Biotechnology Industry Organization

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To Whom It May Concern:

On behalf of the Biotechnology Industry Organization (BIO), I would like to bring to your attention our concerns about recent developments in Australia related to pharmacy-level substitution of biosimilar medicines. BIO represents more than 1,100 companies, research institutions and related organizations utilizing biotechnology to research and develop innovative products and technologies in the area of healthcare, agriculture, and the environment. Our members have expertise in the development and manufacture of biologic medicines- both innovative biologics and biosimilars- and understand the associated concerns with regard to switching patients from one product to another.

As you are well aware, biosimilars are biologic products manufactured using different cell lines and manufacturing processes than those for the innovator biological product to which the biosimilar is intended to be highly similar. Due to the innate complexity of biologics in general, the production of biosimilar products will invariably lead to some differences between the composition of a biosimilar and the original innovator product, and these differences could potentially lead to clinical differences in a patient's experience or reaction. In other words, unlike generic copies of traditional small molecule drugs, biosimilar biologic products will be therapies that are similar to, but not the same as, an innovator therapy. Patient experience with biologic medicines can be as individual as the patients themselves. Therefore, the handling of biologic treatment – including which product a patient receives – must ultimately sit with the prescribing physician who is most familiar with the patient and her circumstances best.

We appreciate and support the government's interest in advancing competition and containing health care costs. However, patient and physician confidence is contingent upon public policy following sound science.

The issue of pharmacy-level substitution, and the risks associated with it, has been debated extensively in – and consistently rejected by – countries with robust regulatory framework and an ability to evaluate the scientific properties of these important medicines. Many countries to date have uniformly clearly determined generics-styled substitution of similar biological medicines as inappropriate. In short, the policies being considered by Australia run contrary to sound scientific policy and medical practice and are thus inconsistent with the global best practice of other advanced economies. To provide but a few examples:

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• In the UK, both NICE (England) and the Scottish Medicines Council (Scotland) have advised that biosimilar medicines should not be substituted, and that the decision to switch a must be left to the treating physician and the patient.

• Germany has outlawed pharmacy-level substitution of similar biological medicines, as have Ireland, Spain, Sweden, Norway, and Finland, among others. Many others, including Italy, Belgium, Switzerland, and Denmark have issued formal guidance that pharmacy-level substitution in not appropriate for similar biological medicines.

• In May this year, the Netherlands' Medicines Agency (MEB) issued updated guidelines advising that "the uncontrolled exchange [a feature of pharmacy-level substitution] between biological medicinal products (regardless of whether they are innovator products or biosimilar medicinal products) must be avoided." Furthermore, in line with NICE and others, the MEB advised that "it is essential for the treating physician and the (hospital) pharmacist to be involved in the decision to switch from one biosimilar medicinal product to another, so that an informed decision can be taken."

• France has undertaken extensive debate on the appropriateness of substituting similar biological medicines. In late 2013, it passed a law that enables a highly restricted and controlled form of pharmacy-level substitution, wherein substitution is permitted only at the point of treatment initiation and with the consent and guidance of the physician. Once a patient begins a biotherapy regimen, the pharmacist is obliged to dispense only the medicine upon which the patient has commenced. The 2013 Law includes the principle of 'treatment continuity" for biological medicines and prefigures extensive safeguards to protect patients against inappropriate and inadvertent substitution.

• In the United States, In the U.S., the law explicitly requires that the risks to patients of repeated switching, which may occur through pharmacy-level substitution, be evaluated specifically by the Food and Drug Administration. The law requires that applicants for approval of a biosimilar medicine submit evidence to demonstrate that such switching will not place any patient at greater risk than if switching did not occur. This is a higher standard of evidence than that required for establishing simple biosimilarity; demonstrating biosimilarity is not sufficient in itself to warrant interchangeability, which would permit pharmacy-level substitution in the US.

We want to be abundantly clear that we are not questioning the overall safety or efficacy of biosimilars. However, the effects of repeatedly alternating among two or more similar biological medicines have not - to the best of our knowledge - been fully evaluated by the Australian regulator. This is an important consideration from product safety and efficacy due to the molecular size, complexity and subsequent propensity of biologics to generate unwanted immune reactions.

It is worth noting that the Council of Australian Therapeutic Advisory Groups (CATAG) recently addressed this issue and these concerns. In particular, we would like to highlight the following Guiding Principles developed by this CATAG concerning the use of biological/biosimilar medicines:

• A biologic is not interchangeable with its biosimilars at dispensing and should only be substituted with the prescriber's knowledge and consent

• Patients should be fully informed when receiving treatment with a biologic/biosimilar

• Switching between a biologic and its biosimilars should be in accordance with a drug and therapeutics committee–approved treatment protocol that includes a monitoring plan

• The selection of a biologic/biosimilar as second-line therapy should be in accordance with a treatment pathway approved by the drug and therapeutics committee

• There should be a patient-centered pharmacovigilance framework within each hospital or health service to monitor and report outcomes and any adverse effects associated with biologic/biosimilar therapy

Ensuring the appropriate uptake and use of biosimilar medicines is an important and pressing subject. Biosimilars have the potential to generate important efficiencies for healthcare systems facing fiscal pressures, but ensuring that this occurs without putting patients at risk is paramount. Many countries in Europe have seen significant savings to pharmaceutical budgets due to biosimilar competition, even without pharmacy-level substitution of these medicines.

We would be happy to discuss our concerns further with you or to answer any questions you may have. Please do not hesitate to contact me.

With Sincerest Regards,

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