Terms of Reference
for

The Consultancy Service to Develop Veterinary Drugs Control Policy

1. Background

Somalia is just recovering from a protracted conflict and fragility and as such the government has given more priority to strengthening of the state and corresponding institutions, a process that has made Somalia attach less attention on developing and operationalzing important polcies for country. However, Somalia, just like how some of the least developed countries perform now, is revamping its instituational structures and appropriate capacity to get back to where it was before on service delivery. In order to reinstate these functional institutions, considering aforementioned scenario, country is propelled into reviewing gaps in its national policies and regulatory standards. Veterinary drugs control policy is one of the guiding standards being prioritised within the national policy reforms. The absence of ideal policies regulating the handling, sell, supply or manufacture of veterinary drugs and chemicals especially the proscribe only medicines (POM) keeps expanding disease prevalence within in the society, both for humans and livestock. Given that the livestock sector contributes significantly to the national GDP, household wealth and the economic equilibrium in the country, animal health and therefore veterinary drugs are valuable parameters within the national community. This is the reason for the prevailing quite significant levels of importion of veterinary drugs through the largely unregulated processes. Somalia's Ministry of Livestock, Forestry and Range (MoLFR) is the national institution that is charged with regulating, controling and guiding the use of the veterinary drugs in the country.The country has quite significant pool of animal health workers who are across the country providing consultation and licensed veterinary services to the vast pastoral production. It is worth to note that veterinary drugs often land in the hands of livestock owners who use them directly on their livestock. Relevant regulations and policies resonate with human and societal spatial dynamics and hence with time they require to align with evolving global trends.

The global approach for One Health is getting momentum as the unconsciousely perpetual use of antibiotics by humans and animals is increasing the resistant bacteria in the bodies of human and animals. Somalia's regulatory framework to regulate the use of the veterianry drugs was less emphasised in the past. And this gave the pastorlaists a leeway to buy drugs directly from drugs outlets and administer them to animals. The unethical acquisation of the veterinary drugs and medically unsupervised treatment of the livestock has been challenge for the Ministry of Livestock, Forestry and Range to battle. The direct administration of medicines by pastoralist who are not qualified animal health practitioners is increasing. The lack of a policy and enhancement

to check on handling of veterinary drugs that leads to quality standards weakness is one of the barriers limiting expansion of the export livestock market for Somalia.

Under the Horn of Africa Initiative, the World Bank Group is funding the De-Risking, Inclusion and Value Enhancement of Pastoral Economies Project (DRIVE). The Ministry of Livestock Forestry and Range is one of the project beneficiaries. DRIVE aims to protect pastoralists against drought shocks using a package of financial services including drought insurance, saving incentives and provision of credit funding where applicable, it connects pastoralists better to markets by upgrading the livestock value chains, quality infrastructure and facilitating regional livestock trade.. Lack of control of the use of veterinary medical substances limits and complicates free market for livestock due to uncontrolled handling and distribution of medcines.The Ministry of Livestock, Forestry and Range therefore will use part of the financial resources of the DRIVE project to facilitate a consultancy to develop a veterinary drug control policy.

2. Objectives of the Consultancy

The consultancy service will enable MoLFR to establish,a well designed, comprehensive and inclusive veterinary drug control policy that will result from the country-wide consultative engagements to serve the whole country. It will assess the domestic challenges related to unregulated utlization of veterinary medications by the people in the livestock value chains, the safe commercial movement of the drugs, accessibility and the quality of supplies. The consulting firm will therefore carry out an indepth and thorough analysis of those challenges and regulatory needs of the sector to produce a working policy which will be used to manage the veterinary drug market systems and use of the drugs. The specific objectives of the assignment are outlined below.

i. To carry out an indepth and through review of the current unregulated systmes of veterinary drugs use,sell, supply, importation and distribution of the veterinary drugs including maping the market actors such as retaliers, distributors and end users;
ii. To evaluate entry points of the veterinary drugs and chemicals to the country to enable formulation of the policy that will be equally applicable to all geographical locations of the country.
iii. Review and apply the standards and systems of the developed coutries, recommedned frameworks of the World Organzation for Animal Health (OIE), the Food and Agriculture Organization of the United Nations, the African Union Interafrican Bureau for Animal Resources, regional relevent policies and regulations and IGAD, to develop veterinary drug control policy for Somalia that is in line with regional and global standards;
iv. To conduct in depth consultations with relevent Somalia Federal Instituations including MOCI and SOBs, Federal Member State Ministries, and carry out thorough review of prevailing relevent polcies, regulations and guidelines from the said institutions to inform the production of a policy that is in harmony and in acceptance by all federal institutions;
v. Review roles and complementarity of the public and private sector in implementing the policy and recommend on the best mechanisms of these two sectors working together

for a common goal of the policy.

vi. Produce a draft of the comprehensive veterinary drugs control policy for Somalia based on broad review of documents mentioned in the above objectives, observations and consultations with relevant stakeholders.

vii. To conduct draft policy validation workshop(s) for the government stakeholders including the client ministry (MoLFR) leading to production of the final draft of the policy, which will also act to create its awareness among the stakeholders and provide recommendations for its implementation;

viii. Propose mechanisms of acquiring legislative backing of the policy to support it by a cabinet council endrosement and therefore standardised mechanisms of policy enforcement.

3. Scope of the Assignment

The assignment will be fulfilled in the following stages:

A. Inception stage:

The firm is expected to conduct a Somalia-wide situational analysis of the handling of veterinary drugs for better preparedness of quality output; review the relevant policies in place, the outputs of other similar works or consultancies, international veterinary drug control frameworks, Somalia general drug control policies, livestock acts, laws and regulations, veterinary drug use and supply frameworks in the country, animal health services, drug inspection, and certification services, one health and antimicrobial initiatives, education/training and communication, emerging and re-emerging animal health issues and zoonotic diseases, interactions and the views of major stakeholders and conduct any other necessary due diligence task. The consultancy will review available reports on animal to human disease transmission trends in the country, public health management strategies, policies and guidelines, and then benchmark for the veterinary drug control policy to be established with best international practices in developed countries. The reviews and assessments will have a climate smart lens to support knowledge development on the nexus between veterinary drugs control and climate adaptation and mitigation, especially the effects of drugs to the environment and vice versa. The consultancy will do prior consultations with the relevant stakeholders to collect as much information as possible to support the development of a pragmatic policy to regulate handling of veterinary drugs as well as a clear elaboration on of the policy implementation.

Additional activities include:

- review and analyze the existing legislation relating to veterinary drug control and any proposed revisions;
- survey the existing and potential institutional arrangements governing the registration, sale, storage and import of veterinary drugs;
- propose the basic principles of veterinary drug legislation and develop a draft veterinary drugs control policy;

Output/Deliverable: prepare a report of the above.

B. Drafting stage (legislation and policy development):

The consulting firm is expected to prepare the initial draft version of the required policy, recommendations for implementation, governance and its presentation to the stakeholders including institutional frameworks and guidelines and get feedback from stakeholders to aid in enriching the final policy document. Specifically, consideration of the following steps will guide the implementation stage.

i. **A veterinary drug control policy establishment** that aims to address the issues of veterinary drugs handling. This will be guided by the relevant policies and legal frameworks, institutional framework, information, education/training and communication, surveillance, policing and control on veterinary drug use, sell, storage and distribution, licensing, inspection and certification. It will also be informed through reference to emerging and re-emerging animal diseases and prevalent zoonotic diseases. The veterinary drugs control policy will present the guiding principles, the drug control system, safe and ethical use of the drugs, veterinary drugs importation guidelines and trade, among other factors for consideration. Additional areas to consider for guidance will include: relevant laws and acts of parliament and regulations, existing regulations pertaining to drugs administration to animals, drug inspection and registration and comparative risk analysis. In addition, further consideration should include review of the role of the private sector and their investments in the supply chain and how these should comply with the policy.

ii. **Governance and Institutional Structure for veterinary drug control:** This pertains to addressing policy implementation framework which will emphasize veterinary drugs control concerns in the broad areas of legislation, institutional frameworks, monitoring and evaluation, resources, foreseeable challenges, and mitigation. It will also touch on financing and monitoring as well as evaluation framework that will form an integral component to ensure the policy objectives are achieved in a cost effective, coordinated and harmonized approach at both the National and Federal Member States levels. Consideration should also be made on quantity of professional human resource and capacity assessment in terms of implementing the policy and regulations.

Activities include:

- draft and discuss with the responsible national veterinary, medical and legal authorities a recommended law on veterinary drugs control and drug veterinary control policy;
- draft any necessary regulations and forms to put into effect a system governing the production, import, sale, storage and use of veterinary drugs in Nepal;

draft report stating findings, conclusions, recommendations and draft legislation and draft for a drug veterinary control policy.

Proposed Outline for the reports

Consultancy: Assessment and Development on Veterinary Drugs Control Policy and Veterinary Drugs Legislation

BACKGROUND

a) Policy framework
b) Legal framework
c) Institutional framework
d) Livestock sector
e) Veterinary drugs needs
f) Present problems with veterinary drugs supply
g) Role of Minister of Livestock, Minister of Commerce and Industry, Somalia Bureau of Standards
h) Potential benefits/challenges: accession to EAC, COMESA, WTO, AcFTA
    a. What Somalia will need to enhance?
    b. Regulations
    c. Standards
    d. Inspections

REVIEW OF THE RELEVANT LEGISLATION (including any legislation existent If they do not exist underscore the one needed)

a) Drugs Act (or equivalent)
    i) Drugs Registration Regulation
    ii) Drugs Standards Regulation
b) Animal Health and Livestock Services Act
c) Somalia Veterinary Council Act
d) Other legislation
e) International Legislations that Somalia must comply:
   Animal Health ('OIE') Standards are: • the Terrestrial Animal Health Code • the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
   Antimicrobial resistance (AMR), antimicrobial use (AMU), and antimicrobial consumption (AMC)
f) Conclusions

REVIEW OF THE INSTITUTIONAL ARRANGEMENTS

a) Drugs administration
b) Livestock services
c) Conclusions

RECOMMENDATIONS

a) Options for reform
b) The recommended option for Somalia

CONCLUSION

C: Stakeholder consultation and validation stage: Stakeholder consultation and concurrence seeking on the consultancy work is critical for building ownership of the document and subsequent adoption of the policy. The successful implementation of the policy will depend on building consensus among concerned stakeholders, around an agreed platform of realistic priorities. Key stakeholders will be identified and included in reviewing and providing feedback on the analysis, policy formulation as well as plan of implementation to promote local ownership and awareness at every stage. The firm is expected to support the Ministry of Livestock by facilitating a series of consultations with stakeholders. Subsequently the consultant firm will be expected to consult the Ministry of Livestock in holding interim and final validation workshops with key ministry officials and other relevant key stakeholders (Somalia Bureau of Standards, plant and animal health inspection departments, state ministries of livestock, forestry and range, etc.) for the veterinary drug control policy to both receive feedback and outline the policy and implementation plans for adoption.

Deliverable: Workshop report with comments incorporated in the Veterinary Drugs Act and in the Veterinary Control Policy

D: Final Reports: Veterinary Drugs Act and Veterinary Control Policy

Outline Proposed for the Veterinary Drugs Act:

Chapter 1: Preliminary

1. Short title and commencement
2. Application of this Act
3. Definitions

Chapter 2: Veterinary Drugs Advisory Committee

4. Establishment
5. Membership
6. Functions
7. Meetings
8. Support services

Chapter 3: Registration of Veterinary Drugs

9. Objectives

10. Applications for registration
11. Essential list
12. Antimicrobial resistance (AMR), antimicrobial use (AMU), and antimicrobial consumption (AMC)
13. Evaluation
14. Registration
15. Classification
16. Period of validity
17. National Formulary of Veterinary Drugs

Chapter 4: Manufacture, Import, Export, Distribution and Sale of Veterinary Drugs

18. Authorisation in general
19. Authorisation to manufacture
20. Authorisation to import/export
21. Sale
22. Vaccines

Chapter 5: Inspection and Offences

23. Inspection
24. Offences

Chapter 6: Miscellaneous

25. Delegations
26. Reviews of decisions
27. Transitional arrangements
28. Regulations
29. Repeals

4. Firm and Core Team Qualifications

In order to be selected, the consultancy firm (or the joint venture) should demonstrate relevant competence and capability to successfully undertake the consultancy works. The minimum qualifications outlined as follows:

i. A minimum of 10 years of relevant experience in veterinary drug control regulations, animal health and public veterinary service, national policy development including in-depth practical experience in establishment and implementation of veterinary drugs standards, drugs trade, pharmacy and dispensing, safe food practices including animal-based livestock foods and supporting public institutions in developing the national policies using best practice approaches.

ii. Familiarity with veterinary drug control challenges faced by developing countries, demonstrated through experience working in these contexts preferably in Sub-Saharan Africa, expressed through at least one past assignment on vet drugs control policy

developed in a developing and fragile country.

iii. Expertise in veterinary drugs dispensing and management standards and protocols such as control, drug registration, good dispensing practices and veterinary pharmacovigilance as well as experience in drug trafficking and hazard analysis and critical control points.

The Consultant firm is required to demonstrate the following technical capacities and skills among its relevant multi-disciplinary team of expert composition for the assignment:

i. **Veterinary Drug Control Specialist (Team leader)**: The firm should provide a team leader with requisite successful experience (at least 10 years) with a minimum of Master of Science (M.Sc. degree) in veterinary medicine or a related field with competencies in veterinary drug control regulating and policing, quality assurance and risk analysis in livestock and veterinary medicines.
ii. **Animal Health and Welfare specialist**. This member will have knowledge to assure safety, quality and efficacy of veterinary medicines.
iii. **Pharmaceutical specialist in Veterinary products**
iv. **Specialist in livestock animals and livestock trade**

v. **Policy Development and Advocacy Specialist**: The firm will also be required to include in the team a policy development specialist to support social economics analysis and peer reviews on the existing policies and their effects to the food systems.

5. Reporting/ institutional arrangement

The consultancy firm will work under the direct supervision of the Director General Ministry of Livestock, Forestry and Range, the Policy Advisor of MLFR and the focal point and shall provide on weekly basis progress reports summarizing progress, challenges and any issues that require action from the MoLFR and the DRIVE Project. When necessary, the consultant firm will consult with the PIU of the DRIVE project and the World Bank, to include their inputs and opinions as well as inputs from the Ministry of Commerce and Industry, Somalia Bureau of Standards, relevant ministries in order to develop the national veterinary drug control policy that is in harmony and coherence with the regulations of the statutes of the other national institutions. Sharing of work progress updates, stakeholder meetings, and workshops shall be conducted within the agreed timelines by the parties and the final validation workshop shall be stakeholder sensitive, consultative and inclusive. A validation workshop shall be conducted for a final consultative opportunity by the stakeholders.

6. Deliverables and Timelines of the Assignment and Payment Schedule

The firm is expected to conclude the proposed assignment within 3 months. Expected deliverables and indicative timelines for delivery are outlined below:

Phase	Deliverable	Timeline	Payment
Inception Stage	work plan	15 days after signing contract	5%

	report on the main findings as per the activities describe in the TOR	5 weeks after signing contract	10%
Drafting (legislation and Policy)	Draft report as the outline above in section B Draft veterinary drug control policy Draft Veterinary Drugs Legislation	45 days after contract signature	25%
Stakeholder Consultation and Validation	Validation workshop with comments incorporated in the Veterinary Drugs Act and in the Veterinary Control Policy	75 days after contract signature	10%
Final Report	Veterinary Drugs Act and Veterinary Control Policy including all the forms needed (application for registration of veterinary drugs, import standards, etc	90 days after contract signature	50%

Final versions of all deliverables, incorporating feedback and recommendations 90 days (3 months) after contract signature), including short read-out consultations with relevant stakeholders and how they have been reflected.

Structure of the final veterinary drugs regulation policy document: The final document should be presented in three hard copies and a soft copy. The text should be presented in font 12 and type Times New Roman. The structure of the document should assume best practices currently used by international and regional policy frameworks