

What are the issues?

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Extended abstract:

Generic immunosuppressive drugs are available worldwide. Between countries there are large differences in the market penetration of generic drugs in general, and for immunosuppressive drugs in particular. The registration criteria for generic immunosuppressive drugs are often criticized. Bio-equivalence testing is done in healthy volunteers only, and according to some clinicians the criteria for registration of narrow therapeutic index drugs should change.

Health insurance companies typically promote the use of generic drugs. In some cases they even argue that the generic versions are identical to the innovator drug. Their main focus is on the price of the drug, and in a tender system contracts with producers are renewed every year. As a result patients are repetitively being faced with new generic versions, that often do not have the same pill appearance (shape and color), potentially leading to errors. Furthermore, repetitive generic substitutions have been shown to affect drug adherence.

Attending this debate session will provide you with insights into:

- The strengths and weaknesses of the registration process of generic drugs
- The position of various stakeholders in generic substitution
- The difference between controlled and uncontrolled substitution
- Impact of pharmacogenetics on bio-equivalence
- How to safely introduce generic immunosuppressive drugs in your practice