FACT SHEET: BIOSIMILAR SUBSTITUTION
British Columbia Policy vs European Policy

BIOSIMILAR USAGE

MISPERCEPTION: Canada has a lower biosimilar use rate (8%) vs EU nations and Norway which have 50-80% biosimilar uptake.

FACT: Market share in Europe for biosimilars approved after 2013 ranges between 0% and 43%. (All but one biosimilar approved in Canada fall into this category). Biosimilar uptake across Europe varies widely by country and product group. Rates range from 0% to 91% with older products - those approved before 2013 and between 0% and 43% for those approved from 2013 onwards.[1] The use of originator biologics and biosimilars combined following biosimilar launch has increased with all products in the majority of countries, suggesting more patients are being treated overall.

MANDATORY 6 MONTHS TRANSITION PERIOD OF WELL-TREATED PATIENTS

MISPERCEPTION: European countries that have very high biosimilar use rates have policies in place similar to the B.C. government's announced policy which (1) requires patients to transition from their current original biologic to a biosimilar by 25 November 2019 and (2) no longer reimburses the original biologic after the transition date of 25 November 2019.

FACTS: Although biosimilars in Europe are approved centrally by the European Medicines Agency (EMA), **biosimilar policies regarding payment and use vary by country.** Even after 13 years of experience with biosimilars in the market place in Europe:

- **No country in Europe has ceased the reimbursement of originator biologics** by a government policy decree such as that issued in BC and only Denmark following a transparent national tender process reimburses ONLY the winning product. Norway also has a National tender process but does allow physicians to prescribe innovator products should they choose to do so.
- **The vast majority of countries leave the decision on what biologic medicine to use with the treating physician in consultation with their patient.**
- In most European countries **switching from an originator to a biosimilar remains a clinical decision made by the treating physician**; furthermore, physicians are in charge of treatment protocols regarding switching between protocols.
- In those few European countries where either national or hospital-driven single-winner tenders exist and where, as a result, the choice of products is limited, **the process is transparent and non-discriminatory against either originator or biosimilar manufacturers** but based on competition and the price offered. The same is true in multi-winner tender environments that allow for multiple winners, preserve physician treatment choice and protect against any supply shortages.

EUROPEAN TAKEAWAY

MISPERCEPTION: Biosimilar uptake across Europe has been driven by policies that force patients who are stable on an originator product to switch to a biosimilar by terminating reimbursement for originator biologics.

FACT: Education, competition and choice have been at the heart of the evolution of the biosimilar market in Europe. Long-term sustainability of the biosimilar market is an essential precondition to all stakeholders benefiting, i.e., patient access, physician prescription choice, healthcare budget savings, competition and supply.

FACT: Forced switching from an originator to a biosimilar is not a policy in Europe. During the 13 years of experience with biosimilar medicines in European markets, no country has directed well-treated patients to either transition to a biosimilar or to change to a different biologic as a condition for the reimbursement of additional innovative drugs and to expand coverage of existing drugs.

1 IQVIA: The Impact of Biosimilar Competition, September 2018; pp. 14, 16, 18, 21, 23, 26, 28; columns 1 and 7

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