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United Nations Office on Drug and Crime

**« Scaling Up the Implementation of International Drug Policy
Commitments on Improving Availability of and Acces to Controlled
Substances for Medical and Scientific Purposes – An Exchange of
National Perspectives and Good Practices »**

By
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Excellency Mr. Chair of the 65th session of the Commission on Narcotic
Drugs (CND),
Excellencies,
Dear colleagues,

First of all, allow me to thank Ambassadors Ghislain D'HOOP and Umej
BHATA for convening this meeting on a vital subject and for having thought
to invite us to share the experience of my country the DRC.

Mister Chair,

You were right when you stated in your letter of invitation that "improving the
availability of, and access to, controlled substances for medical and scientific
purposes is an issue of considerable significance to the Government of the
Democratic Republic of the Congo".

Indeed, the President of the Republic, H.E.M. Felix-Antoine Tshisekedi
Tshilombo, has since his accession to the head of the country, made it one
of his main concerns and is doing everything possible to materialize this wish
of the Congolese people inscribed in its Constitution.

Mr. Chair,

In order to respond to the provisions of article 47 of the Constitution which
guarantees the right to health to all Congolese, the Government of the DRC
is organizing to improve the availability and access to controlled substances
for medical and scientific purposes, as well as to meet national challenges in
the sector, in particular through the establishment of various regulatory
frameworks. These are mainly legal, organizational, and institutional
frameworks.

1. Regarding the **legal framework**, it must be said that national
legislation is based on the one hand on international conventions, particularly
the three Drug Control Conventions of 1961, 1971 and 1988; and other parts
on the needs of the populations.

Several ordinances and ministerial decrees have been issued by the
authorities of my country with a view to regulating the sector, in particular:

- **Ordinance No. 27 bis relating to the practice of Pharmacy, the traffic in toxic, soporific, narcotic, disinfectant or antiseptic substances, serums, vaccines and biological products and the cultivation of plants to pharmaceutical use.**

- Ordinance Law No. 18/035 of December 13, 2018, setting the fundamental principles relating to the organization of Public Health.

- Ministerial Order No. 1250/CAB/MIN/SP/008/CPH/OBF/2015 of September 28, 2015 regulating the trade in pharmaceutical products in DR Congo.

- **Ministerial Order No. 1250/CAB/MIN/S/0002/DC/OWE/2021 of February 27, 2021 setting the conditions for the exploitation of narcotic drugs and psychotropic substances for medical and scientific purposes.**

- **And, in relation to universal health coverage, the Ordinance No. 21/032 of June 01, 2021 on the creation, organization and functioning of the National Council for Universal Health Coverage.**

2. With regard to the **organizational framework**, it should be noted that the Ministry of Public Health, through the Department of Pharmacy and Medicines, is the competent National Authority responsible for the regulation and control of psychotropic and narcotic substances.

Within this Department, there is a Technical Division which deals with:

- The design, development, standardization, regulation and coordination of policies and strategies regarding narcotics, psychotropic substances, chemical precursors, and radioelements.

The Technical Division also, among others:

- Ensure the control of the manufacture, possession, trade and use of narcotics, psychotropic substances, chemical precursors and other toxic substances;

- Assess the needs for narcotics, psychotropic substances, chemical precursors and other toxins;

- **Apply national and international laws and regulations on the trade and use of drugs;**

- **Certify imports and exports of narcotics, psychotropic substances, chemical precursors and dangerous substances;**

- Develop strategies likely to combat drug abuse.

3. About the **institutional framework**, there is an inter-ministerial committee to combat the abuse and illicit trafficking of all products under international control involving all the ministries.

It should be noted that, every quarter, the Department of Pharmacy and Medicine organizes a control as well as the monitoring of the management of controlled substances for medical and scientific purposes with the pharmaceutical establishments that import or manufacture them.

4. To ensure **access to and availability of controlled substances**, the Government carries out certain operations, in particular the selection of substances, the approval of products, the use of the procedure for granting the import license substances under control, distribution to hospitals and pharmacies, and finally delivery to patients.

a/ Selection of substances

Molecules of substances under international control deemed essential for the care of patients are listed on the National List of Essential Medicines.

b/ Approval of products

No imported or locally manufactured product can circulate in the Democratic Republic of the Congo without the Marketing Authorization (AMM), so that controlled substances are also approved and listed in the national directory of authorized drugs.

c/ Procedure for granting the import license for controlled substances

The import of controlled substances for medical and scientific purposes is subject to the prior obtaining of an import license granted by the Department of Pharmacy and Medicine. The import license application process is currently digitized and secured with a license QR code for authentication.

This process is very long and can take a total of 6 months or more, from the initial request to the shipment of the products.

d/ Distribution to hospitals and pharmacies

Healthcare facilities and pharmacies obtain supplies of substances under international control on presentation of an order form signed by the responsible pharmacist. The Department of Pharmacy and Medicine provides them with a book of secure order forms.

e/ Delivery

The dispensing of controlled substances to patients is by presentation of a prescription.

5. Challenges:

The main challenges that we are facing are:

- Financing the supply of controlled drugs in the public sector;
- Out of stock;
- Real estimates of needs;
- Cost/Price;
- Health insurance not very developed;
- Local manufacture of morphine oral solution for the management of pain in patients in palliative care;
- The length of procedure;
- The very long conflict situation in the East part of the Country.

6. Collaboration with the United Nations Entities (INCBs)

To sustain the accessibility and availability of controlled substances, the Government works in collaboration with its bilateral and multilateral partners, particularly those of the United Nations system, including the WHO. Indeed, the DRC transmits necessary data through the Department of Pharmacy and Medicine to the United Nations Entities for better coordination in the actions to be taken, the Government share with them in particular:

- Annual statistics and information on the state of manufacture, production, use, consumption, stocks, and seizures. (Form C)
- Annual Assessment of Needs, Manufacture of Synthetic Narcotics and Opium Poppy Cultivation (Form B)
- quarterly statistics of imports and exports (Form A)
- forecasts of annual medical and scientific needs for psychotropic substances in Tables II, III and IV; (Form B/P)
- annual statistics on psychotropic substances (Form P)
- quarterly statistics of imports and exports of psychotropic substances in Table II of the 1971 Convention (Form A/P)
- annual information on the substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. (Form D).

Mr. Chair,

To conclude, I will say that, limited access to controlled medicines is a major global health problem, which calls for an urgent solution to save the lives of millions of people.

Our participation to this meeting should be seen as an expression of my country's readiness to contribute to strengthening the work of the CND in its mission to ensure the availability of and access to controlled substances for medical and scientific purposes, a commitment enshrined in the three international drug control conventions.

I thank you.