Overview

• Regulatory Science Ireland (RSI)
• Reducing the Information Gap on Biosimilar Medicines among Stakeholders in Ireland
  – HPRA Guide to Biosimilars for Healthcare Professionals and Patients
  – Recent Irish Guidance on Biosimilars
  – RSI Biosimilars Research Project
Regulatory Science Ireland (RSI)
The Rationale for RSI

The ever increasing complexity of health care products requires a data driven, evidence based approach to their regulation.

This realisation has driven the development of the discipline of Regulatory Science.

Regulatory Science Ireland (RSI) is a national response to these developments.

Regulatory Science

“Develop new tools, standards & approaches to assess the safety, efficacy, quality & performance of regulated products” ¹

“Defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision making throughout the lifecycle of a medicine.” ²

¹ Advancing Regulatory Science at FDA: A strategic plan (August 2011)
² European Medicines Agency’s contribution to science, medicines and health Road map to 2015

Regulatory Science Ireland

• RSI is committed to the development of an integrated Irish response to the Global Regulatory Science effort.
HPRA Guide to Biosimilars

HPRA Guide to Biosimilars for Healthcare Professionals and Patients

➤ Gives overview of the following areas:

- Regulation
- Product information
- Prescribing
- Dispensing
- Traceability
Who to target?

➤ Guide is targeted primarily at healthcare professionals but is also relevant to
  • Patients
  • Manufacturers
  • Distributors
  • Hospital procurement staff

Reasons for producing the HPRA Guide

• Uncertainty among healthcare professionals
• Approval process not clearly understood
• Uncertainty around substitution/interchangeability for prescribers and pharmacists
• Misconceptions around indication extrapolation
• Perceived lack of awareness among healthcare professionals (and patients) of the differences between a biosimilar and a generic
• Possible dependence among healthcare professionals on anecdotal information about biosimilars
HPRA Guide: Public Consultation Process

- Hospital pharmacists
- Clinical specialists
- Academia
- Pharmaceutical Society of Ireland (PSI)
- Irish Pharmacy Union (IPU)
- HSE’s Corporate Pharmaceutical Unit
- A range of marketing authorisation holder companies
- Irish Pharmaceutical Healthcare Association (IPHA)
- European Generic and Biosimilar Medicines Association
- Department of Health
- Irish Platform for Patients Organisations, Science and Industry (IPPOSI)
- Members of the public

HPRA Guide: Topics covered

- Generics v's Biosimilars
- Biosimilar approval process and comparability exercise
- Indication extrapolation
- Why biosimilar medicines are used
- Pharmacovigilance and adverse drug reaction reporting
- Prescribing and interchangeability
Recent Irish Guidance on Biosimilars

NMIC – Targeted information for Prescribers and Pharmacists

INTRODUCTION

Biological medicines (biologics) have been used in clinical practice for many years in the management of conditions such as diabetes mellitus, blood clotting disorders and in the field of immunisation. Advances in technological expertise over the last 30 years have enabled the development of more complex biological medicines, and they now play a vital role in the management of many other conditions, including cancer and autoimmune diseases. Since 2000, biosimilar medicines – biologics that are highly similar to approved (reference) biologics – have started to be introduced into the market, due to patent expiry of the reference biologics. It is anticipated that increasing numbers of biosimilars will be available over the next few years, including recombinant proteins and monoclonal antibodies. For the management of certain cancers, autoimmune diseases and diabetes mellitus. The availability of less-costly alternatives to reference biologicals may provide an opportunity to increase access to biological medicine and improve patient outcomes. However, biosimilars are not the same as generic (chemical-based) medicines; therefore they may not be regarded as interchangeable with the reference biological medicine. Biological and biosimilar medicines should be prescribed by brand name to enable ongoing safety monitoring of individual medicines.
HSE – Medicines Management Programme

Biosimilar Medicines in the Irish Healthcare setting

**Introduction**

Biological medicines (or "biologics") are treatments where the active ingredients are proteins such as hormones (erythropoietin, insulin and growth hormones), enzymes that are naturally produced in the human body, or monoclonal antibodies. They may also be blood products, immunological medicinal products and advanced technology products such as gene and cell therapies. As biological agents are complex molecules the production process is significantly more complicated than that for chemically synthesised medications.

A biosimilar medicine (or "biosimilar") is a biological medicine that is developed to be highly similar to an existing biological medicine in physicochemical and biological terms. Due to the complex manufacturing process biosimilars are not identical versions of the reference product so they are not considered to be generics. Therefore the issue of interchangeability and equivalence has become an area of intense review both in Europe and worldwide. The Health Products Regulatory Authority (HPRA) and the National Medicines Information Centre (NMIC) have recently produced comprehensive guides to biosimilar medicines, outlining the background, authorisation requirements and the role for biosimilar medicines in clinical practice, including guidance for practitioners. 1, 2, 3

RSI Biosimilars Research Project

Industry   Academia   Regulator
Biosimilars Research Project: who is involved?

- **Research activities**: Health Products Regulatory Authority (HPRA) and University College Cork (UCC)
- **Supported by**: Irish Pharmaceutical Healthcare Association (IPHA), HPRA and UCC
- **Project Advisory Panel includes**: MSD, AbbVie, Novartis, NIBRT, PCI, IDA, patient representative

Biosimilar Research Project

**Project Objectives**
- Compare international approaches and emerging trends related to the safe and effective use of biosimilars
- Position paper on maintaining public health while assuring patient access to biosimilar medicines
- Peer reviewed scientific publications on Biosimilars – Practical considerations for Healthcare Professionals
Biosimilars Research Project

Project objective

- Raise awareness on Biosimilars among patients and healthcare professionals
  - Survey of healthcare professionals
  - Development of training materials and online resources
  - Outreach activities

Reducing the Information Gap on Biosimilar Medicines

- Prescribers
- General Practitioners
- Pharmacists
- Patients
Prescribers of Biological Medicines

- Consultants and Specialist Registrars
- Survey to assess understanding, attitudes and behaviours towards biological medicines and biosimilars
- Link to online questionnaire will be distributed to members of Irish medical societies
- Survey will facilitate further engagement with prescribers

Issues addressed in questionnaire

- Pharmacovigilance of biological medicines
- Learning resources
- Knowledge of biosimilars
- Behaviours around biosimilars
- Attitudes to pharmacist led substitution
- Concerns
- Naming implications
Engagement with General Practitioners

- General Practitioners not directly involved in prescribing of biological medicines (apart from vaccines)
- Tailored survey
- Responses will influence development of relevant information materials
- Educational session at ICGP summer school

Pharmacists

- Survey of Irish Pharmacists on Biologics/Biosimilars conducted on behalf of AbbVie (August/Sept 2015)
- Postal survey via Ipsos MRBI nationwide pharmacy panel
- Objective: to measure pharmacy perceptions and behaviours relating to Biologics and Biosimilars
- 125 completed responses
Almost one in four Pharmacists consider biosimilars to be the same as generic medicines

Would you consider Biosimilars to be the same as generic medicines?

The batch number is very rarely recorded in the pharmacy administration/patient record

When dispensing a Biologic medicine is the batch number recorded in the pharmacy administration/patient record?
Engagement with Pharmacists

- **Publications**
  - Biosimilar Medicines: Opportunities and Challenges in the clinical use and supply of Biosimilars
  - Biosimilar Medicines: Recent Developments
- **Further engagement**
  - Continuing professional development events
  - Hospital Pharmacist conferences
  - Webinars
- **Specific focus on awareness of traceability requirements**

Engagement with Patients

- **Patient Organisations**
- **IPPOSI – Biologics and Biosimilars**
  - Breakfast Seminar
- **Feedback**
  - Patient information on biosimilars not freely available
- **Focus on development of patient information**
- **RSI Biosimilars website**
Patient Information

- What is a biological medicine?
- What is the difference between a biological and a chemical medicine?
- What is a biosimilar medicine?
- Biosimilars v’s generics
- How are biosimilars evaluated in EU?
- What are the benefits of biosimilars
- Who decides whether I receive a reference or biosimilar medicine?
- How are biological medicines prescribed and recorded?
- Reporting side effects for biological medicines

Conclusion

Key output from RSI Biosimilar Project: Reduce the information gap on biosimilar medicines amongst stakeholders

- Identify and implement mechanisms to achieve increased understanding of healthcare professionals, patients and healthcare providers involved in use of biosimilar medicines
Any questions?
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