁹ RAND, *Pharmaceutical Pricing*, 2013

⁴⁰ The WHO Collaborating Centre for Pricing and Reimbursement Policies, Glossary
<http://whocc.goeg.at/Glossary/PreferredTerms/External%20price%20referencing>

⁴¹ Rémuzat et al., *Supply-side and Demand-Side Policies for Biosimilar: and Overview in 10 European Member States*, 2017

⁴² Mestre-Ferrandiz et al., *Biosimilars: How Can Payers Get Long-Term Savings?*, 2016

Section F - Questions to consider :

1. To what extent, if any, do you see a role for internal and/or external referencing pricing in Ireland?
2. Should price linkage play a greater role in Ireland and what level of discounts off the reference drug should be sought?
3. Should the price of the reference treatment be reduced automatically on loss of exclusivity in the Irish market? Please explain your answer.

Inappropriate Business Practices

The OECD have previously highlighted the existence of inappropriate business practices aimed at increasing demand for medical products or services. These practices include instances when stakeholders act inappropriately to promote their individual business and situations where the organised action of groups of stakeholders undermines achievement of health care systems' goals.⁴³ These lead to higher pharmaceutical costs and are a source of wasteful spending on healthcare. These include practices such as 'Direct Funding', 'Direct and Indirect Persuasion', 'Financial Incentives' and 'Free-of-Charge Provision'. Further discussion of these issues can be found in their report, 'Tackling Wasteful Spending on Health'.⁴⁴

To address these issues, OECD countries have introduced policies to limit their effects. For example, in the EU, direct-to-consumer advertising for prescription medicines is banned. In Australia and France, prescribing physicians may not sell medicines. Germany discourages drug company interference with educational institutions, through specific rules to ensure neutrality of education and training. France and Germany have laws banning physicians from receiving gifts from pharmaceutical companies. These are just a few examples of policies, highlighted by the OECD, to inhibit inappropriate business practices in relation to pharmaceuticals. The OECD has identified that regulation and an emphasis on increasing transparency in clinical trials play key roles in tackling inappropriate business practices.

⁴³ OECD, *Tackling Wasteful Spending on Health, Chapter 7 section 3*, 2017

⁴⁴ OECD, *Tackling Wasteful Spending on Health, Table 7.3*, 2017

Section G - Questions to consider:

1. Considering what has been highlighted by the OECD, are you aware of any inappropriate business practices operating in Ireland?
 - i. If so, in your opinion, how might these affect biosimilar uptake in Ireland?
2. Are there any other inappropriate business practices, not outlined by the OECD, operating in Ireland that might affect the uptake of biosimilars? Please explain your answer.
3. Should measures be put in place to manage the practices you have identified in your answers to section G, questions 1 & 2?

CONSULTATION QUESTIONS

Below you will find a list of the questions highlighted throughout the paper. We ask you to give your views on these important issues, to support the development of the National Biosimilar Medicines Policy. It is not necessary to provide an answer for each question; however you may wish to answer every question. When responding, please indicate which question(s) you are responding to and whether you are contributing to the consultation process as a patient, prescriber, nurse, pharmacist, procurer, manufacturer, etc.

Section A - Introduction

1. Before reading this consultation paper, were you aware of biosimilar medicines?
2. Before reading this consultation paper, what was your understanding of Ireland's legal and regulatory position on biosimilars? Has this understanding changed from reading this paper? Please explain your answer.
3. Before reading this consultation paper, were you aware of the low uptake of biosimilars in Ireland? What, in your view, are the primary reasons behind this?

Section B - Legislation, National Guidelines and Quotas

1. Do you see a role for national, statutory or clinical prescribing guidelines for biosimilar medicines in Ireland? Please explain your answer.
2. Do you think that prescriber-led switching of patients to biosimilars should be encouraged in Ireland? Please explain your answer.
3. Do you think that pharmacy-led substitution of biosimilars should be implemented in Ireland? Please explain your answer.

4. Do you see a role for prescription quotas in Ireland in order to increase biosimilar uptake?
 - i. What is an appropriate prescription quota to implement?
 - ii. Should quotas only be employed for a limited duration?
 - iii. Should quotas apply at a local or national level, and should they apply equally to new and existing patients?

Section C - Education & Supports

1. Before reading this paper, were you aware of any educational programmes and/or national guidelines in place in Ireland aimed at increasing knowledge of biosimilars?
2. Do you see a role for educational programmes and/or national guidelines in increasing biosimilar knowledge and awareness in Ireland? Please explain your answer.
 - i. If so, should these programmes and/or guidelines be tailored for specific groups i.e. patients, clinicians, pharmacists, nurses etc.? If so, which groups? Please explain your answer.
 - ii. Is there a need to provide education or guidance to biosimilar suppliers on entering the Irish pharmaceutical market? Please explain your answer.

Section D - Incentives & Disincentives

1. Considering what has been seen in other countries, should incentives and/or disincentives be used in Ireland to increase the uptake of biosimilars?
 - i. If so, should there be different incentives and/or disincentives for prescribing biosimilars to new patients and for switching existing patients?
2. Do you see a role for gain-sharing agreements in promoting the uptake of biosimilars in Ireland? How might this be structured in an Irish setting?

3. Do you see a role for patient incentives, such as patient co-payment systems, in promoting the uptake of biosimilars in Ireland? How might this be structured in an Irish setting?

Section E – Tendering

1. To what extent, if any, are you aware of tendering processes for pharmaceutical procurement in Ireland currently? Please explain your answer.
2. Do you see a role for tendering in biosimilar procurement in Ireland? Please explain your answer.
3. What role, if any, should healthcare providers play in a tendering process?
4. If tendering is used in biosimilar procurement, what level should the tender be conducted at i.e. national tender, hospital group tender, hospital tender? Please explain your answer.
5. Should exclusive tenders (i.e. single winner tenders) be used for biosimilar procurement? Please explain your answer.

Section F – Pricing Policies

1. To what extent, if any, do you see a role for internal and/or external referencing pricing in Ireland?
2. Should price linkage play a greater role in Ireland and what level of discounts off the reference drug should be sought?
3. Should the price of the reference treatment be reduced automatically on loss of exclusivity in the Irish market? Please explain your answer.

Section G - Inappropriate Business Practices

1. Considering what has been highlighted by the OECD, are you aware of any inappropriate business practices operating in Ireland?

- i. If so, in your opinion, how might these affect biosimilar uptake in Ireland?
2. Are there any other inappropriate business practices, not outlined by the OECD, operating in Ireland that might affect the uptake of biosimilars? Please explain your answer.
3. Should measures be put in place to manage the practices you have identified in your answers to section G, questions 1 & 2?

Observations and comments are welcome on any aspect of biosimilar medicines, and not just the issues identified in this consultation paper.

THE CONSULTATION PROCESS

The consultation period will run for 6 weeks until September 22nd 2017. Any submissions received after this date may not be considered.

The preferred means of response is by email to:
biosimilar_consultation@health.gov.ie

Alternatively, your response may be posted to:

Biosimilar Medicines Consultation
Community Pharmacy Policy Unit
Department of Health
Hawkins House
Dublin 2, D02 VW 90
Ireland

Please include your contact details if responding by post.

Freedom of Information

Responses to this consultation are subject to the Freedom of Information Acts. Parties should also note that it is the Department's intention to publish responses to the consultation on its website, www.health.gov.ie, after the deadline for receiving submissions.

It is important to be aware that, unless you clearly identify any commercially or personally sensitive information in your submission, you are making the submission on the basis that you consent to it being made available in full on the Department of Health website. Potentially defamatory material will not be placed on the website.

What happens after this consultation?

National Biosimilar Medicines Policy – Consultation Paper 2017

Submissions received for this consultation will be published on the Department of Health website. They may be used to inform the development of the National Biosimilar Medicines Policy in Ireland.

The Department reserves the right to follow up with any respondent.