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Adverse reactions to herbal drugs and other forms of natural and traditional medicine in Cuba from 2001 to 2004

Téc. Jenny Ávila Pérez^I; Dra. Giset Jiménez López^{II}; Dra. Blanca González Delgado^{III}; DrC. Francisco Morón Rodríguez^{IV}; DrC. Rogelio Fernández Argüelles^V

ABSTRACT

OBJECTIVES: to characterize the notifications of suspicions of adverse reactions to herbal drugs and other procedures of traditional and natural medicine during these 4 years in Cuba.

METHODS: a descriptive and retrospective study of pharmacovigilance was undertaken by the spontaneous notification of adverse reactions. The notifications corresponding to 2001 and 2004 were reviewed and classified.

RESULTS: the reports of suspicions of adverse reactions to these techniques of traditional medicine were under 5 % of the total of reports received, which also included drugs, biological products, vaccines, contrast media and others. The age group 16-49 showed the highest incidence and the females prevailed. The greatest percentage corresponded to the phytodrugs (57.8 %) in the whole period, followed by acupuncture and related techniques (37 %). In the causality assessment the highest percentage of adverse effects was classified as probable. According to the national behaviour of the suspicions of adverse reactions and severity, the mild reactions were the most notified (around 70 %), followed by the moderate. There was no mortal adverse effect.

CONCLUSIONS: the study of the natural medicine products is still insufficient, and it is difficult to make an evaluation of causality before a suspicion of adverse reaction. However, it is very useful to report the most minimum reaction detected by the patient or the health professional.

Key words: Pharmacovigilance, herbal drugs, medicinal plants, phytotherapy, adverse reactions, traditional medicine.