reason for use was lack of appetite and cancer pain and in two cases headache. In 15 cases concomitant use of drugs was reported.
Psychiatric reactions were reported (dysphoria, panic attack, visual hallucinations, stupor, drowsiness, major depression...); lack of efficacy; dermatological symptoms (itchiness, redness and swallowing of eyelids and face); laryngospasm. Causality assessment was performed for all reactions and the association between cannabis use and the reaction was always probable. Cannabis was assumed almost in all cases but one by decoction. In one case cannabis was extracted in oil.
Conclusion: Cannabis for medicinal use is usually well tolerated. The adverse effects collected are mainly due to dosage errors, mode of administration or individual differences in THC absorption and metabolism. However, it is important to monitor cannabis medical use in the population and to continually evaluate its safety.
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68 Tailoring signal detection methodologies in a global database to focus on safety concerns reported by patients

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Introduction: A recent systematic review summarized the current evidence on the value of patient reporting into pharmacovigilance systems. [1] There is literature to suggest that patient reports contribute to signal detection [2–3]. However, descriptions of methodologies for using patient reports in signal detection are scarce, and published experiences of how patient reports are used in national pharmacovigilance centers are limited to a few countries [4–6].
Aim: To explore the contribution of patient reports to signal detection in an international database of suspected adverse drug reactions (ADRs).
Methods: Data was retrieved from the WHO global database of individual case safety reports (ICSRs), VigiBase, in September 2016. Suspected duplicate reports and reports from studies were excluded. Drug-ADR combinations were generated and restricted to report series with at least 50% patient ICSRs. Further, only combinations with at least one report received after 2014, from ≥2 countries, and with ≤30 patient ICSRs were included. vigiRank, an algorithm using multiple-strength-of-evidence aspects, was used to prioritize combinations for assessment. In the assessment of each combination, the product information for health care providers as well as patient information leaflets were reviewed for information on ADRs.
Results: A total of 212 combinations were assessed; 20 (9%) combinations resulted in 8 signals communicated within the WHO program for international drug monitoring. Five signals described new, unlabeled suspected ADRs; 3 described new aspects of known ADRs. An example of the former is the signal of panic attacks with levothyroxine; an example of the latter is the signal of severe genital pruritus leading to non-compliance with SGLT-2 inhibitors. Reviews of patient information leaflets were performed; examples of poor consistency with product information for physicians were found, such as placement of ADR terms and descriptions of ADRs. Patient narratives were confirmed to provide details regarding the experience of the ADR and its impact on the quality of life of the reporter; furthermore, there is evidence in narratives that patients make causality and benefit/harm assessments themselves.
Conclusions: Safety concerns described in patient reports can be identified in a global database including previously unknown ADRs as well as new aspects of known ADRs. Patient reports provide unique information valuable in signal assessment, and they should be included in signal detection as far as is possible. Novel methodologies to highlight patient reports in statistical signal detection can further improve the contribution of patient reports to pharmacovigilance.
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69 Adverse Drug Reactions Notifications by Patients

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Introduction: Adverse drug reactions (ADRs) are an important public problem in terms of patient morbidity, mortality and costs for health systems. Therefore, reporting of suspected ADRs is fundamental to drug safety surveillance. Substantial underreporting exists and is the system's