



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

By Vanessa Plate

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...



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