CANNABINOID USE THERAPY: FIRST MONITORING OF ADVERSE REACTION

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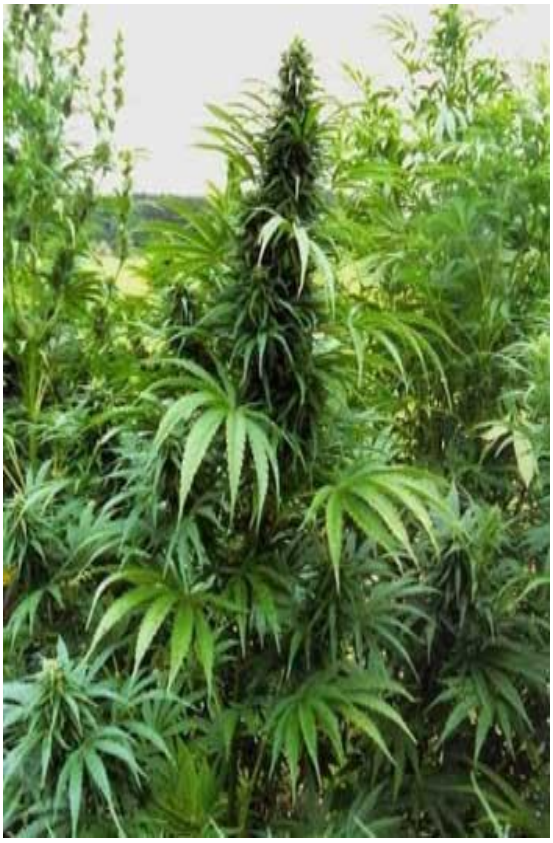
Background: With the new laws, herbal based cannabis substances were introduced in the Italian Pharmacopoeia Table II section B, concerning narcotic and psychotropic substances, making possible the prescription of galenic preparations. The Italian Drug Agency instead authorised the marketing of delta-9-tetrahydrocannabinol/ cannabidiol (THC/CBD) sprays for muscle spasticity in multiple sclerosis (MS) patients not responders to first or secondline treatments. In the scientific literature several studies have reported on the use of cannabis and its derivatives in many clinical settings with different levels of evidence about effectiveness and tolerability. These studies showed different adverse drug reactions (ADRs) including: respiratory, gastrointestinal, CNS, cardiovascular, kidney, urinary and psychiatric disorders.

Purpose: The objective of this work was to monitor ADRs reported in Italy, after intake of cannabinoid based medications.

Material and methods: Data were performed using the network of pharmacovigilance, for the period 1 January 2014 to 30 June 2015. The analysis included ADRs assumed to be due to the galenical preparations and the medicinal product already on the market.



Results: Reports in Italy were 124, of which the suspected drug was: galenical preparations (7) and commercial product (117). 102 ADRs were not serious, 20 were serious and 2 were undefined; 60% resulted in complete resolution, 9% in improvement and in 30% the outcome was not available. Regarding the source, the largest number of reports were reported by hospital doctors (59), by pharmacists (30) and by specialists (29). Most of these reports came from the regions of Puglia (28), Lombardy (27), Sicily (26) and Emilia Romagna (14). In all cases there was complete resolution of the adverse reaction. The sources of the reports were in line with the sources of national alerts. Among all ADRs, almost all related to disorders such as mental confusion, dizziness, vertigo and muscle weakness.

Conclusion Cannabis and its derivatives have powerful pharmacological action that can cause adverse reactions, even if expected. Given the current reporting framework, it will be necessary to continue monitoring in order to determine the actual safety of using these molecules and identify any unexpected ADRs.

References and/or Acknowledgements
Regional Law n. 18/2012, Ministerial Decree in 23/1/13, Determine 387 of 04/09/2013.