Presidential Decree No. 253/21
October 14

Considering that Presidential Decree No. 180/10 of 18 August, which establishes the General Principles of the National Pharmaceutical Policy, provides for pharmacovigilance as one of the ways to promote the rational use of medicines and other health products with a view to ensuring that the consumer has access to effective, safe and quality medicine;

Bearing in mind the provisions of Article 20 of Law No. 21-B/92 of August 28 regarding the Principles of the National Health System;

The President of the Republic decrees, pursuant to paragraph 1) of Article 120 and subsection 3 of article 125, both of the Constitution of the Republic of Angola, the following:

REGULATION
REGARDING PHARMACOVIGILANCE

CHAPTER I
General Provisions

ARTICLE 1
(Object)

This Diploma establishes the rules for the exercise of the activity of pharmacovigilance of medicines for human use, traditional medicines, blood products and other health products, carried out by the National Pharmacovigilance System.

ARTICLE 2
(Scope)

This Decree applies to pharmacovigilance carried out by public and private entities and users of the National Health System who are involved in the management or use of medicines and other health products.

ARTICLE 3
(Definitions)

For the purposes of this Document, the following definitions apply:

a) *"Abuse"* - excessive and voluntary, permanent or intermittent use of medicines that do not conform to the recommendations of the package leaflet or to usual medical use;

b) *"International Pharmacovigilance Agencies"*— competent international bodies to which Angola shall regularly transmit all relevant information in the field of pharmacovigilance;

c) *"Alert"* — information about possible harm arising from the use of medicines and other health products;

d) *'Risk Assessment'* — analysis of the probability and severity of the identified harm;

e) *"Good Pharmacovigilance Practices"* — a set of recommendations aimed at ensuring the authenticity and quality of the data collected in pharmacovigilance, allowing the assessment of risks related to medicines and other health products at any time;

f) *"Serious Undesirable Effect"* — an effect that endangers life, leads to disability or incapacity, causes or prolongs hospitalization;

g) *"Unexpected Undesirable Effect"* — an effect not mentioned in the summary of product characteristics, with regard to its type, severity or frequency;

h) "Undesirable Effect" — a harmful and unwanted reaction to a medicine in humans during the prophylaxis, diagnosis or treatment of a disease or modification of a physiological function;

i) "Pharmacovigilance" — public health activity, whose objective is the identification, assessment and prevention of risks in the use of medicines and other health products;

j) "Notification Form of Suspected Adverse Reactions to Medicines and Other Health Products" — document of the pharmacovigilance system filled in by the notifier in order to collect undesirable effects, comprising the set of data necessary for the constitution of a notification dossier;

k) "Sources of Information on Pharmacovigilance" — dossier referring to information on pharmacovigilance, report of a telephone conversation, first mail from the notifier, clinical history of the patient, pharmacovigilance form completed by the notifier or person in charge of pharmacovigilance or other sources of information. information, namely news, summaries, tables concerning the dossier;

l) "Imputability" — case-by-case analysis of the causal link between taking the medicine and the occurrence of the undesirable event;

m) "Survey" — assessment work carried out at the request of the competent authorities whenever there are reasons to assess or reassess the risks of a medicine;

n) "Notification" — communication to a pharmacovigilance organization of a suspected adverse reaction to a medicine or other health product;

o) "Notifier" — healthcare professional or user who has noticed a suspected undesirable effect of a medicine or other health product and reports it to a pharmacovigilance organization;

p) "Focal Point" — professional responsible for pharmacovigilance in the workplace and who reports to a pharmacovigilance organization under the guidance of the highest body of the institution;

q) "Risk" —degree of probability that harm will occur;

r) "Provincial, Municipal or District Pharmacovigilance Services" — functional units of the peripheral administration or part of the local bodies responsible for health, aimed at developing pharmacovigilance in the respective administrative districts;

s) "National Pharmacovigilance System" — technical-administrative structure responsible for implementing pharmacovigilance in the country.

CHAPTER II
Stakeholders and Operation of the National Pharmacovigilance System

SECTION I
General Provisions

ARTICLE 4
(National Pharmacovigilance System)

1. Pharmacovigilance is exercised through the National Pharmacovigilance System.

2. The National Pharmacovigilance System is coordinated by the Regulatory Agency for Medicines and Health Technologies, and the following are part of it:

a) Provincial Pharmacovigilance Services;

b) Municipal or District Pharmacovigilance Services;

c) Public and Private Health Units;

d) Pharmaceutical Establishments;

e) Health professionals who diagnose, prescribe, dispense and administer medicines for human use;

f) Traditional and Complementary Medicine Healers;

g) Users of the National Health System.

ARTICLE 5
(Objectives)

The National Pharmacovigilance System has the following objectives:

a) To ensure the quality, efficacy and safety of marketed medicines and all activities related to pharmacovigilance;

b) To ensure the maintenance or withdrawal from circulation of medicines or other health products according to the risk-benefit ratio;

c) To promote the rational use of medicines through the appropriate training of staff who prescribe and dispense medicines and carry out information and education activities for the population in the Health Area;

d) To serve as an instrument for solving priority problems defined within the framework of the National Health Policy;

e) To supervise, monitor, collect, evaluate and disseminate information on adverse reactions to medicines and other health products used in the country.

ARTICLE 6
(Methodology)

The methodology for collecting information in pharmacovigilance comprises:

a) The sending of information regarding the suspected undesirable effect to the Coordinator of the National Pharmacovigilance System through the notification form of suspected adverse reactions to medicines and other health products, according to the model defined by the System Coordinator;

b) The compilation, recording, evaluation and exploitation of data concerning the signs identifying the undesirable effects of medicines and other health products in order to prevent them;

c) Studies concerning the safety of the use of medicines and other health products;

d) Research and analysis of data contained in the pre-clinical dossier of animal experimentation or clinical trials of a medicine or other health product;

e) Assessment of the causal link between the medicine and the appearance of the suspected undesirable effects according to the imputability method and the respective information to the notifier of the conclusions.

ARTICLE 7
(Good Pharmacovigilance Practices)

1. All Pharmaceutical Establishments, health units and organizations that handle medicines or other health products shall comply with the rules of good pharmacovigilance practices to be established by the Regulatory Agency for Medicines and Health Technologies.

2. In order to promote the rational use of medicines and other health products, good practices for the treatment of undesirable effects associated with the use, misuse or abuse of one or various medicines or other health products.

3. The authors of publications, when other than the Regulatory Agency for Medicines and Health Technologies, shall previously declare serious or unexpected effects to the competent authorities before the date of publication.

ARTICLE 8
(Duty of Confidentiality)

1. All information on pharmacovigilance is confidential and should only be disclosed in the terms set out in this Decree and other legislation in force.

2. The duty of confidentiality falls on all stakeholders of the National Pharmacovigilance System.

ARTICLE 9
(Focal Point)

1. The stakeholders of the National Pharmacovigilance System as established in paragraphs a), b), c) and d) of Article 4 of this Decree shall have a Focal Point, whose designation as such shall be communicated to the Regulatory Agency for Medicines and Health Technologies.

2. With the necessary adaptations, the provisions of the previous item also apply to the intervening parties of paragraphs e) and f) of Article 4 of this Decree.

SECTION II
Medicines and Health Technologies Regulatory Agency

ARTICLE 10
(Responsibilities)

The Regulatory Agency for Medicines and Health Technologies is specifically responsible for the following:

a) To ensure the effectiveness of the pharmacovigilance system, ensuring compliance with the pharmacovigilance procedures established by this Decree;

b) To establish technical standards to guide and direct the actions of the different participants in the system;

c) To analyze the notifications and decide on the maintenance or withdrawal of the respective medicines or other health products in collaboration with the competent authorities;

d) To apply appropriate measures to ensure the safe use of medicines and other health products and to stop incidents and accidents that have been shown to be linked to their use;

e) To inform the World Health Organization of any undesirable effect concerning medicines and other health products that are declared or notified, as well as the Pharmaceutical Establishment or body responsible for the medicine or product in question;

f) To provide methodological support to the Provincial, Municipal or District Pharmacovigilance Services;

g) To contribute to the proper use of medicines within the context of the protection of public health and the information of Health Professionals;

h) To collect and record all information on the suspected undesirable effect from any source, particularly a health unit or a pharmaceutical establishment;

i) To publish information on pharmacovigilance, always respecting the confidentiality of the identity of the patients in question, as well as that of the notifiers;

j) To apply the fines provided for in this Decree;

k) To exercise other powers established by law or determined by a higher authority.

SECTION III
Provincial, Municipal or District Pharmacovigilance Services

ARTICLE 11
(Definition and Responsibilities)

1. The Provincial, Municipal or District Pharmacovigilance Services are those that form part of the corresponding local administrative health structures and act in this area in the respective administrative districts.

2. The Provincial Pharmacovigilance Services have the following powers:

a) To collect, record and collate all information and notifications about undesirable effects that are sent to them by Provincial Public and Private Health Units, poisoning treatment centers, other organizations that handle medicines, as well as those coming from users;

b) To report serious undesirable effects within 24 hours to the Medicines and Health Technologies Regulatory Agency;

c) To report its activities to the Medicines and Health Technologies Regulatory Agency regularly;

d) To conduct investigative studies on its own initiative or at the request of the Medicines and Health Technologies Regulatory Agency;

e) To contribute to the increase of knowledge on pharmacovigilance methods and on the nature and mechanisms of undesirable effects of medicines and other health products;

f) To provide training for Health Professionals in the field of pharmacovigilance, as well as providing advice to users in this matter;

g) To provide expert opinions on pharmacovigilance materials of the health units in the province, in collaboration with the internal pharmacies of these units;

h) To keep a record of requests for information and record responses;

i) To exercise other powers established by law or as determined by a higher authority.

3. The Municipal or District Pharmacovigilance Services have the following powers:

a) To collate all information and notifications about undesirable effects that are sent to them by the Public and Private Municipal Health Units and other organizations that handle medicines, as well as those from users;

b) To report serious undesirable effects to the Provincial Pharmacovigilance Services within 24 hours;

c) To report its activities to the Provincial Pharmacovigilance Services regularly;

d) To carry out investigative studies on its own initiative or at the request of the Provincial Pharmacovigilance Services;

e) To contribute to the increase of knowledge on pharmacovigilance methods and on the nature and mechanisms of undesirable effects of medicines and other health products;

f) To provide training to Health Professionals in the field of pharmacovigilance;

g) To provide expert opinions on pharmacovigilance material at the municipal health units, in collaboration with the internal pharmacies of these units;

h) To provide advice on pharmacovigilance to Health Professionals and users;

i) To keep a record of requests for information and record responses;

j) To exercise other powers established by law or as determined by a higher authority.

ARTICLE 12
(Direction)

1. The Provincial, Municipal or District Pharmacovigilance Services are managed by the Focal Point, who shall be a Health Professional and trained in Pharmaceutical Sciences, Pharmacoepidemiology, Pharmacology or Clinical Toxicology.

2. It is incumbent upon the Head of Provincial, Municipal and District Services, respectively:

a) To direct the activities of the Service;

b) To exercise other powers established by law or as determined by a higher authority.

SECTION IV
Public and Private Health Units

ARTICLE 13
(Responsibilities)

Public and Private Health Units have the following powers:

a) To develop continuous surveillance of the safety and efficacy of medicines and other health products used in their clinical practice;

b) To monitor medicines and other health products in order to reduce the morbidity and mortality rate through early detection of the problem of adverse reactions to medicines;

c) To make mandatory reports on suspected adverse reactions to medicines and other health products to the competent bodies;

d) To document all notifications in accordance with the means and deadlines appropriate to the severity of the undesirable effect, to record all information regarding the taking of medicine during pregnancy and breastfeeding, and ensure follow-up in order to know the possible teratogenic effects;

e) To assess the risks associated with the use of the medicine, taking into account its advantages and therapeutic alternatives;

f) To exercise other powers established by law or as determined by a higher authority.

SECTION V
Pharmaceutical Establishments

ARTICLE 14
(Pharmacovigilance Service of Pharmaceutical Establishments)

1. Pharmaceutical Establishments shall have a Pharmacovigilance Service under the responsibility of a Pharmacist or Pharmacy Technician in permanent communication with the Regulatory Agency for Medicines and Health Technologies.

2. The Pharmacovigilance Services of Pharmaceutical Establishments or bodies that handle or market medicines or other health products shall immediately declare to the Regulatory Agency for Medicines and Health Technologies any serious or unexpected undesirable effect caused by the medicine or other health product for which they are responsible.

3. Pharmaceutical Establishments shall prepare a risk management plan for the products sold and, whenever requested, submit it to the competent authorities.

SECTION VI
Health Professionals

ARTICLE 15
(Responsibilities)

1. In the exercise of their functions or outside of them, Health Professionals who diagnose, prescribe, dispense or administer medicines or other health products shall report adverse reactions that come to their attention.

2. Health Professionals are also responsible for:

a) Notifying their pharmacovigilance organization, as soon as possible, of any suspicion of serious or unexpected undesirable effects related to the use of one or more medicines or other health products, the observation of abuse or misuse and other effects that they deem relevant to declare;

b) Responding to requests from the recipient of the notification confirming and completing it in writing, particularly if it was transmitted orally or by telephone, in order to document the initial observation;

c) Keeping the documents concerning the suspected undesirable effect in order to support, if necessary, the addition of information to that previously transmitted;

d) Cooperating with pharmacovigilance organizations, particularly in the context of investigations or expert assessments;

e) Being aware of the tolerance of the medicines they prescribe, dispense or administer;

f) Informing the user of the adverse reactions that may occur from the use of the prescribed medicine or other health products, recommending that they go to the nearest health unit in the case of reactions.

SECTION VII
Traditional and Complementary Healers

ARTICLE 16
(Remission)

The provisions of the previous article are applicable to Traditional and Complementary Healers, with the necessary adaptations.

SECTION VIII
Users of the National Health System

ARTICLE 17
(Procedure)

1. The involvement of users of the National Health System in pharmacovigilance is limited to the provision of information of any adverse reaction to medicines or other health products to the professional who diagnosed, prescribed, dispensed or administered the product.

2. If it is not possible to follow the provisions of the previous items, the communication may be made to any of the stakeholders of the National Pharmacovigilance System closest to the user.

3. Users are exempt from any obligation arising from this Decree.

CHAPTER III
Violations

ARTICLE 18
(Administrative Violations)

1. Administrative violations committed against the provisions of this Decree are punished with fines, without prejudice to other actions that may be taken by competent bodies under the terms of current legislation.

2. Violation of Article 7 hereof constitutes an administrative offense punishable by a fine of 5 to 10 national minimum wages in the case of an individual, and 10 to 15 national minimum wages in the case of a legal entity.

3. Violation of Articles 8, 9, 13, 14, of paragraphs a), b) and f) of paragraph 2 and paragraph 3 of article 15 and article 16 of this Decree constitutes an administrative transgression punishable by a fine of 5 to 25 national minimum wages in the case of an individual, and 25 to 50 national minimum wages in the case of a legal entity,.

4. The provisions of the previous items in relation to fines are not applicable when the offender is a public health unit, in which case the transgression is punished under the terms of the competent legislation.

ARTICLE 19
(Destination of the Fines)

1. The amount of the fines imposed under this Decree is credited to the Single Treasury Account (CUT), using the Single Reference for Payment to the State (RUPE).

2. The amount of revenue collected is allocated as follows:
   a) 60% in favor of the Medicines and Health Technologies Regulatory Agency;
   b) 40% in favor of the National Treasury.

CHAPTER IV
Final and Transitional Provisions

ARTICLE 20
(Special Commissions)

The Head of the Ministerial Department responsible for the Health Sector may establish Special Commissions on Pharmacovigilance of a temporary nature when proposed by the Regulatory Agency for Medicines and Health Technologies.

ARTICLE 21
(Doubts and Omissions)

The doubts and omissions that result from the interpretation and application of this Presidential Decree are resolved by the President of the Republic.

ARTICLE 22
(Entry into Force)

This Presidential Decree comes into force on the date of its publication.

Discussed by the Council of Ministers, in Luanda, on August 11, 2021.

Be it published.

Luanda, on September 6, 2021.

The President of the Republic, JOÃO MANUEL GONÇALVES LOURENÇO. (21-7413-D-PR)