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ABSTRACT

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TITLE :	THE WEBER-CURVE PITFALL. EFFECTS OF A FORCED INTRODUCTION ON REPORTING RATES AND REPORTED ADVERSE EVENT PROFILES.
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ABSTRACT :	<p>Introduction: In The Netherlands the forced switch from Losec (omeprazole) capsules[®] to Losec MUPS[®] (Multiple Unit Pellet System) in 1999, evoked an unexpected raise in spontaneous reports of adverse events (AE's). A substantial part of these MUPS-related reports concerned a lack of therapeutic efficacy. Because of an assumed similar benefit-risk ratio and the forced nature of the switch, these reports were studied in more detail.</p> <p>Methods: Firstly, three time windows were distinguished: 1. capsules only, 2. capsules and MUPS, 3. MUPS only. The reporting rates (number of reports per month) between capsules and MUPS were compared. After dividing the reported adverse events over the System and Organ Classes (SOCs), as defined in the WHO adverse drug reaction terminology, differences in reported adverse event profile were analysed. In order to make a reliable comparison between both groups, a second analysis after elimination of the preferred terms "therapeutic effect decreased" and "lack of efficacy" was conducted.</p> <p>Results: The reporting rate on MUPS rises sharply after the withdrawal of the capsules from the market and gradually decreases over time. This reflects the so-called Weber-effect, due to the forced introduction of MUPS [1]. The prevalence of six SOC's (e.g. body as a whole-general disorders and gastro-intestinal disorders) differed significantly between capsules and MUPS. The preferred terms nausea, dyspepsia and therapeutic response decreased were reported more frequently in MUPS, while alopecia was reported more frequently in capsules.</p> <p>Conclusion: Shortly after the introduction of MUPS and the consequent withdrawal of capsules, the Netherlands Pharmacovigilance centre was confronted with a sharp rise in reports on omeprazole. Initially, this rise was suspected to represent a shift in benefit-risk ratio of the MUPS, but longer follow up revealed a normalisation in reporting rate. However, the remaining differences in adverse event profiles between capsules and MUPS may reflect a reporting bias or a true difference between both formulations.</p>
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