

Chapter 3

Towards Secure Off-Label Drug Prescribing and Improved Drug Supply

ABSTRACT

Worldwide, among healthcare professionals an uncertainty as to what medical uses exactly fall under the theme of off-label-use is noticeable. The lack of a common definition complicates the comparison of methods of resolutions in different countries. A current ambiguity is shown to cause false patient education and invalid informed consent, hence leading to liability concerns. Due to several legal restrictions in Western countries, healthcare professionals are facing more legal actions (lawsuits) than their colleagues in developing countries. The health systems in the developing countries, particularly in Sub-Saharan Africa, are facing, in addition, severe drug supply issues. This chapter analyzes the issues from the viewpoint of the information and communication technology and proposes solution approaches.

INTRODUCTION

One of the problems in healthcare in developing countries is the bad accessibility of medicine in pharmacies for patients.

The insufficient supply of pharmaceutical products for the population is a major care delivery issue in the healthcare systems in the developing countries (Edoh & Teege, 2011). For the individual patient, a high time and effort are required to purchase all medicine prescribed by a physician.

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A case study in a representative developing country, the Republic of Benin, had revealed that although the public pharmacies and dispensaries are relatively frequent, the supplied medicine or pharmaceutical products are very limited. The most supplied medicines are intended for common therapy such as malaria treatment. Patients are sometimes obliged to procure at the black market counterfeits (Edoh, 2010).

More than 90% of all private pharmacies are in few large cities of the country. The countries are facing low density of pharmacies and frequent drugs stock-out. In large cities as well as in rural regions, it is often difficult to purchase all medicines on a prescription in a single pharmacy, due to stock-out (Edoh & Teege, 2011).

The situations described above lead in several cases to the use of drugs off the label to overcome the lack of appropriate medicines.

Off-Label-use is worldwide a common practice that is not restricted (J., 2003). *In Canada and the United States, it is illegal to promote or advertise any medication for any indication other than that for which it was approved* (F. Christine Fukada, et al. in (Christine Fukada, MSc; Jillian Clare Kohler, PhD; Heather Boon, PhD; Zubin Austin, PhD; Murray Krahn, MD, MSc, n.d.)), while theoretically in high-income countries for example in Germany, no law prohibits a physician or other healthcare practitioner from prescribing an approved medication for other uses than their specific approved indications (off labeling use) (KVBW, 2012).

In developing countries, however, we do not find any stipulation that regulates the HCP liability.

Off-Label-Use is widely practiced in all areas of the medicine (estimated to 21% worldwide (Jansen, 2011)). In German, the Off-Label-Use is widely practiced and is generally, “*consider legal*” unless it violates some costs reimbursement regulations set by German healthcare insurances., specific ethical guidelines or safety regulations defined by the German Drugs Law (AMG).

Unfortunately, due to the legal uncertainty, the risk of financial ruin, insolvency and possible legal liability for the health practitioner in case of health damage, most of the health professionals do not accept having practiced it

The dissemination of off-label-use related information is authorized in the USA by American’s regulation and largely accepted, while the European and South-African regulations are more restrictive. This fact generates, in European countries (e.g. Germany) and in Africa (e.g. South-Africa) an uncertainty among HCP (Jansen, 2011). The healthcare professionals could

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