Drug Registration in African countries

Dr.G.V.R.Joseph

Department of AYUSH
Ministry of Health and Family Welfare
Government of India.

African countries : National policy and Regulation of TM / CAM & Herbal medicine

Angola	Benin	Botswana
Burkina Faso	Burundi	Cameroon
Central African Republic	Chad	Comoros
Congo	Cote d'Ivoire	Democratic Republic of the Congo
Equatorial Guinea	Ethiopia	Gabon
Gambia	Ghana	Guinea
Guinea-Bissau	Kenya	Madagascar
Malawi	Mali	Mauritania
Mozambique	Niger	Nigeria
Rwanda	Sao Tome and Principe	Senegal
Seychelles	Sierra Leone	South Africa
Togo	Uganda	United Republic of Tanzania
Zambia		

Drug registration :

Permission granted by the relevant state authority to use and distribute a certain drugs;

Main aim of registration is to ensure that the users get only safe, effective drugs of high quality.

Angola

There is no national policy on TM/CAM in Angola. There is no regulation of herbal medicines in Angola. Herbal medicines are classified as over-the-counter medicines. By law, no claims may be made about herbal medicines. There is no registration system for herbal medicines; no herbal medicines are included in the essential drug list.

Benin

Benin established a national policy, a law or regulation concerning TM/CAM. A TM/CAM office has existed since 1997 under the Ministry of Health. Benin does not regulate herbal medicines; herbal medicines are classified only as over-the-counter medicines and for self-medication and can be sold with medical, health, nutrient content, and structure/function claims. There is no registration system of herbal medicines and nor included on the essential drug list.

Botswana

Botswana currently does not have a national policy on TM/CAM; and` does not have any control mechanism for the manufacture of herbal medicine. No regulatory requirements exist regarding safety; unprocessed herbal medicines without clinical claims are exempt from regulation as a medicine nor there registration system.

Burkina Faso

Burkina Faso currently has no national policy, laws or regulations, nor a national programme on TM/CAM, but has reported that all three are being developed. The rule of GMP is applied for national regulation on herbal medicine .The relevant regulatory categories of herbal medicine are over-the-counter drug and dietary supplements. No registration system for herbal medicines exists, and herbal medicines are not included on a national essential drug list. In Burkina Faso, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners.

Burundi

The Republic of Burundi does not currently have national policy or laws and regulations on TM/CAM, but they are currently in development. Burundi does not regulate herbal medicine, but it was reported that herbal medicines have the regulatory statues of over-the-counter sale medicines and for self-medication only. Burundi does not have a registration system for herbal medicines, nor are herbal medicines included on the national essential drug list. Herbal medicines in Burundi are sold in special outlets and by licensed practitioners with no restrictions.

Cameroon

The Republic of Cameroon currently does not have national policy or laws and regulations on TM/CAM, but a national policy is being developed. Herbal medicines in Cameroon have regulatory status as prescription medicines, over-the-counter medicines and for self-medication. A registration system for herbal medicines exists in Cameroon, and currently 10 medicines are registered.

Central African Republic

In the Central African Republic, a national policy and laws and regulations and a national programme on TM/CAM are in development. There is no regulation of herbal medicines in the Central African Republic and there is no regulatory status applied to herbal medicines. In the Central African Republic, there is also no registration of herbal medicines, nor are herbal medicines included on the essential drug list. No restrictions exist on the sale of herbal medicines in the Central African Republic.

Chad

In the Republic of Chad, a national policy, laws and regulations on TM/CAM are currently in development. Chad does not regulate herbal medicines, therefore there is no regulatory status for herbal medicines, nor can claims be made by law. There are no manufacturing or safety assessment requirements, nor is a registration system in place.

Comoros

In the Islamic Federal Republic of the Comoros (now the Union of the Comoros), there are no national policy, laws or regulations, and none is in development. Comoros does not regulate herbal medicines, although herbal medicines have a regulatory status of over-the-counter medicines. There are no manufacturing or safety assessment requirements, nor is a registration system in place.

Congo

The Republic of the Congo does not have a national policy on TM/CAM, and is not currently establishing one. Congo does not regulate herbal medicines; there is no regulatory status given to herbal medicines and no claims can legally be made. No registration system exists, and herbal medicines are not included on an essential drug list.

Cote d'Ivoire

In the Republic of Cote d'Ivoire, the national policy on TM/CAM was established in 1996. Herbal medicines are not regulated in Cote d'Ivoire; no regulatory status is given to herbal medicines and no claims can be legally made. No registration system exists, and herbal medicines are not included on an essential drug list.

Democratic Republic of the Congo

In the Democratic Republic of the Congo, herbal medicines have regulatory status as prescription medicines and over-the-counter medicines. There is a registration system for herbal medicines; 15 medicines are registered.

Equatorial Guinea

In the Republic of Equatorial Guinea, a national policy on TM/CAM was issued in 1999 and laws and regulations on TM/CAM were issued in 1985.Herbal medicines have the regulatory status of over-the-counter medicines and self-administered medicines. There is no system of registration, and herbal medicines are not included on the essential drug list.

Ethiopia

In the Federal Democratic Republic of Ethiopia, the national policy on TM/CAM was issued in the Health, Drug, Science and Technology Policy of 1999. Ethiopia does not regulate herbal medicine and no regulatory status exists for herbal medicine: however, herbal medicines are sold with medical claims. There is no registration system, herbal medicines are not included on an essential medicines list, nor is there a post-marketing surveillance system.

Gabon

The Gabonese Republic issued its national policy in 1995 in Ordinance No. 001/95, which officially recognizes traditional medicine in the overall Gabon health policy. No development, as is the national programme. Gabon does not regulate herbal medicine. No regulatory status is given to herbal medicines and no claims can legally be made. No registration system exists, and herbal medicines are not included on an essential drug list.

Gambia

In the Republic of the Gambia Laws and regulations on TM/CAM do not exist, nor are they currently in development. No regulatory status is given to herbal medicines, and no claims can legally be made. No registration system exists, and herbal medicines are not included on an essential drug list. There are no restrictions on sale of herbal medicines in the Gambia.

Ghana

In the Republic of Ghana, the national policy on TM/CAM was issued in 2002. Laws and regulations on TM/CAM were issued in 1992. and the national programme in 2000. Herbal medicines are regulated as over-the-counter medicines and as a separate regulatory category. There are 340 registered herbal medicines in Ghana; however none is included on the national essential drug list. In Ghana, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners.

Guinea

The Republic of Guinea established its national policy on TM/CAM in 1994; laws and regulations on TM/CAM followed in 1997. Herbal medicines are regulated as prescription medicines, over-the-counter medicines self medication and as herbal medicines in a separate regulatory category. There is no registration system for herbal medicines and they are not included on the essential drug list. Herbal medicines in Guinea are sold in pharmacies as prescription and over-the counter-medicines without restriction.

Guinea-Bissau

The Republic of Guinea-Bissau has no national policy, laws or regulations, national programme, national office, expert committee or research institutes related to TM/CAM. Guinea-Bissau does not regulate herbal medicines and they are treated as over-the-counter medicines. There are no regulatory requirements for manufacturing or safety assessment. No registration system exists, and herbal medicines are not included on an essential drug list. There are no restrictions on sale of herbal medicines in Guinea-Bissau.

Kenya

Herbal medicines are not regulated in Kenya. There is no registration system for herbal medicines and they are not included on the essential drug list. Herbal medicines in Kenya are sold without restriction.

Madagascar

The Republic of Madagascar has a national policy, laws and regulations and a national programme on TM/CAM in development. Madagascar does not regulate herbal medicines; they are classified as over-the-counter medicines. There is no registration system for herbal medicines and they are not included on the essential drug list.

Malawi

In the republic of Malawi, no information is available about the national policy on TM/CAM. Herbal medicines are regulated by the law that are used for pharmaceuticals. Herbal medicines may be sold by law with medical and structure/function claims. There is no registration system for herbal medicines and they are not included on the essential drug list.

Mali

While the Republic of Mali does not currently have a national policy on TM/CAM, such a policy is in development. Herbal medicines are regulated as over-the-counter medicines and may, by law, be sold with medical claims. The registration system for herbal medicines includes seven medicines, as does the essential drug list. Herbal medicines in Mali are sold in pharmacies as over-the-counter medicines and in herb shops.

Mauritania

Although the Islamic republic of Mauritania does not currently have a national policy on TM/CAM, one is in the process of development. No laws or regulations yet exist on TM/CAM; a national programme has also not been issued. Mauritania does not regulate herbal medicines; they are categorized as over-the-counter medicines, self-medication, herbal medicines, dietary supplements or health foods. No Registration system exists for herbal medicines.

Mozambique

Herbal medicine is not regulated in Mozambique so no regulatory status exists for herbal medicines. There is no registration system for herbal medicines, and they are not included on the essential drug list. Herbal medicines are sold in pharmacies as over-the-counter medicines with no restrictions.

Niger

Laws and regulations were issued in 1997, the regulation of herbal medicines is same as that of pharmaceuticals. There is a registration system for herbal medicines, and currently one product is registered. Herbal medicines in Niger are sold in pharmacies as over-the-counter medicines, in special outlets and by licensed practitioners.

Nigeria

Herbal medicines are regulated as dietary supplements Health foods, Functional food as an independent regulatory category. There is registration system and currently 107 registered herbal medicines in Nigeria, but none is listed on the essential drug list. In Nigeria, herbal medicines are sold without restriction by licensed practitioners.

Rwanda

The Rwandese Republic currently developing laws ad regulations on TM/CAM, but neither a national policy nor a national programme are planned. Herbal medicines are not currently regulated in Rwanda; they are categorized as over-the-counter medicines, self medication and dietary supplementary. There is no registration system for herbal medicines, and no herbal medicines are included on the national essential drug list. Herbal medicines in Rwanda are sold in pharmacies as prescription and over-the-counter medicines.

Sao Tome and Principe

Herbal medicines are not regulated in Sao Tome and Principe. There is no registration system and no herbal medicine included on the national essential drug list. Herbal medicines in Sao Tome and Principe are sold in special outlets.

Senegal

In the Republic of Senegal, information on the status of national policy on TM/CAM is not available. Herbal medicines in Senegal are not regulated and no information is available about regulatory status. There is no registration system for herbal medicines and they are nor included on the essential drug list.

Seychelles

In the Republic of Seychelles, national policy, laws and regulations on TM/CAM are currently in development. Herbal medicines are not regulated in Seychelles but are given as self medication. There is no registration system for herbal medicines, and none are listed on the essential drug list. In the Republic of Seychelles, herbal medicines are mainly sold on the premises of herbalists.

Sierra Leone

The Republic of Sierra Leone is in the process of establishing a national policy, a national programme and a national office for TM/CAM. Herbal medicines are not regulated in Sierra Leone however; they are classified as over-the-counter medicines and as dietary supplements. There is a registration system for herbal medicines, but there are no available data on the number of herbal medicines registered. No herbal medicines are included on the national essential drug list.

South Africa

The national policy on TM/CAM of the Republic of the Republic of South Africa was issued in 1996 as part of the National Drug Policy. No regulatory status exists for herbal medicines, currently they are sold for self medication only. There is currently no national registration system for herbal medicines, although one is in development. South Africa, herbal medicines are sold in pharmacies as over-the-counter medicines, in special outlets, by licensed practitioners and without restriction.

Togo **Country wise information on regulatory mechanism**

In the Togolese Republic, the national policy on TM/CAM was issued in 1996, and laws and regulations were issued in 2001. Herbal medicines have the regulatory status of over-the-counter medicines or self medication as an independent regulatory category. There is no registration of herbal medicines and they are not included on the essential drug list. In Togo, herbal medicines are sold without restriction in special outlets and as over-the-counter medicines in pharmacies

Uganda

There is no specific regulatory status for herbal medicines. A registration system for herbal medicines was established in 2002; however no medicines are yet registered. In Uganda, herbal medicines are sold in pharmacies as over-the-counter medicines, by pedlars and in food markets, without restriction.

United Republic of Tanzania

In the United Republic of Tanzania, a national policy was issued in 2000; laws and regulations and a national programme on TM/CAM are being developed. Herbal medicines are currently not regulated and have no regulatory status in United Republic of Tanzania and herbal medicines are mainly used for self medication. There is no registration system for herbal medicines, nor are herbal medicines included on the essential drug list. There are no restrictions on the sale of herbal medicines in the United Republic of Tanzania.

Zambia

In the Republic of Zambia, the national policy on TM/CAM is part of the National Drug Policy, approved in 1997. Herbal medicines are currently not regulated in Zambia. Likewise, there is not yet a registration system for herbal medicines, nor are herbal medicines included on the essential drug list. There are no restrictions on the sale of herbal medicines in Zambia.

PRODUCT REGISTRATION FORMATS

A COMPARATIVE STUDY

Sl. No.	Format title	Australia	Botswana	Ethiopia	European Union	Ghana	Kenya	Nigeria	South Africa	Tanzania	UK MHRA	USA
1.	**Definition**	√			√		√				√	√
2.	**Synonyms**	√			√	√						
3.	**Vernacular names**	√			√	√						
4.	**Geographical distribution**											
5.	**Identification**										√	√
	5.1 Botanical description	√			√		√					√
	5.2 Morphological or organoleptic characters	√			√		√					√
	5.3 Microscopy	√			√							
	5.4 Powder microscopy	√			√							
	5.5 Qualitative chemical Tests	√										

6	**Commercial sources and Handling**											
	a. Cultivation				√							
	a. Collection				√							
	a. Drying				√							
	a. Storage		√		√			√	√	√	√	
	a. Adulterants b. Substituent											
7.	**Purity tests**	√			√							
	a. Total Ash											
	b. Acid-insoluble Ash											
	c. Water-soluble extractive											
	d. Alcohol-soluble extractive											
	e. Foreign Organic Matter											

	f. Loss on Drying											
	g.Pesticide Residues				√							
	h. Radioactive Residues				√							
	i.Heavy Metals				√							
	j. Microbial residues				√							
	k. Aflatoxin residues				√							
	l. Other Purity Tests											
8.	**Major chemical constituents**	√			√	√	√	√	√		√	√
9.	**Chemical assays**	√			√		√					
10.	**Stability data (Shelf life)**	√		√	√	√	√	√	√	√	√	
11.	**Therapeutic use**	√	√	√		√			√	√		
	a.Traditional use	√			√							

	b. Well established use	√										
12.	**Pharmaceutical form**	√			√	√	√			√		
	a. Traditional											√
	b. Modern											
13.	**Posology and method of administration**	√	√		√	√			√			
14	**Pharmacology**			√	√			√				
	a. Experimental pharmacology i. *In vitro* ii.*In vivo*	√			√				√			
	b. Clinical pharmacology	√		√	√		√		√			√
	c. Pharmacokinetics		√	√			√	√	√			
15.	**Safety profile**		√									
	a.Acute toxicity		√	√		√			√			√

	i.Repeated dose toxicity	√		√								√
	i.Over dose		√		√	√						
	i.Mutagenicity		√	√								
	i.Teratogenicity	√	√	√								
	i.Carcinogenicity		√		√							√
	i.Reproductive toxicity				√							√
	i. Pregnancy and Lactation	√			√	√						
	xi. Influence on driving and use of machines				√							
	x. Efficacy											
16.	**Contraindications**		√		√	√			√		√	
17.	**Interactions**	√			√	√			√		√	

18.	**Special warnings and precautions for use**		√	√	√				√		√	
19.	**Undesirable effects**	√			√				√		√	
20.	**Regulatory status**	√	√ √	√								
21.	**References**	√							√		√	
	Other information										√	
22.	**Active ingredient**			√						√		
23.	**Inactive ingredient**		√									
24.	**Excipients**							√		√		
25.	**Packaging Specifications**		√	√				√				
26.	**Method of use**		√					√				
27.	**Analytical control procedures**			√				√				
28.	**Physical appearance of the product**							√				

29.	**Packaging materials**			√								
30.	**Quality control / Quality Assurance process**			√								
31.	**Pharmacodynamics**			√								
32.	**Bioavailability report**			√								
33.	**General information**											
	Trade name of the product	√	√		√	√	√	√	√	√		
	Name and address of manufacturer	√	√		√	√	√	√		√	√	
	Manufacturing process	√	√	√	√	√	√	√	√		√	
	List of countries where product has been registered		√							√		
	Certificate for free sale						√		√			
	Certificate of analysis					√			√			

	Certificate of GMP								√			
	Certificate of ISO								√			
	Certificate of sterility											
	Price Certificate											
	Application for registration			√		√			√	√	√	
	Manufacturing License								√			
	Registration number of product in country of origin			√			√				√	
	Fees	√							√		√	

Comparative Chart with respect to details of Plant Monographs in standard books

S. No.	Headings	WHO	AHP	ESCOP	PDR	EMEA community monograph & Quality tests	BHC	BHP	SLM	IP	API	UP	HP	IHP	ICMR
01	Definition	√	√	√		√	√	√		√	√	√	√	√	√
02	Nomenclature		√		√	√			√	√		√	√	√	√
a.	Botanical Nomenclature	√	√			√				√	√	√	√	√	√
b.	Botanical Family	√	√			√			√	√	√	√	√	√	
03	Synonyms	√				√	√	√	√	√	√	√	√		√
04	Selected vernacular names/ Common Name	√	√						√	√		√	√		√
05	Description	√			√	√			√	√		√	√	√	
06	History		√										√		√
07	Plant Material of interest	√				√									
i.	General Appearance	√				√				√					√
	Botanical Identification		√			√						√			
ii	Organoleptic properties	√				√						√			√
	Macroscopic Identification		√			√		√		√	√	√	√	√	√
iii	Microscopic characteristics	√	√			√		√	√	√	√	√	√	√	√
iv	Powdered plant material	√	√			√			√		√				√

Comparative Chart with respect to details of plant Monographs in standard books Cont..

S. No.	Headings	WHO	AHP	ESCOP	PDR	EMEA community monograph & Quality tests	BHC	BHP	SLM	IP	API	UP	HP	IHP	ICMR
08	Commercial Sources & Handling		√												
i	Collection		√			√									
ii	Cultivation		√			√									
iii	Drying		√												
iv	Handling		√			√									
v	Storage		√			√				√					
vi	Adulterants		√			√									
vii	Preparations		√			√									
09	Geographical distribution	√	√			√			√				√	√	
10	General identity tests	√				√				√		√		√	
11	Purity tests	√				√					√	√			
i.	Microbiology	√	√			√				√					
ii.	Total Ash	√	√			√				√	√	√			
iii	Acid-insoluble ash	√	√			√		√		√	√	√			
iv.	Water-soluble extractive	√	√			√				√	√	√			
v.	Alcohol-soluble extractive	√	√			√				√	√	√			
vi	Foreign Organic Matter		√			√		√		√	√	√			
vii	Loss on Drying		√			√				√					
viii.	Pesticide residues	√				√									
ix	Heavy Metals	√				√				√	√				

Comparative Chart with respect to details of plant Monographs in standard books Cont..

S. No.	Headings	WHO	AHP	ESCOP	PDR	EMEA community monograph & Quality tests	BHC	BHP	SLM	IP	API	UP	HP	IHP	ICMR
x	Radioactive residues	√				√									
xi	Other purity tests	√													
12	Chemical assays	√	√			√		√	√	√	√				√
13	Major Chemical constituents/ Constituents	√	√	√		√	√		√	√		√		√	√
14	Dosage forms	√	√	√	√	√	√				√	√	√	√	√
15	Adulterants and Substitutes													√	√
16	Therapeutics		√	√		√	√	√			√	√		√	
a.	Pharmacokinetics		√	√		√									
b.	Pharmacodynamics		√	√		√									
c.	Preclinical Safety Data					√									
17	Medicinal uses	√	√			√		√						√	√
i.	Uses supported by clinical data	√	√	√		√									
ii.	Uses described in pharmacopoeias and in traditional systems of medicine	√				√			√						√
iii	Uses described in folk medicine, not supported by experimental or clinical data	√													

Comparative Chart with respect to details of Plant Monographs in standard books Cont..

S. No.	Headings	WHO	AHP	ESCOP	PDR	EMEA community monograph & Quality tests	BHC	BHP	SLM	IP	API	UP	HP	IHP	ICMR
18	Pharmacology	√	√	√	√	√	√		√						√
a.	Experimental pharmacology	√	√												
b.	Clinical pharmacology	√	√	√		√									
19	Contraindications	√	√	√		√	√								
20	Warnings	√		√											
21	Pregnancy and lactation		√	√		√									
22	Effects on ability to drive and use machines		√			√									
23	Overdose		√	√		√									
24.	Precautions	√	√		√	√		√						√	√
a.	Carcinogenesis, mutagenesis, impairment of fertility	√	√												
b.	Other precautions	√													
c.	Adverse reactions	√	√	√	√	√									
d.	Interactions		√	√											
e.	Posology	√				√									
f.	Toxicology		√					√							
25	Regulatory Status		√				√								
26	References	√	√	√	√									√	√

Abbreviations:

WHO- World Health Organization
AHP- American Herbal Pharmacopoeia and Therapeutic Compendium
ESCOP- German Commission E Monograph
PDR- Physician Desk Reference for Herbals
ICMR- Indian Council of Medical Research
EMEA- European Medicines Evaluation Agency
BHC – British Herbal Compendium
BHP – British Herbal Pharmacopoeia
SLM – Sri Lanka Monograph
IP – Indian Pharmacopoeia
UP- Unani Pharmacopoeia
API- Ayurvedic Pharmacopoeia
HP- Homeopathic Pharmacopoeia
IHP- Indian Herbal Pharmacopoeia


Thank You
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