INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

The crucial role of generic & biosimilar medicines in increasing access to high-quality medicines

Contribution of the generic and biosimilar medicines industries to the 2030 United Nations Agenda for Sustainable Development

Generic and biosimilar medicines have improved the quality of life of patients all over the world by increasing access to high-quality medicines. It is useful to report data that shows the actual impact of generic and biosimilar medicines in everyday life.

- In **Australia**, the genericised medicine market accounts for just over 84% of the volume of subsidised medicines but only 28.7% of the cost and, over the past 3 years, whilst the reimbursed script rate by volume has grown by 7%, the cost has fallen by 12%. This demonstrates the significant savings that generics have provided to the Pharmaceutical Benefits Scheme (PBS). Furthermore, in 2018, 7 out of the top 10 subsidised medicines by value were biologic medicines. This highlights the emerging importance of biosimilar introduction and uptake in Australia to ensure sustainability of the Australian PBS and broader healthcare sector. 10 biosimilars have been approved so far by the Therapeutic Goods Administration (TGA) in Australia (status March 2019)
- In **Canada** in 2018, generic drugs were dispensed to fill 71.8% of retail prescriptions in Canada, or 502 million prescriptions. Growth of generic prescriptions was 5.6% compared to the previous year. Sales of generic pharmaceuticals accounted for only 20.0% of the total cost of Canada's total annual prescription drug expenditure of 28.8-billion dollars.
  14 biosimilars have been approved so far by Health Canada (status March 2018).
- In **Europe,** almost 50 million people are taking generic medicines every day for hypertension and in 2017 there have been already over 700 million patient days of clinical experience with biosimilar medicines. Generic medicines have doubled access to therapy for hypertension, diabetes, cardiovascular, epilepsy and mental health over the last 10 years in Europe. Currently generic medicines account for 67% of dispensed medicines, with a value of 29%.
  Biosimilar medicines have increased access by between 10-250% in different EU countries and therapy areas. The potential to increase access to biological therapies is massive over the next few years especially for immune disorders and cancer.
  51 biosimilars have been approved so far by the European Commission for the European Economic Area (EEA) markets (status March 2019). 90% of the biosimilars market is currently in Europe.
- In **India**, 95% of all prescribed medicines are branded generics, which contribute substantially to patient access and expenditure savings. For example, cancer generic medicines of paclitaxel, docetaxel, gemcitabine, oxaliplatin and irinotecan have generated an estimated savings of about ₹ 47 billion (US$ 843 million) in 2012 (source: WHO Information session for Member States and Non-State Actors in official relations: Technical report on pricing of cancer medicines and its impacts. 25.4.2019).

- In **Japan,** the share volume of generic medicines is increasing every year and the rate of generic sharing as of September 2018 is around 73% of the substitutable market. This was an increase of the share by 6.8 % compared to the previous year. Saving of drug expenditures in the fiscal year of 2017 is estimated to amount to 1.3 trillion JPY (= US $11.8 billions).
  17 biosimilars have been approved in Japan so far by the Pharmaceutical and Medical Devices Agency (PMDA) Japan (status March 2019).
- The total market of **South Africa** is about 3.4 billion Euros. Across both State and Private sectors, generic medicines have a volume market share of 87%. By value, this market share is 51%, or 1.5 billion Euro, which indicates the high pricing of the originator products.
  One biosimilar (filgrastim) has been approved so far by the South African Health Products Regulatory Agency (SAHPRA) (status March 2019).
- In **Taiwan**, generic medicines account for about 80% of dispensed medicines but only 28% of the total annual drug expenditure in 2017.
- In the **U.S.A,** generic drugs have saved $1.79 trillion in the last decade, generating $265 billion in savings in 2017 alone. Medicare savings amounted to $82.7 billion ($1,952 per enrolee) and Medicaid savings of $40.6 billion ($568 per enrolee). Generics account for 90% of prescriptions dispensed but only 23% of total drug costs in the U.S.
  20 biosimilars have been approved so far by the U.S. Food and Drug Administration (FDA), 7 of which are marketed (status June 2019).

The abovementioned data are not empty numbers but represent the benefit that generic and biosimilar medicines are bringing with access to necessary treatments for patients and with support to the long- term sustainability of the healthcare systems. It is an important contribution of the generic and biosimilar medicines industries to the 2030 UN Member States Agenda for Sustainable Development.

One of our future challenges is to address the medium and long-term sustainability of the generic and biosimilar medicines industries. We are aware that there are growing concerns about the availability of essential generic medicines and the risk of shortages. We believe that the sustainable supply of high-quality medicines will be an important issue over the next few years.

June 2019