

suggested as contributors to the interaction in two case series [1, 4]. When increased INR values are observed with broad spectrum antibiotics and warfarin and there is no obvious pharmacokinetic mechanism, reduced bacterial synthesis of vitamin K is the proposed likely cause. Is there likely to be a more pronounced effect in patients with VKORC1 variants? Would the effect on bacteria be in keeping with the rapid onset of high INR values?

**Conclusion:** The INR increases observed in the CARM reports suggests that even advice to measure the INR on day 3 of roxithromycin treatment [5] may not be early enough for some patients. Further avoidance of harm may be possible with greater understanding of the mechanism.

**Further sources of information/References:**

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## 66 How do Adverse Drug Reactions Influence the Patient's Daily Life? Qualitative Analysis on Spontaneous Reports by Patients

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**Background:** Patients bring a new dimension to pharmacovigilance by reporting frequently about the impact of adverse drug reactions (ADRs) on their daily life. However, little is known about what aspects of the patient's daily life are being influenced due to ADRs.

**Objective:** To analyse how ADRs, reported to a pharmacovigilance centre, influence the patient's daily life.

**Methods:** A qualitatively analysis on information about the impact of ADRs on the patient's daily life. Since March 2017, the Netherlands pharmacovigilance centre Lareb added a question about the impact of the ADR, asked for each reported ADR, to the patient reporting form. The answer option was a 5-point scale ranging from 'not at all' to 'very much', followed by an open text field in which patients could explain their given answer in their own words.

All patient reports from 6 to 29 March 2017 were selected from the Lareb database. Only those in which the patient reported for themselves, and the open text field was filled, were included for analysis. All open text fields were coded individually by two researchers (LR, MH), using content analysis. Differences were discussed until consensus was reached. Prior to

the analysis a coding scheme was drafted. This was adapted during this interactive coding process.

**Results:** In total 194 reports were selected, including 236 drug-ADR associations. Content analyses indicated that ADRs influenced the patient's daily life on several aspects. Table 1 summarizes the five items most mentioned.

The severity of the ADR was most often mentioned. This e.g. included that the ADR was distracting, annoying or painful. But there were also patients that considered the ADR to have little or no impact, e.g. when they were treated for it. Interestingly, for the impact on mood or concentration, over half of the reactions was about anxiety because of possible consequences of the ADR. For physical impairment, reactions were mainly general descriptions, e.g. fatigue or problems with walking. For limitations in social activities, it was often specifically mentioned that the ADR influenced their work or family-life.

**Conclusion:** Several aspects causing ADRs to influence the patient's daily life were indicated. Patients took the opportunity to explain in their own words how ADRs influenced their daily life. This is valuable to understand the actual impact of ADRs. Moreover, it enables healthcare professionals to provide dedicated information on the consequences of these ADRs from a patient's perspective.

**Table 1.** Five most mentioned items of how ADRs influence the patient's daily life

Item	Number (%)
Severity of the adverse drug reaction	153 (40%)
Impact on mood or concentration	56 (15%)
Overall (change in) health	50 (15%)
Physical impairment	39 (10%)
Limitations in social activities	34 (9%)

## 67 Suspected adverse reactions to cannabis galenic preparations for medical use in Italy

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**Introduction:** The interest of the scientific community and of patients for medical use of cannabis is currently very strong. Only one drug containing cannabis was registered for second line treatment in moderate to severe spasticity due to multiple sclerosis (MS). However, some evidence in the literature suggests cannabis use for neuropathic pain, pain in cancer patients, nausea and vomiting induced by chemotherapy and fibromyalgia [1,2,3].

**Aim:** To describe suspected adverse reactions (ARs) associated with cannabis galenic preparations for medical use.

**Methods:** Spontaneous reports of suspected ARs to natural health products (including galenic preparations containing herbals) are collected in Italy within the Italian Surveillance System of suspected adverse reactions to Natural Health Products coordinated by the National Institute of Health, in collaboration with the Italian Medicines Agency and the Ministry of Health.

**Results:** At December 2016 twenty-six suspected adverse reactions to cannabis for medical use were reported. Median age of patients was 56 years (range 22–80), women represented 69% of reports. Six reports were related to serious reactions. Cannabis was used mainly for neuropathic pain, in two cases cannabis was assumed as palliative care, in one case the