

## A Step Forward: Suggestions for Improving the National list of Veterinary Medicines in Libya

Sughir, Abdussalam<sup>(1),(2)</sup>; Khalf, Abdurraouf<sup>(3)</sup>; Abu-abdallah, Khadija<sup>(2)</sup> and Al-Sharif, Shukri<sup>(4)</sup>

<sup>(1)</sup> Department of Pharmaceutics, Faculty of Pharmacy, University of Elmergib, Alkhoms, Libya. <sup>(2)</sup> Libyan Supreme Committee for Registration of Veterinary Drugs, Preparations and Appliances (LSCVDR), Tripoli, Libya. <sup>(3)</sup> Department of Pharmaceutics, Faculty of Pharmacy, Zawia University, Al-Zawia, Libya. <sup>(4)</sup> Department of Medicinal Chemistry, Faculty of Pharmacy, Zawia University, Al-Zawia, Libya.

### ABSTRACT

The listing of the highest quality, safest and most efficacious medicines are essential to any national health system. Decision about addition of any drug to a national list of veterinary medicines can be country specific and dependent. This assessment attempts to objectively review the current national veterinary essential drug list in Libya that was drafted and approved in 2010. This evaluation compares and contrasts both the strengths and weaknesses of the current list. In order to update the National Veterinary Drug List by using the current advances of veterinary medicines and include practical information for relevant stakeholders, revision of the veterinary essential drug list is required.

**KEY WORDS:** Veterinary drugs, NVDL, LSCVDR, Libya.

### INTRODUCTION

Then I would link Listing as part of ensuring prudent use of antimicrobial of veterinary importance especially in controlling the introduction of drugs of unknown quality say counterfeit, unlabeled and strengthening legislation.

A component of protecting public health requires prudent use of veterinary antimicrobials, and availability of safe, effective and legal pharmaceuticals and antimicrobials. Protection of human and animal health is commonly accepted as the highest priority of national interest for sovereign nations. In support of protecting human and animal health, the Libyan Ministry of Agriculture, Livestock and Marine Resources (MALMR) has made an effort to review and legislate veterinary drug policies, regulations, and guidelines. The Libyan Supreme Committee for Registration of Veterinary Drugs, Preparations and Appliances (LSCVDR) is the competent authority responsible for the evaluation, approval, and surveillance of drugs used for animal. The National Veterinary Drug List (NVDL) was created in order to keep the minimum range of veterinary drugs available in Libya at all time. NVDL is a tool used by the LSCVDR to maintain a stable drug market in order to ensure drug safety and effectiveness [1, 2]. The NVDL attempts to anticipate the veterinary drug needs for a majority of animal diseases, and the use of this list has been linked to ensuring quality and cost-effectiveness of the veterinary drug supply in Libya, when combined with best veterinary practices. Animal health economics is highly dynamic and malleable given the globalization of trade

and translocation of various human and animal diseases across the world. These international pressures are forcing Libya to modernize and keep pace with its regulatory approach over drug review and registration to support greater pressures for maintaining human and animal welfare. However, a considerable challenge is providing availability of current veterinary products, and this requires continued efforts to address this problem.

Moreover, veterinary drug manufacturing today has much greater flexibility in demonstrating the safety and effectiveness of their products and with increased international harmonization has increased incentives to bring them to the market [3]. As a result, veterinarians have access to a greater number of veterinary products to treat and cure animals. Animal owners, including pet owners, are benefiting from healthier animals, and consumers are benefiting from better and safer food from the animals.

In Libya, veterinary drugs are chiefly used for food production animals because companion animals are culturally not as widely accepted into the home. Drugs used for food production animals are nationally regulated under the Health Law number 106 (HL-106) issued at 1973[4,5]. The HL-106 outlines the regulations, the approval and use of veterinary drugs analogous to the human drug approval process [4].

The concept of a national list of veterinary drugs was based on a human list of essential medicines defined in 1977 and modified in 1999 by the World Health

Organization (WHO) Expert Committee on the Selection of Essential Drugs. The Committee stated that, "Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford" [1, 6]. The intent and purpose of the NVDL in Libya was to define the "population" as animal population. Furthermore the NVDL was built on the principle that carefully selected veterinary medicines will improve the overall quality of animal health, provide cost-effective animal health care, and afford better management of veterinary treatments [1, 7]. Veterinary drugs, preparations and appliances are important tools in the prevention, treatment, and control of animal diseases. The World Organization for Animal Health (OIE) veterinary products classification includes vaccines, veterinary medicines including antimicrobial agents, and diagnostic kits to ensure effective and sustainable animal disease control while minimizing risks to humans and animals. The OIE provides guidance for the authorization, manufacturing, distribution and the use of veterinary products through government veterinary legislation [8]. Veterinary products are defined differently among different nations [8], although efforts are underway to harmonize the regulation and oversight of veterinary products and recognize product quality and uniformity through OIE sanctioned meetings such as the Veterinary International Conference on Harmonization (VICH).

A specialized scientific Committee was established to review NVDL in Libya. The Committee, formed according to ministerial decree from the Minister of Agriculture, operated under the supervision of the Libyan Supreme Committee for Registration of Veterinary Drugs, Preparations and Appliances [9]. The committee consisted of nine members, six members comprising teaching staff at the Faculty of Veterinary Medicine – Tripoli, representing different subspecialties including medicine, poultry, microbiology and parasitology. The remaining members of the committee represented the Libyan company for distribution of veterinary medicines and pesticides, a government sector responsible for distribution of veterinary medicines and pesticides in the country. The committee completed their review in six months after conducting 20 meetings. At conclusion the committee adopted the existing NVDL. The NVDL was issued to Libyan People by the decree of the minister of agriculture No. (12) 2010.

The existing NVDL was prepared as follows:

1. Review of all existing NVDL
2. The commission collected scientific and technical information required to develop NVDL based on the following:
  - a. scientific references for veterinary pharmaceuticals by the Faculty of Veterinary Medicine,
  - b. available internet information,
  - c. the OIE List of important veterinary antimicrobials,
  - d. an internationally banned drugs list, and
  - e. the United States Food and Drug Administration (FDA) regulations, lists and guidelines.
3. The selection of 286 pharmaceuticals to be included in NVDL were listed according to:
  - a. scientific name, and legal designation without further product specification or information (Table 1).

The critique of the NVDL 2010 is a subjective and objective assessment solely based on the current understanding and perceived interpretations of the essential medicines concept presented. The weaknesses were subjectively classified based on a general lack of information or misinformation provided to relevant stakeholder such as veterinarians, animal breeders, drug procurement managers, and policy planners [7]. Such information includes the drug dosage form, the concentration and the animal species. Ethiopian veterinary drugs list and OIE list for antimicrobial agent could be a good example for such lists [8, 10].

The 2010 NVDL-Libya contained errors of omission, typographic errors and lacked sufficient details. There was a general expectation that the present list would be current using the most up-to-date drug formulations and be based on current available literature available as of 18 June 2009 [9]. Though this list was subjected to review and revision over the course of 20 meetings, experts outside of this group were not actively solicited to make notable contributions. The NVDL did not adhere to the rigorous standards expected for a document of this significance, and there was also a lack of independent expert consultation. Initially, the NVDL existed only in print, resulting in limited distribution to all the relevant authorities and stakeholders. This evaluation compares and contrasts both the strengths and weaknesses of the current list, but concludes by acknowledging a revision of the veterinary essential drug list that is essential in order to update these veterinary medicines using the most current scientific advances and findings.

**Table 1. Examples of registered veterinary drugs in the NVDL 2010**

<b>Name of group</b>	<b>Number of Medicines in the NVDL</b>	<b>Example of veterinary drugs</b>
Antimicrobial agents	41	Amoxicillin, Ampicillin, Apramycin
Antiparasitic Drugs	53	Albendazole, Amitraz, Carbaryl
Emergency drugs and Antidotes	8	Adrenaline, Bethanechol
Antifungal Drugs	8	Amphotericin B, Griseofulvin, Nystain
Anti-inflammatory and Antihistaminic Drugs	29	Aspirin, Alimemazine, Carprofen
Antiseptics and Disinfectants	26	Acriflavine, Carbolic acid, Boric acid
Hormones	19	Alternogest, Estrogen
Anesthetics, Analgesics, Muscle relaxant and Sedative	45	Acepromazine maleate, Carfentanil
Fluid therapy	<i>All crystalloid solutions and Colloids</i>	-----
Vitamins, Minerals and Amino Acids	<i>All vitamins, minerals and amino acids</i>	-----
Miscellaneous	54	Activated Attapulgit, Allopurinol, Camphor

#### **NVDL 2010 (THE STRENGTHS)**

- **Issuance of Decree (69) 2009:**

The first embraced step was the issuance of decree of the minister of agriculture no. (69) 2009 to revise the NVDL under the direction of the LSCVDR [9]. Many countries do not revise their lists regularly due to many causes such as deficiency of, financial constraints or motivation. MALMR and LSCVDR must be recognized for conducting and completing these revisions.

- **Revising process:**

During the revision process, documentation and archiving of all relevant NVDL committee meetings was done transparently, and archived in LSCVDR. An executive summary was issued summarizing the process and data analysis. This archive provides a historical reference that will serve as a base for future updates.

- **Listing and classification:**

The revised NVDL gives abbreviated names with coding for all drug groups in alphabetical order and their associated classified therapeutic use, table 2. This is helpful for regulation and procurement purposes.

Fourthly, experts from different veterinary subspecialties were included in the Committee for the preparation of the list. This helped ensure that all the veterinary medicines required for priority diseases in Libya were included.

#### **NVDL 2010 (THE WEAKNESSES)**

Unfortunately, neither the executive summary nor relevant features of the NVDL were disclosed to the public. Without transparency to all stakeholders, the NVDL becomes a less effective tool to combat animal disease and protect human health.

- **Essential list or Positive list- the question**

The NVDL-2010 was established away from the recommendation of WHO e.g. the dosage form and concentration as well as animal species should be included in national essential list [6,11] while was not seen in NVDL.

Consequence of that is that the information provided under medicines columns remain incomplete [11,12]. A specific example from the NVDL 2010 is the antibiotic chloramphenicol, a drug included in the list only for ophthalmic uses without any other specifications relevant to drug concentration and dosage form.

- **Improper selection of medicines**

The very first medicine listed in the NVDL Libya 2010 is 'amoxicillin' as an antibiotic. It is well known that this drug is a broad-spectrum antibacterial agent belonging to beta lactam antibiotics and used to treat many bacterial infections in humans and animals. Amoxicillin like all drugs in the NVDL is mentioned without any details relevant to dose, dosage form, concentration or targeted

animal species. It is rather surprising that in all lists, drug details like those mentioned are crucial to distinguish the targeted animal species by the drug in the NVDL [8-11]. Another example from the NVDL 2010 is chloramphenicol, a drug included in the list for ophthalmic uses only. This classification suggests the drug is considered as banned in Libya for all other purposes, however, the drug is currently used for treatment of some infections in animals not intended for food production, such as in pigeons, particularly against *Salmonella paratyphus*. It may also be used against other bacterial infections of the gastro-intestinal tract; *E. coli* infections or respiratory tract and against systemic infections and septicemia.

The NVDL cannot be accessed from the Internet, and the printed copies must be officially requested from the National Center of Animal Health (NCAH), LSCVDR or MALMR. The lack of broader availability for the NVDL makes this document less useful, especially in a world experiencing increasing globalization due to internet access and increased communication. Also the lack of regular meetings or seminars organized by the government to help in disseminating information regarding the NVDL to all relevant stakeholders were supported factors in the poor accessibility to the NVDL.

### CONCLUSION

Based on our evaluation, the concept of the NVDL 2010 list is medically important as a valuable resource, but

**Table 2. Pharmacological groups, approbations and number of veterinary drugs included in the NVDL 2010**

Name of group	Group Code	Number of Medicines in the NVDL
Antimicrobial agents	AMA	41
Antiparasitic Drugs	APR	53
Emergency drugs and Antidotes	EDA	8
Antifungal Drugs	ANF	8
Anti-inflammatory and Antihistaminic Drugs	AIH	29
Antiseptics and Disinfectants	ASD	26
Hormones	HOR	19
Anesthetics, Analgesics, Muscle relaxant and Sedative	ANS	45
Fluid therapy	FLT	<i>All crystalloid solutions and Colloids</i>
Vitamins, Minerals and Amino Acids	VMA	<i>All vitamins, minerals and amino acids</i>
Miscellaneous	MIS	54

### OMISSION OF IMPORTANT VETERINARY MEDICINES

The insertions of veterinary medicines that are not taken into account by the principles of selection of National veterinary medicines are needed to treat or prevent the majority of animal diseases in the country. In case of veterinary medicines, veterinarians treat a variety of animal species kept for many different purposes. For example, according to the classification of OIE for antimicrobial agents, Spectinomycin is considered as veterinary critically important antimicrobial agent [13] due to its wide range of applications and the severity of diseases it is used to treat. Spectinomycin is only used in animals and few alternatives are available on the market. This antimicrobial is not found in the NVDL, and several other similar examples of critically important, very important and important veterinary medicines listed in table 3, against their relevant pharmacological class are also not included.

because of the lack of input in its construction and contents, and some flaws in distribution, the current draft of NVDL 2010 does not provide harmonization in terms of listing the medicines in the national animal health programs. A large number of veterinary medicines were inadvertently omitted in the NVDL. The list also lacks additional medication details such as medication forms and drug strengths. The NVDL 2010 list serves the purpose of being the official essential veterinary drug list in Libya. Unfortunately the list rather serves the purpose of being simply a less informative list of veterinary drugs permitted in Libya, lacking sufficient reference information for veterinary stakeholders. To better improve decree no. (69) 2009 would be to foster the collaboration for including greater professional and practical experience perspectives by expanding the consultation of national or international expertise to update and expand the NVDL in reference to guidance provided internationally by the WHO and OIE.

**Table 3: Examples of drugs omitted from NVDL and their classes**

Class	Drug	Class	Drug
Antimicrobials	Florphenicol Thiamphenicol Ciprofloxacin Danofloxacin Orbifloxacin Ofloxacin Difloxacin HCl Spectinomycin Fosfomycin	Antiparasitics	Clorsulon Oxyclozanid Bithionol sulfoxide Nitroxinil Doramectin Pyriproxyfen Flumethrin Permethrin Isometamidium chloride Diaveridine
Anti-inflammatories	Tolfenamic acid Dipyron (metamizole) Dicyclomine HCl	Tonics	Butaphosphan Toldimphos
Miscellaneous	Acetbutylate Heptaminol Volatile oils Bromhexine Diprophylline		

- Poor access to NVDL

### ACKNOWLEDGEMENT

This work was supported by Libyan Society of Pharmaceutical Scientists, (LSPS). Authors' wishes to thank LSCVDR for providing the necessary documents to accomplish this work.

### REFERENCES

1. The selection of essential medicines (2002): WHO Policy perspectives on Medicines. Geneva: World Health Organization.
2. National Drug Policy (2005): Nigeria, Federal Ministry of Health in collaboration with WHO, available on: <http://apps.who.int/medicinedocs/documents/s16450e/s16450e.pdf> or [https://www.google.com.ly/search?q=to+maintain+a+stable+drug+market+in+order+to+ensure+drug+safety+and+effectiveness&ie=utf-8&oe=utf-8&rls=org.mozilla:en-US:official&client=firefox-a&channel=sb&gws\\_rd=cr&ei=3FPMU-dsx-08uJaB6A4](https://www.google.com.ly/search?q=to+maintain+a+stable+drug+market+in+order+to+ensure+drug+safety+and+effectiveness&ie=utf-8&oe=utf-8&rls=org.mozilla:en-US:official&client=firefox-a&channel=sb&gws_rd=cr&ei=3FPMU-dsx-08uJaB6A4) (Accessed at 13.Oct.2014).
3. Smith M. V. (2013): The role of veterinary medicine regulatory agencies. *Rev. sci. tech. Off. int. Epiz.* 32(2): 393-408.
4. Libyan Health Law No.106 (1973): Available from: <http://www.aladel.gov.ly/main/modules/sections/item.php?itemid=105>. (Accessed at 16.Oct.2014).
5. Decree Minister of Health No. (456): (issuing the executive regulations of the health law No. 106). 1975 20/07/2014]; Available from: <http://www.seha.ly/site/index.php/2013-02-25-10-44-57> (Accessed at 16.Oct.2014).
6. WHO Expert Committee on the Selection and Use of Essential Medicines (2002): (12th: 2002: Geneva,

Switzerland), The selection and use of essential medicines: report of the WHO Expert Committee, 2002: (including the 12th model list of essential medicines). Available on; <http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html#Js4875e.5.2>. (Accessed at 17.Oct.2014).

7. Manikandan S and Gitanjali B (2012): National list of essential medicines of India: The way forward. *J. Postgraduate Med.* 58(1): 68 - 73.
8. World Organization for Animal Health. Veterinary products (2014): [cited 2014 22/07]; Available from: <http://www.oie.int/our-scientific-expertise/veterinary-products/>. (Accessed at 13.Oct.2014)
9. Decree of the Minister of Agriculture No.69 (2009): On the revision of the NVDL and decree Minister of Agriculture No.12 2010 on the adoption of the NVDL.
10. List of veterinary drugs for Ethiopia, First edition (2002): Drug administration and control authority (DACA) of Ethiopia, available at : <http://www.fmhaca.gov.et/documents/lvd4.pdf> (Accessed at 1.Mar. 2015).
11. The selection of essential medicines (2002): WHO Policy perspectives on Medicines. Geneva: World Health Organization.
12. WHO model list of essential medicines, 17th list (2011): Available from: <http://www.who.int/medicines/publications/essentialmedicines/en/index.html>. (Accessed at 17.Oct.2014).
13. Hamdy AH (1975): Efficacy of lincomycin and spectinomycin on canin.