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Clear naming, traceability of biological medicines will protect patients

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As more biological medicines and biosimilars become increasingly available worldwide, clear product identification is critical for accurate pharmacovigilance.

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When a patient experiences an adverse event from a medication or the medicine stops working, it is important for both the patient and their physician to know which medicine produced these effects. Yet, with a fairly new and effective class of medicines called biologicals, it is becoming more difficult for physicians worldwide to accurately track patient's response and monitor potential problems. Luckily, the World Health Organization (WHO) – which assigns the scientific or 'non-proprietary' names for medicines – has developed a solution that will help physicians and regulators keep patients safe in whatever country they seek treatment.

Biological medicines – effective therapies grown in living cells – are used to treat patients suffering from serious conditions like rheumatoid arthritis, Crohn's disease and cancer. Biosimilars are highly similar (but not exact) copies of these medicines and are becoming increasingly available worldwide. Biosimilars offer patients more treatment options at a lower healthcare cost. The complexity of biologicals and how they are produced in living cells mean that no two biologicals – whether originator or biosimilar – will ever be identical. This complexity can make these medications vulnerable to unintended properties that could result in adverse events or reduced efficacy. Clear product identification is particularly important with biologicals due to the risk of unwanted immune reactions in patients, and the sensitive and complex nature of these medicines.

For these reasons, WHO has proposed a modification to their naming system to ensure precise identification of biologicals. Biological naming is currently governed by a patchwork of policies that vary widely by country.

For example in Europe, five different biological medications manufactured by seven different companies, all sharing the non-proprietary name 'filgrastim' are currently being sold. While each is marketed by its trade name in Europe, many physicians around the world, including in Europe, prescribe using the non-proprietary name alone. This ambiguity leaves it unclear to the dispenser which biological medicine was intended, and unclear to the prescriber which was actually received by the patient. This makes it difficult to accurately assess which drug the patient is responding to or having a side effect from.

In addition, adverse events could be pooled or potentially misattributed to the wrong medication, making tracking the problem difficult. This leaves untraceable patients at risk for the adverse event. In Thailand, more than 15 biological medicines shared the same non-proprietary name. When a significant increase in adverse events occurred, the regulator could not easily determine which product (or products) was responsible.

Distinct naming, however, ensures accurate tracking to the exact medicine responsible, if any problems should arise. This also promotes greater manufacturer accountability for their products.

WHO, which assigns International Nonproprietary Names (INNs) to medicines, has proposed a solution that will make a uniform option available for national regulators to adopt. Their plan consists of a four-letter code called the Biological Qualifier (BQ), which will be attached to the INN name and will indicate where and by whom the biological was manufactured. When fully implemented, the BQ will extend the protections of distinct naming to patients worldwide, regardless of which country they seek treatment. This is especially helpful in the many countries without a robust pharmacovigilance system in place. For those countries which do, the BQ serves as an additional safeguard.

We commend WHO for their leadership in proposing a global solution to this problem, and await its availability for implementation. National regulatory authorities should follow suit and volunteer to be among the first to implement the WHO's BQ proposal, bringing the many benefits of distinguishable biological naming to their patients.

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