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ACCEPTED MANUSCRIPT

Finding hidden treasures in old drugs: the challenges and importance

of licensing generics

Melek Simsek^{1,*}, Berrie Meijer¹, Adriaan A. van Bodegraven^{1,2}, Nanne K.H. de Boer¹ and Chris J.J.
Mulder¹

¹Department of Gastroenterology and Hepatology, VU University Medical Center, Amsterdam, The Netherlands

²Department of Gastroenterology, Geriatrics, Internal and Intensive Care Medicine (Co-MIK),

Zuyderland Medical Center, Heerlen-Sittard-Geleen, The Netherlands

*Corresponding author: Simsek, M. (m.simsek@vumc.nl).

Highlights:

- The successful repositioning of a generic drug for a new indication
- Obstacles in and suggestions for a European generic drug regulation
- Differences between American and European generic drug regulation
- Own primary data on drug prescriptions before and after license approval

Teaser: Drug rediscovery comprises an emerging but challenging field in the area of drug development.

A regulatory procedure for the repositioning of generic drugs is warranted, as illustrated by the case of thioguanine in The Netherlands.

Identifying new indications for existing drugs creates new therapeutic options while bypassing much of the costs and time involved with bringing a new drug to market. The rediscovery of a generic drug, however, is a challenging pursuit because there is no formal regulatory approach and a lack of

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