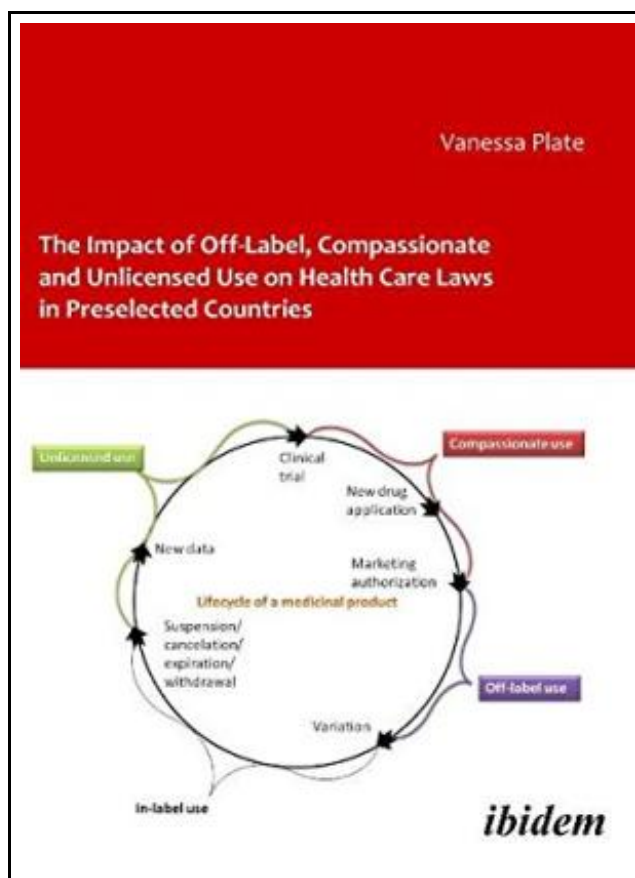


## The Impact of Off-Label, Compassionate and Unlicensed Use on Health Care Laws in Preselected Countries



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Ibidem-Verlag Jul 2010, 2010. Taschenbuch. Book Condition: Neu. 209x149x20 mm. Neuware - In times of situational therapeutic impasse, health care professionals (HCPs) are under pressure to conduct off-label, unlicensed and compassionate drug use generally summarized under the term non-licensed drug use (NDU). Liability, contractual and penal risks pose a problem when treating a patient in a non-licensed way. There is a knowledge gap about institutional and governmental methods to resolve these problems. Different countries have developed strategies to manage NDU. In her book, Vanessa Platé compares the effects of NDU on pharmaceutical legislation in selected industrial countries and determines strategies brought forth by NDU. Furthermore, the development of a general regulatory approach to the management of NDU is sought. Semi-structured qualitative interviews, comparison of laws, and literature research are part of this study, which includes Canada, the U.S., the U.K., Japan, France, Germany, Switzerland, Austria, and the transnational E.U. The comparison of the impact of NDU focuses on terminology for NDU, supply and necessity of NDU, pharmaceutical promotion of NDU, legal responsibility for NDU, and public policies related to NDU. The results of the study suggest there is indeed a circumstantial need for off-label, unlicensed and compassionate use, but also showed isolated evidence suggesting intermittent non-rational NDU. Furthermore, the legal comparison showed evidence of legal obligations for physicians to perform off-label, unlicensed and compassionate drug use. Vanessa Platé also found proof of inappropriate off-label marketing on the part of market authorization holders (MAH). On the other hand, a demand for information on NDU on behalf of HCPs was present. Obtained results illustrate cross-liability for HCPs and MAH. Finally, results demonstrated regulatory strategies of different efficiencies: In the E.U., for instance, incentives for new indications were (a) limited to one year or (b) restricted to (i) pediatrics or (ii) rare disorders....



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