

New trend for generic products (1)

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In EU and USA, the generic products have been commonly utilized after declaration of the FIP Vancouver Statement in 1997. However, in our country the spread of generics still hover around at a lower level. In this statement, generic substitution is defined as the act of dispensing a generic alternative, medicinal product intended for administration by the same route and the same dosage form, containing the same amount of the same active ingredients, the same satisfactory standards of quality, safety and efficacy and are bioequivalent. Where generic substitution is allowed by legislation or the prescriber indicates that a generic alternative is acceptable, the responsibility for selection of the generic medicinal product will be that of the pharmacist. The promotion of generic substitution must be essential in the ordinary work of medical staffs to improve the economic burden in patient and payer without significant compromise of patient outcome.

What is the barrier against distribution of generics in our country? The most important factor is the reliance of the patients and medical staffs on the generics. Second important factor is the quality of all generic products. More than 30 products for one active ingredient have been usually commercialized after expiration of patent of the branded product. The quality of all generics must be guaranteed with a therapeutic equivalency and safety. We have established the Generic Drug Association, Japan (GEDA) in May 2007 for the popularization of generics in our country. In this presentation, the new trends surrounding generics in our country and the new organization GEDA were introduced.