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WHO signs MoU with IGBA to promote access of medicines

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The new agreement is an important step in WHO's drive towards universal health coverage

Full access to medicines is hampered by a variety of factors. Two important barriers are high prices and regulatory issues such as long lag times in bringing medicines to market.

To address these issues, Dr Tedros Adhanom Ghebreyesus, WHO Director-General, and Jim Keon, Chair of the International Generic and Biosimilar Medicines Association (IGBA) has signed a memorandum of understanding (MoU).

The new agreement is an important step in WHO's drive towards universal health coverage by underscoring the importance of generic and biosimilar medicines to increasing access to affordable, quality treatment.

WHO is an active supporter of expanding use of generic medicines: The vast majority of the products in the WHO Essential Medicines List are generic.

WHO's prequalification programme – which assesses the quality of priority medicines supplied by UN agencies and other organizations in low-income countries – has prioritized generic medicines as a way to treat more people with the funds available; around 70% of the medicines it prequalifies are generic.

A recent independent study by McKinsey estimated WHO prequalification saves the world up to US$ 590 million every year. Every $ 1 invested in WHO Prequalification has a return in terms of savings of between $ 30-40.

WHO has also supported use of and access to generics through normative guidelines. Implementation of WHO guidance on interchangeability of generic medicines is further supported by the WHO List of International Comparators, which provides information on reference products for clinical trials into bioequivalence – i.e. whether two different products achieve the same results. Another tool is the WHO Biowaiver List which describes generic medicines that are eligible for a waiver from such studies.

Regional and national regulatory normative guidance aligned with WHO guidance has now paved the way for the approval of many biosimilars with regulators. Last year, the Organization launched a pilot prequalification project for biosimilars for two anti-cancer drugs: rituximab and trastuzumab. In parallel, WHO is working to increase reliance between regulatory authorities to facilitate registration of generics and biosimilars, thereby getting the products to patients quicker.

The new agreement between WHO and IGBA highlights the role of the pharmaceutical Industry in helping WHO maintain tools that can facilitate registration of generic and biosimilar medicines. It will facilitate cooperation between the two organizations to reduce the burden of clinical trials for biosimilars, speeding up registration and increasing access.

It is an important first step towards increased collaboration with the generic and biosimilar industry for long-lasting impact on access to health products and progress towards universal health coverage.