Biosimilar Medicines for Patients' Organizations

The International Alliance of Patients’ Organizations (IAPO) is an alliance of over 200 patient groups that represents the interests of patients worldwide. In November 2013, IAPO published its Information and Advocacy Toolkit on Biological and Biosimilar Medicines for Patients' Organizations [1]. The Toolkit was developed to provide up-to-date, evidence-based information on the science, technology, and regulatory information relevant to biological and biosimilar medicines.

IAPO believes patients should be aware of what biological and biosimilar medicines are and the implications of their increasing availability. The Toolkit was developed to allow patient advocates to make informed judgements on the value of biological and biosimilar medicines and actively engage in debate and discussion with other stakeholders involved in health care.

The Toolkit contains a briefing paper on biological and biosimilar medicines, a quick guide, a guide on what patients’ organizations can do, as well as a number of fact sheets. It is available free of charge to patients’ organizations around the world. It is unique in that it explores the perspectives of a variety of different stakeholders including patients’ organizations, regulators, medical associations, academics and biological and biosimilar medicine manufacturers.

IAPO’s Toolkit covers important issues for patients’ organizations and other stakeholders, identified through an online consultation and through in-depth interviews. Topics include the safety of biological medicines, how they are regulated and monitored, how they are prescribed and dispensed, as well as who can access them and what information and support is available to patients.

In December 2012, IAPO held an online consultation with its members to understand the level of awareness of biological and biosimilar medicines, their regulation and use, and the issues and concerns that patients’ organizations found most important. Raising patient awareness is essential, since the acceptance of generics substitution worldwide has been slow, with research showing that many patients get confused or feel apprehensive about having their drugs changed [2].

IAPO found varied awareness of biosimilar medicines among respondents. Most (54%) of the patients’ organizations that responded represented patients who were currently using biological medicines for treatment of their disease, and 20% of the respondents represented patients who were using biosimilar medicines. The majority of respondents had no (36%) or some (32%) awareness of how biosimilar medicines were regulated in their country or region.

Ensuring the safety of biosimilar medicines is an important issue for patients’ organizations. Safety includes a broad range of issues from how biosimilars are defined and named, to their ability to cause immune reactions, regulation and pharmacovigilance.

Pharmacovigilance is critical in ensuring the safety of all medicines. As all biological medicines can potentially cause an immune response after approval, surveillance and monitoring are absolutely essential to track any adverse effects caused by the medicine [3, 4].

IAPO’s online consultation revealed that 50% of respondents had some to high awareness of the pharmacovigilance system in their country while 33% had little awareness and 19% had no awareness at all. A number of patients’ organizations from both developed and developing countries highlighted the importance of a strong pharmacovigilance system, and how this was lacking in their countries.

Pharmacovigilance depends on being able to track and trace biological and biosimilar medicines. Being able to differentiate between medicines is essential [5]. Manufacturers of medicines can apply to the World Health Organization for an International Nonproprietary Name (INN). INNs facilitate the identification of pharmaceutical substances or active ingredients in medicines [6].

Each unique INN, sometimes called a generic name, is different to the brand name but shared between identical pharmaceutical substances. INNs are important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among healthcare professionals and scientists. However, the structural complexity of biological medicines means that a biosimilar cannot be identical to the original biological medicine or to other biosimilars.

If doctors or pharmacists use only the INN when prescribing a biological or biosimilar medicine, and if several biosimilars exist, it will not be known exactly which medicine the patient is being given. If an adverse effect occurs it will not be clear which medicine – either the original biological or any of several biosimilars – caused it [4]. Automatic substitution of approved biosimilars by the pharmacist without notifying the patient and physician/healthcare provider would circumvent pharmacovigilance, putting patient safety at risk [7], as could prescribing medicines using only the brand name.

Each biosimilar medicine should have a unique identifier (or brand name) in addition to its INN to make it clear which medicine a patient is taking [8, 9]. Patients should ensure that when they are prescribed a biological or biosimilar medicines they know the unique identifier (or brand name), manufacturer’s name and where to find the batch number of their medicine.

Biological medicines have revolutionized the treatment of many diseases and have benefited millions of patients worldwide. IAPO believes that ensuring access to high quality, safe and efficacious biological and biosimilar medicines depends on education of patients, doctors and health authorities. Stringent regulatory guidelines based on those of the European Medicines Agency, World Health Organization or US Food and Drug Administration, and robust pharmacovigilance and adverse event monitoring systems are key to ensuring patient safety.

To see the Toolkit and for more information on IAPO’s work on biological and biosimilar medicines please visit www.patients-organizations.org/biosimilars

Competing interests: None.
Due to a combined effect of the so-called ‘patent cliff’ (when a drug’s exclusivity period ends as a result of patent expiration, allowing generics to enter the market) and the current economic climate, pharmaceutical companies face a significant challenge to continue investing in research and development. This necessitates the need for appropriate patent protection and enforcement to ensure that the innovation incentives are maintained.

In a knowledge-based society, pharmaceutical companies and policymakers alike must ensure that intellectual property (IP) rights are of critical value. Effective competition between originator and generic pharmaceutical companies can play a major role in reducing the budgetary burden. The world market for medicinal products is expected to reach US$1 trillion in 2014. Global spending on medicines is expected to grow to nearly US$1.2 trillion by 2017 [1].

As governments around the world try to rein in healthcare expenses, generics and biosimilars have emerged as a key strategy to mitigate these costs. The European Union (EU) has introduced several measures, such as a centralized procedure for the authorization of medicinal products, to ensure the availability of high quality biosimilars on the basis of the EU’s regulatory framework, i.e. through access to unbiased information and education of patients, healthcare professionals, and payers. This is crucial for the responsible allocation of public funds while opening up promising treatment options for patients by increasing their affordability. However, to realize the full potential of biosimilars, several conditions are required for market uptake:

1. Physician perception
   - Experience to date suggests that the most important conditions required for market uptake of biosimilars are factors such as:
     a. High quality biosimilars
     b. Assurance of safety and efficacy
     c. Robust regulatory framework, i.e. through access to unbiased information
     d. Education of patients, healthcare professionals, and payers
     e. Access to unbiased information

2. Patient acceptance
   - Patients must trust the use of biosimilars and perceive them as a legitimate alternative to brand-name drugs. This involves robust communication strategies, education, and patient engagement.

3. Procurement policies and terms
   - Procurement policies must be conducive to the uptake of biosimilars, including:
     a. Price controls
     b. Tendering processes
     c. Contracting

4. Local pricing and reimbursement regulations
   - National and regional pricing and reimbursement policies must be aligned with the European regulatory framework to ensure consistent access to biosimilars across the EU.

5. International cooperation
   - Regions and countries within the EU should coordinate their biosimilar policies to facilitate cross-border access and improve patient care.

6. Public awareness-raising campaigns
   - Public awareness campaigns are critical for increasing patient and healthcare provider awareness and trust in biosimilars.

7. Legislative efforts to limit prescription information sharing
   - Legislative changes to protect patient data are necessary to maintain patient trust and privacy.

Despite these measures, pharmaceutical expenditure in the EU is still high, accounting for a considerable percentage of total healthcare funding. Co-operation and Development (OECD) countries have even experienced a consolidation or decrease in pharmaceutical expenditure since the economic crisis, in recent years most OECD (Organisation for Economic Co-operation and Development) countries have even experienced a consolidation or decrease in pharmaceutical expenditure.

Other changes have also been introduced to reduce spending on medicines, including the use of international non-proprietary names (INNs) for prescribing, making international price comparisons, and utilizing methodologies allowing lower reference prices, broader clusters of similar medicines, and/or the pricing of generics in a cluster methodology allowing lower reference prices, broader clusters of similar medicines, and/or the pricing of generics in a cluster.

Reducing the European healthcare budget with generics and biosimilars is a complex task that requires a multifaceted approach. Efforts must be made to ensure patient trust, effective competition, robust regulatory frameworks, and public awareness campaigns to realize the full potential of these therapies.

References

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