

Generic interchangeability

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Generic Interchangeability: between science and regulation

Pieter Jelte Glerum
Maastricht, 29 maart 2023

1. Any difference in drug exposure following a generic drug switch is more likely the result of intrasubject variability than the result of the formulation switch. (this thesis)
2. There is no reason to believe bioequivalence is different for patients compared to healthy subjects. (this thesis)
3. Shortages and the Dutch Preference Policy are the two main causes of drug switches. (this thesis)
4. Reported adverse drug reactions related to drug switches should be studied with the number of drug switches involved. (this thesis)
5. Most drug switches occur without any problems.
6. The psychological impact of having to rely on a drug should not be underestimated.
7. Drug switches are almost predestined to be perceived as high risk, as a switch gives a patient a feeling of non-control, is often involuntary, is not well understood, is to a drug product with which a patient is not familiar, and is executed by the pharmacist who is in general less trusted than the prescribing doctor.
8. Patients should be allowed to choose a different product than the reimbursed product, and only be charged the price difference.
9. Pill shape, size, and color should be identical for all products of the same drug and doctors should not use brand names.
10. A part-time PhD program is not for everyone.
11. Scientists are inherently inflationary. – Sir James Black