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# Pharmacovigilance of herbal medicines in Africa: Questionnaire study

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ABSTRACT

In order to describe and evaluate Herbal Medicine (HM) pharmacovigilance in African countries who are members of the WHO International Programme for Drug Monitoring a survey questionnaire was sent to the national centres and national drug regulatory agencies of these countries. Data collection was carried out from October 1st to 31st December, 2014. Among the total of 39 African countries, 34 (87.2%) answered the questionnaire and 25 (64.1%) accepted to share their data in this publication. Spontaneous adverse reaction reporting for HM is voluntary in 7 (43.7%) countries. HM pharmacovigilance programmes covered suspected adverse HM reactions in 14 (87.5%) countries; HM information in 7 (43.7%) countries; HM dependence or abuse in 6 (37.5%) countries; medication errors in 5 (31.2%) countries; falsification and adulteration in 2 (each 12.5%) countries and HM-drug interactions in 1 (6.3%) country. Groups in countries encouraged to submit herbal reports were pharmacists and physicians (both $n=15$); nurses ($n=13$); herbal therapists ($n=12$); patients ($n=11$) and local manufacturers ($n=8$). The number of herbal reports received by most countries was very low or even insignificant. VigiFlow is used by 10 countries. Information from pharmacovigilance activities is disseminated using many means. Only five countries have regulatory status and quality control of their HM products. The participants identified a need for HM regulation, technical and training assistance, and funding as being major challenges to HM pharmacovigilance in countries. Particular attention to the development of pharmacovigilance of HM is required in Africa.



## 1. Introduction

Herbal medicines (HM) include herbs, herbal materials, herbal preparations (comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials) and finished or manufactured herbal products found in pharmaceutical dosage forms (tablets, capsules) (WHO, 2004). As with all medicines, HM have been shown to have adverse effects which are related to a variety of causes, including adulteration, mistaken use of the wrong species, incorrect dosing, errors in use, contamination, and toxic constituents. Furthermore, HMs can affect pharmacokinetic and pharmacodynamic properties of conventional drugs and thus can cause herb–drug interactions (Skalli et al., 2007). For these reasons, there is an increasing awareness of the need to develop pharmacovigilance for HM. This is particularly true in African societies due to the particular circumstances of use, the influence of religious, sociocultural, and socioeconomic factors, traditional practices, and belief in the use of their indigenous system of medicine, as well as specific public health diseases programs (e.g., malaria, tuberculosis, and HIV/AIDS). Indeed, in Nigeria, an ethnobotanical survey of medicinal plants used by the indigenous people of Ogbomoso for the treatment of malaria infection showed that 40 plant species from 32 plant families were mostly used for treating malaria infection in Ogbomoso, Southwest Nigeria (Olorunnisola et al., 2013) and in Ethiopia, the Ethiopian government firmly supports and encourages traditional medicine through its policies as part of the national heritage (Kassaye et al., 2006).

Polypharmacy can result in a variety of negative outcomes for both patients and healthcare facilities. These include negative outcomes such as adverse drug effects, hospitalisations, and poor patient health, as well as economic outcomes. For all these reasons, HM are utilized significantly instead or in association with conventional drugs and in relation with this finding, further justification for widespread implementation of pharmacovigilance of HM is needed.

The pharmacovigilance of HM involves the assessment of risks and benefits of HM and plays a key role in pharmacotherapeutic decision-making. The ultimate aim is to protect patients from herb-induced harms and allow them to derive the maximum benefit from HM. The WHO offers for its Member States (national pharmacovigilance centres participating in the WHO International

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Drug Monitoring Programme and Drug Regulatory Authorities), many guidelines and other documents which help to identify the particular challenges in monitoring the safety of HM effectively and which propose approaches for overcoming them (WHO, 2005, 2002). In addition to this, the WHO Programme for International Herbal Monitoring aims to develop a comprehensive global pharmacovigilance strategy that responds to the healthcare needs of low- and middle-income countries such as African countries. Until now, no investigations have carried out a systematic assessment of the HM Pharmacovigilance landscape in African countries. It is in this context that the Centre Anti Poison et de Pharmacovigilance du Maroc, in its role as a WHO Collaborating Centre, conducted the present study to describe and evaluate the programme of HM pharmacovigilance in African countries who are members of the WHO International Programme for Drug Monitoring. The information collected provides the current situation of HM pharmacovigilance in Africa and identifies the HM pharmacovigilance gaps, priorities and the way forward.

## 2. Methods

A survey of the pharmacovigilance of HM in 39 African countries who are official ($n=34$) and associate ($n=5$) members of the WHO International Drug Monitoring Programme was carried out between October 1st to December 31st, 2014. A questionnaire was developed in English and translated into French (Table 1). It was based on a questionnaire developed by Olsson et al. (2010), because it concerns the same aim of the study. But Olsson's questionnaire which examined pharmacovigilance activities in general, was adapted to pharmacovigilance of HM programme in countries as the monitoring of HM constitutes a component of pharmacovigilance in general (Skalli and Soulaymani Bencheikh, 2012).

The questionnaire was distributed via the Vigimed system, and also sent by personal email to the study participants. Vigimed is an e-mail distribution list set up to stimulate discussion and facilitate rapid exchange of information between representatives of National Centres participating in the WHO International Drug Monitoring Programme. It is a restricted list, open only to individuals connected to the National Centre for Pharmacovigilance or to the Drug Regulatory Authority in participating countries (Johansson et al., 2007).

The questionnaire was designed to collect information on the structure, resources, functions and achievements of pharmacovigilance of HM in Africa. It referred to six broad areas:

- background information about the country and the person who completed the questionnaire;
- an overview of the pharmacovigilance of HM programme;
- spontaneous adverse herbal reaction reporting;
- use of information from the pharmacovigilance of HM activities;
- regulation of HM;
- challenges and future activities.

Regular reminders spaced by two weeks were sent in order to stimulate the participation of countries. A consent letter for giving permission to publish the questionnaire data was sent to the contacts responsible for pharmacovigilance in the participating countries.

Because we have judged that questions are simple and most of them have multiple choice of answers, no pre-test of the questionnaire was carried out to help identify potential difficulties in the wording and design from the participants' viewpoints. Indeed, during the study no question or comment has been received about the difficulty to fill the questionnaire.

Frequency analysis was conducted for the questions. The analyses of the survey results were performed using Epi Info 3.3.2 version.

## 3. Results

### 3.1. Background information

Among the 39 African countries belonging to the WHO International Drug Monitoring Programme, 34 (87.2%) answered the questionnaire. The answers came from pharmacovigilance bodies or from Drug Regulatory Authorities. Of these countries 25 (64.1%) accepted to share their data in this publication and are depicted in Table 2.

### 3.2. Overview of the pharmacovigilance of HM programme

Eighteen (72%) of national centres are affiliated with the Ministry of Health and 28% with Drug Regulatory Agencies (Table 2). Nine responding countries, Burundi, Cape Verde, Eritrea, Guinea-Bissau, Kenya, Madagascar, Rwanda, Senegal and Uganda have reported that they do not currently have HM pharmacovigilance programmes.

The pharmacovigilance of HM is still a new activity in the majority of countries which have included it in their pharmacovigilance system. Except in Morocco where a HM pharmacovigilance programme was created in the year 2000, the other countries set up this activity in the last 10 years, mainly from 2009 to 2013 (Table 3). When the pharmacovigilance of HM is organised with other medicines, it is done so either as part of a national centre or a pharmacovigilance section only 8 (50%) countries, as a network with national and regional centres for 7 (43.7%) countries or as regional centres for one (6.3%) country. Of the countries which took part in the survey, 78.1% have their pharmacovigilance of HM activities combined with other services such as Drug information; Pharmacovigilance of other health products; Poison Control Centre and Registration and Evaluation of HM (Table 3).

The centres in 16 countries are apparently understaffed; two countries, Morocco and Nigeria mentioned having respectively two and one staff members dedicated specially to HM pharmacovigilance programme. The other country's herbal reports are managed by pharmacovigilance staff not specialized in pharmacovigilance of HM. No information about this aspect was received from Egypt, Sudan and Tunisia.

Among African countries with HM pharmacvovigilance programme, nine (56.3%) have access to a library with basic current reference books on HM safety or had access to such sources over the internet and 7 countries (43.7%) do not have access to any reference books on HM safety and they do not have access to such sources over the internet: Angola, Botswana, Burkina Faso, Ghana, Liberia, Mauritius and South.

### 3.3. Spontaneous adverse herbal reaction reporting

All countries have one national form for reporting suspected adverse health product reactions including HM. Herbal medicines cover raw material, natural herbal preparations and finished herbal products found in pharmaceutical dosage forms (Table 4).

In addition to reports of suspected adverse HM reactions for 14 (87.5%) countries, many other problems related to HM are covered by HM pharmacovigilance programmes in the surveyed countries: HM information in 7 (43.7%) countries; HM dependence or abuse in 6 (37.5%) countries; medication errors in 5 (31.2%) countries;