

GE, Guarantee of Equivalency and Quality in Generic Products

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Generic medicines are launched after patent expiration, with cumulative information on efficacy, safety, dosage and regimen that has been built by patients, doctors, pharmacists, government and pharmaceutical companies.

Generic medicines in Japan are approved by the Authorities through deep scientific evaluation as in the USA or EU, of chemical specification of bulk chemicals and pharmaceutical products, stability, and bio-equivalency with the reference products.

Compliance and reliability of these data is well supported in the process of approval reviews by the Authorities, for example, compliance reviews and conformity to GMP for each product.

The governments of USA and countries in EU have been promoting the use of generic medicines by many effective campaigns and public advertisements.

Generic pharmaceutical companies have been supplying products with good quality and Japan Generic Pharmaceutical Manufacturers Association constituted Compliance Advancement Project in August 2007, addressing stable supply, good qualified products, and solid/full medical/pharmaceutical information.

It is the task of scientists in R&D, either working for generic medicines or innovative medicines to develop and supply pharmaceutical products that are welcomed by patients, physicians and pharmacists.