Generic interchangeability

Chapter 6

Societal and scientific impact

This chapter discusses the societal and scientific value of the research presented in this thesis. Generic interchangeability is a highly relevant topic for patients, prescribers, regulators, and scientists.

Patients should be able to trust the quality, safety, and efficacy of the drugs they use—in the case of this research, generics in particular. In the Netherlands, there are almost 11 million prescription drug users, and about 2/3 of all dispensed drugs are generic (1, 2). Thus, a large portion of patients use generic drugs and, as demonstrated in chapter 2.1, often switch between generic versions of the same drug.

When we combined data from the National Health Care Institute in the Netherlands with data from the Netherlands Pharmacovigilance Centre Lareb, as discussed in chapter 2.2, we estimated that 5.7 ADRs are reported per 100,000 drug switches on average. This reporting rate may be low, but the impact of these ADRs on individual patients is high, especially in the absence of any obvious personal benefit to the patient.

Therefore, patient organizations are fierce advocates of system reform, in which patients are switched between drugs less often and unavoidable switches are better guided by the physician and pharmacist. In April 2018, 14 patient organizations published a report on the unwanted effects of drug switches for patients (3, 4). This report was described by several Dutch newspapers with the following headline: “1 in 3 patients sicker after drug switch” (5).

In response, the Dutch Ministry of Health, Welfare, and Sport initiated a working group with representatives of patients, physicians, pharmacists, and health care insurers to come to a mutual agreement on how generic drug switching can be performed responsibly (6). The Ministry commissioned Vektis Intelligence to research the number of drug switches and Gupta Strategist to research the incentives for drug switching (7, 8). We collaborated with the researchers in both these investigations. Results from both these investigations aligned with the results we described in chapter 2.1 and chapter 2.3.

We also participated in the first discussions of the working group mentioned above. Additionally, we were involved in creating an overview of drugs for which drug intake mistakes caused by confusion of drug switches could result in serious clinical complications (9). These efforts led to publication of a guideline in which all stakeholders found common ground on how to reduce the number of drug switches and assure drug switching could be performed responsibly in Dutch pharmaceutical practice (10).

The societal and scientific value of the research presented in this thesis can also be found in the realm of science and drug regulation, that is, regulatory science. Regulatory science is defined by the European Medicines Agency as “a range of scientific disciplines that are applied to the quality, safety, and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied medicinal science and social sciences, and contributes to the development of regulatory standards and tools” (11). In chapter 3.1 and chapter 3.2, we described our efforts to challenge the robustness of bioequivalence, the most important regulatory requirement for generic drug approval. As shown in chapter 2.1, most (80%) of the drug switches occur between two generic drugs. Therefore, challenging the current regulation of demonstrating average bioequivalence only to the originator drug is of particular importance. As described in the corresponding chapters, our results (considering their limitations) support generic interchangeability and the regulatory requirements for generic drug approval.

Dissemination of our contribution to the scientific community was ensured by scientific publications, particularly by the opinion paper on the view of the regulator regarding generic interchangeability (chapter 1.2). A wider audience was also targeted by providing background information for a newspaper article (12) and a public information leaflet on generic medicines (13).

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