

No.X.11035/385/2019-DRS
Government of India
Ministry of Health & Family Welfare
(Drugs Regulation Section)

Nirman Bhavan, New Delhi

Dated the 18th Nov., 2020

NOTIFICATION

The Government of India had constituted a committee under the chairmanship of Dr. R.K. Singh, Director, Indian Veterinary Research Institute for preparation of list of essential medicines for animal use. The committee has since submitted its report to the Government and after examination of the report, the Government of India has accepted the recommendations of the Committee *in toto* and adopted the National List of Essential Medicines for animal use as finalized by the Committee alongwith other recommendations as contained in the Committee's recommendations (Annexed).

2. The Government of India has further decided that the List will be operational with immediate effect.



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**Report of Committee for preparation
of
National List of Essential Medicines
(NLEM) for Animal Use**

Government of India

Ministry of Health and Family Welfare

Year: 2020

1. Introduction

The outbreaks of disease in the animals have major social and financial impacts. Animal diseases are not only danger to the Indian economy but also equally important in respect to the human health. During the recent years, majority of the infectious emerging diseases affecting the human have originated from animals. Thus, it is logical to safeguard the animal health which important for sustaining the human health. National Guidelines are required to be prepared based on the disease burden, priority health concern(s), affordability concerns and to be harmonized with the International Guidelines or literature for selecting the use of Veterinary medicines as per the diseases prevalence and objective evidences. Therefore, there is a need for preparation of the National List of Essential Medicines (NLEM) for Veterinary use.

2. Background

National Animal Disease Control Programme (NADCP) on Foot on Mouth Disease (FMD) and Brucellosis was launched by the Hon'ble Prime Minister of India from Mathura (UP) in coordination with the Ministry of Fisheries, Animal Husbandry and Dairying which envisages to fully control the FMD by 2025 through vaccination and to eradicate it by 2030, while control of brucellosis by calf-hood vaccination with *Brucella abortus* S19 strain vaccine.

In this regard, Department of Animal Husbandry and Dairying has made communication with the Ministry of Health and Family Welfare conveying that in the light of the essentiality and disease burden in the country along with other considerations of efficacy and safety, etc., the FMD (Trivalent) Oil Adjuvant Vaccine and *Brucella abortus* S19 live vaccine to be included in the National List of Medicines (NLEM) on priority so that the safe and effective veterinary vaccines can be made available to the stakeholders on reasonable cost to help make the national flagship programme successful within the stipulated time-frame.

Accordingly, considering the need to examine the issue holistically, the Committee was constituted by the Ministry of Health and Family Welfare (MoHFW), Government of India, vide File No. X-11035/385/2019-DRS, dated 15/10/2019 under the Chairmanship of Dr R.K. Singh, Director, Indian Veterinary Research Institute, Izatnagar, U.P, India to prepare List of Essential Medicines for Animal Use (Annexure I).

3. Proceedings of the committee

The Committee in its first meeting held on 14/02/2020 deliberated on the issue concerning with NLEM for veterinary use considering the prevalence of disease in animal sector and to adopt a mechanism by which the Veterinary Drugs including veterinary vaccines can be made available to the stakeholders, and veterinary healthcare providers, etc., at an affordable cost. Keeping in view of the above parameters, it was decided that NLEM is essential component and the committee unanimously decided to include that name of FMD (Trivalent) Oil Adjuvant Vaccine and *Brucella abortus* S19 Live vaccine in list of essential medicine for veterinary use. The committee also discussed on the irrational use of the antibiotics in food supplements, poultry, aquaculture and livestock, etc., that leads to

antimicrobial resistance (AMR) issue which is a major area of concern. Second meeting of the committee was held virtually on 17.07.2020.

Committee, after detailed deliberation, recommended the following points for consideration:

3.1 Essential Medicines for Animal Use:

As such, the meaning & list of essential medicines for animal use is not published by the national and international agencies. However, in the Indian context, the essential medicine may be defined as under:

Essential medicines for veterinary use are the medicines, which address the majority of animal or livestock health needs of the country based on the disease prevalence and objective evidences.

The essentiality of such medicines is generally based on safety, efficacy, and affordability in the context of the access of these medicines for veterinary use in the country.

4. Unique characteristics of Animal Disease

4.1 Patterns of Disease Prevalence:

Livestock sector has immense potential for growth in India. The animal husbandry department is a major contributor to the Indian economy and overall contribution is 28-32% in agricultural GDP and 4-6% of the national GDP. India possesses largest livestock population in the world with 528 million of domesticated animals. Livestock population in India is threatened by disease outbreaks, droughts, floods, and other climatic anomalies.

There are several diseases affecting livestock that cause serious adverse effects on the production and productivity of the animals, human health, trade of livestock, and animal products which ultimately adversely impact the overall economic development. In recent times, emerging and re-emerging diseases of livestock, poultry, and humans have tremendously increased. Many of the diseases bacterial disease like Brucellosis, Tuberculosis, and Glanders, as well as viral diseases like Corona, Influenza, Hendra and Nipah are of zoonotic significance. Beside them, several other viral diseases of animals in India, *Viz.*, Foot and Mouth Disease (FMD), Bluetongue (BT), peste des petits ruminants (PPR), Sheeppox, Goatpox, Camel pox, Infectious Bovine Rhinotracheitis (IBR), Malignant Catarrhal Fever (MCF) and bacterial disease like Haemorrhagic Septicaemia (HS), Black Quarter (BQ), Anthrax, and Brucellosis are endemic and a few of them do have potential of crossing the continental boundaries.

Emergence of new pathogens creates additional risk and warning to the livestock and human population. Higher occurrences of emerging and re-emerging diseases might be due to various factors like crowded livestock and human population, deforestation, lack of public awareness, and increased contact between livestock and humans with wild animals and birds. The global expansion of cultivable land, population growth, intensive industrialization, climate changes, movement of vectors, illegal and unregulated trade, hiding/under reporting of the disease outbreaks

are other reasons for the emergence and spreading of the disease. Recently, many outbreaks of emerging diseases like Bovine Spongiform Encephalopathy (BSE), Paramyxovirus Infection in pigs (Nipah) and horses (Hendra), Severe Acute Respiratory Syndrome (SARS), Rabies, Tuberculosis, Bovine Corona Virus, Lyme disease, Crimean-Congo Hemorrhagic Fever, West Nile virus and zoonotic H₅N₁ Avian Influenza were detected, which cause significant morbidity and mortality in the developing world. Emerging and re-emerging diseases arise due to genetic changes because of immunological pressure and recombination with other viral or cellular genes.

There has been a constant risk of emergence of novel pathogens/diseases into a disease-free country resulting in grave impact on animal health due to high morbidity and mortality. Exotic (non-native) diseases/organisms, after entering in a country can become more intense into an epidemic if overlooked by the veterinarians due to its non-recognition or being prejudice of its non-occurrence.

4.2 Expenditure on Veterinary Health in India:

In most developing countries including India, resources for controlling zoonoses and foodborne diseases are scarce. Therefore, funding for existing and new Veterinary Public Health (VPH) programmes – such as the strengthening of animal disease and zoonosis surveillance and control as well as the modernization and expansion of slaughterhouses – should be allocated on a priority basis. Strong government support is essential for improving VPH services in India. While the industry is in a growth phase, some challenges remain to be tackled. The issues of concern include lack of penetration of modern veterinary care and unscrupulous unorganized sector activities. Given the vast spread of India's rural population and the fact that the modern animal husbandry concepts are not uniformly present, the industry still has long strides to make. The reach of modern veterinary care is indeed limited with market penetration impacted both by cost of distribution & price of modern medical care, apart from knowledge gaps in the customers. Many states are providing free medicine to the farmers. The NLEM may act as a guidance document for governments to frame strategy in this regard.

4.3 NLEM and its importance for access and availability.

In order to make medicines affordable, the Ministry of Fisheries, Animal Husbandry and Dairying, Government of India has recently launched The National Animal Disease Control Programme on Foot on Mouth Disease (FMD) and Brucellosis which envisages to fully control the FMD by 2025 through vaccination and to eradicate it by 2030 while control of brucellosis by calf-hood vaccination with *Brucella abortus* S19 strain vaccine. The main objective of NLEM is undoubtedly to promote the rational use of veterinary medicines and optimum utilization of resources available for healthcare delivery to animals. The center of discussion of the constituted committee was based on the main theme of efficacy, safety, comparative cost-effectiveness, and the prevalence of disease as major criteria for drafting NLEM.

4.4 Innovation and NLEM

Considering the huge disease burden on animal health in a country like India, research and development is of paramount importance for bringing new medicines into the market. Discovery and development of new veterinary medicine molecules is a complex, knowledge-intensive activity requiring involvement of expertise from various fields, considerable time and resources. Indian animal health industry should be encouraged for incremental innovations. The user of NLEM may consider this aspect while using the NLEM for providing services in the animal health care system.

4.5 Country Specific Disease Burden

Animal Disease scenario in India is encouraging for the fact that India could eradicate Rinderpest - the most dreaded livestock disease - that vanished herds of cattle. But there are several infectious and non-infectious diseases, both old and new, like FMD, Bluetongue, Classical Swine Fever, Sheeppox, Goat pox, and Brucellosis, *etc.*, that are prevailing in the country causing huge economic loss annually. FMD and Brucellosis are endemic in India and it has been estimated that the economic loss suffered due to these two diseases together is around Rs 50,000 Crores annually through direct usage and trade implication affecting export potential. There are only a very few manufacturers involved in manufacture of FMD and Brucella vaccine in private sector and none so far in public sector. The total capacity of the manufacturers for the two vaccine is barely sufficient to meet the annual demand of vaccines in the country which would involve vaccination twice of all cattle and buffalo (about 30 crore), sheep and goat (about 20 crore) and pigs (about 1 crore) for FMD and vaccination of about 3.6 crore cattle and buffalo calves once a year for Brucellosis. Apart from this, there is a risk for outbreak of the emerging diseases like BSE (Bovine Spongiform Encephalopathy) and exotic Disease incursion (introduction of new pathogen) in the country.

4.6 Priority Livestock Healthcare Concerns; Prevalence of Disease

A significant obstacle for the growth in terms of production from livestock and poultry is the prevalence of diseases of economic importance as these cause huge economic losses nationally. Livestock are more prone for diseases because of huge population, lack of awareness among farmers, backyard system of rearing, inadequate nutritional status of the animals and prevalence of diseases like FMD, HS, Haemoprotozoan infections (Babesiosis, Trypanosomiasis, Theileriosis *etc.*), Brucellosis, and PPR, *etc.*

4.7 Affordability and Availability Concerns

Affordability of a veterinary medicine for livestock medical care depends on a number of factors such as the status of the veterinary healthcare, lack of basic infrastructure and equipment, farms, dairies, and socioeconomic status of the people. There may be situations where some veterinary medicines or formulations may have advantage over the other veterinary medicines/formulations in similar class, but the high cost differential and unaffordability by common man may not merit their inclusion in NLEM for animal use. In India, where out-of-pocket expenditure for healthcare is quite high, NLEM for animal use may act as an important tool in government's initiative to make the veterinary medicines affordable and available to the public. The high cost of the veterinary medicines available to the rural population having the highest percentage of livestock makes it mandatory to provide veterinary drugs easily available for the prevention of the livestock diseases.

There may be a situation where one formulation of a veterinary medicine may have higher cost but with significant advantage of safety and/or efficacy over the other formulation of the same veterinary medicine. Because of the advantage, the costlier formulation may be included in the list. However, considering the socioeconomic conditions, formulations which are less expensive may also find a place in the list.

4.8 Drug residues and Antibiotic Resistance

Veterinary drug residues in animal products, especially milk and meat, is something that requires serious contemplation. Though there are standards for withdrawal periods for various drugs before milk from the animal can be used, it is hardly followed in our country. The situation gets further aggravated due to indiscriminate use of antibiotics for therapeutics and, at times, for prophylaxis that could lead to a range of problems in the consumers, like, emergence of drug resistant strains of bacteria, cancer, allergy, reproductive disorders, and hepatotoxicity, etc.

5. Purpose of the National List of Essential Medicines for Animal Use

The NLEM for animal use may have multiple uses. It can:

1. Guide safe and effective treatment of prevalent, endemic, and zoonotic disease conditions of livestock,
2. Promote the rational use of veterinary medicines,
3. Optimize the available livestock health resources of a country.

It can also be a guiding document for:

- a) State governments to prepare their list of essential veterinary medicines,
- b) Procurement and supply of veterinary medicines in the public sector,
- c) Re-imbursment of cost of veterinary medicines by organizations to the farmers,
- d) Identifying the 'MUST KNOW' domain for the teaching and training of veterinary care professionals, and,
- e) Guiding on the safe use of veterinary medicines to avoid emergence of antibiotic resistance.

6. Considerations for Framing the NLEM for Animal Use

6.1 Essentiality

Every veterinary medicine may be necessary or even critical for specific disease conditions for which it is indicated. But in the context of NLEM, a veterinary medicine may be essential considering the large population of livestock and should fit into the definition mentioned earlier. Hence, a medicine which is critical for a specific condition may not be listed in the list of essential medicines if the disease condition for which it is indicated has low prevalence or is rare. This does not mean that if a particular medicine is not included in the list of essential medicines, it is not necessary. In no way, exclusion of such medicines from the list undermines their importance in therapeutics and need of their availability at an affordable cost.

The NLEM for animal use can serve as a reference document for veterinary medicines of national importance so that administrative, scientific, pharmaceutical, and logistic efforts are appropriately directed leading to optimum utilization of the resources available for effective healthcare delivery to animals.

6.2 Changing Disease Burden

Disease burden is an important consideration for identifying the essential medicines. Medicines needed to manage diseases in animals that are highly prevalent or are emerging diseases in the livestock population will qualify for inclusion in the NLEM for animal use. For example, FMD and Brucellosis are endemic and it has been estimated that the economic loss suffered due to these two diseases together is around Rs 50,000 Crores annually through direct usage and trade implication affecting export potential.

6.3 Efficacy and Safety

Safety and efficacy are the most important criteria for considering essentiality of a medicine. For a medicine to be considered essential, it should have an unequivocal evidence of efficacy and wider acceptance in veterinary medical science. The medicine should have a safety profile which is acceptable in terms of risk benefit assessment. The safety profile of a medicine may change over time as new adverse effects may be discovered after wider use of the veterinary drug. This may change the risk benefit assessment and a veterinary medicine once preferred may no longer remain so.

6.4 Comparative Cost-effectiveness

This is especially important when selecting more than one veterinary medicine from the same therapeutic category and when they do not differ significantly in their efficacy & safety. Sometimes per unit price of the veterinary medicine may be more but it may be required to be given at a lesser frequency. Thus the total price of the treatment schedule should be taken into consideration and not the unit price alone.

6.5 Fixed Dose Combinations (FDCs)

As a principle, single veterinary medicines are to be preferred. The Fixed Dose Combinations (FDCs) are included only if the combination is rational and has a proven advantage with respect to therapeutic effect, safety, and compliance or in decreasing the emergence of drug resistance. Some examples are agents like nematodes, helminths, which may be partly caused by poor compliance. In these therapeutic categories, certain FDCs have been considered as essential for animal use.

In certain other cases where FDCs are critical for their optimal efficacy, such FDCs are also considered as essential.

6.6 Licensing

The veterinary drugs including veterinary vaccines are licensed as per the provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder. The drugs including veterinary vaccines are licensed based on the field trial data generated by the firm and after thorough evaluation of the safety and potency parameters. The proposal of the firm for the manufacturing and import permission is also examined and evaluated by the Ministry of Fisheries, Animal Husbandry and Dairying in coordination with CDSCO. For inclusion of the drug in the NLEM for animal use, the drug should be licensed by the approving authority and have documented its safe and effective use in veterinary practice.

7. Rationale of Essential medicines for animal Use– a Dynamic Document

The list of essential medicines cannot be static but has to be ever dynamic. It needs to be updated/revised periodically due to the following reasons:

7.1 Changing Disease Burden Profile

The disease burden in animal population does not remain static and keeps on changing both in short- and long-term. Diseases which are highly prevalent or newly emerging diseases in the livestock population are becoming major animal health issues. Therefore, the veterinary medicines shall be updated from time-to-time basis.

7.2 Antimicrobial Resistance

Antimicrobials are essential for treatment of sick animals, but even if used correctly, may eventually lead to antimicrobial resistance. Veterinary pharmaceuticals, therefore, contribute in many ways to the emergence of antimicrobial resistance either directly in suboptimal usage in animals or indirectly in human who consume sub-therapeutic doses in animal products. The emergence of the resistant pathogens necessitates inclusion of newer antimicrobials or efficient use of antibiotics for the treatment of such infectious conditions which, in turn, require updation of NLEM regularly.

7.3 Development of Newer and Better Medicines

Considering the huge disease burden in a country like India, research and development is of paramount importance for bringing new veterinary medicines into the market. Discovery and development of new veterinary medicine molecules is a complex, knowledge-intensive activity requiring involvement of expertise from various fields, considerable time and resources.

8. Conclusion

The committee framed the following guideline and procedure for preparation of NLEM for animal use.

8.1 Procedure and Guideline :

The criteria for inclusion of the medicines (Drugs and Biologicals) in National List of Essential Medicines (NLEM) for animal use are as under:

- The Veterinary medicine with its dosage forms, strengths should be approved/licensed in India.
- The Veterinary medicine should be useful in disease which is prevalent in animals in the country.
- The Veterinary medicine should have proven efficacy and safety profile based on valid scientific evidence.
- The Veterinary medicine should be cost-effective.
- The Veterinary medicine should be aligned with the current treatment guidelines for the disease.
- The veterinary medicine should be stable under the storage conditions in India. When more than one veterinary medicines are available from the same therapeutic class, preferably one prototype/medically best suited veterinary medicine of that class to be included after due deliberation and careful evaluation of their relative safety, efficacy, and cost-effectiveness. Price of the total treatment to be considered and not the unit price of a medicine.
- Fixed Dose Combinations (FDCs) for veterinary use are generally not included unless the combination has unequivocally proven advantageous over the individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.
- The listing of veterinary medicine in NLEM is based according to the categories /species of the animals in which it is to be used.

8.2 The committee finally recommended following two vaccines as Essential for Animal use in Indian context at this point of time.

1. Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine
2. Brucella Abortus (S19 strain) Vaccine, Live Freeze Dried

The committee also mentioned that NLEM is a dynamic document and there is scope to explore the possibility to include other veterinary vaccines like Camelpox Vaccine, Sheeppox Vaccine, PPR Vaccine, Goatpox Vaccine, Orf Vaccine, Buffalopox vaccine, and Poultry vaccines, *etc.*, in the NLEM at the appropriate stage based on the deliberations and inputs of disease prevalence and objective evidences.

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Based on the discussion of the committee, it was unanimously decided that the National List of Essential Medicines (NLEM) for Animal use at this stage is as following.

S No.	Name of the vaccines
1.	Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine
2.	Brucella Abortus (S19 strain) Vaccine, Live Freeze Dried

Annexure I:

No. X.1 1035/385/2019-1485
Government of India

Ministry of Health & Family Welfare
Department of Health & Family Welfare
Drugs Regulation Division

Human Resource, New Delhi,

the 16th October 2019

Subject: Constitution of a Committee for preparation of a list of essential medicines for animal use - reg.

The Government has decided to constitute a Committee for preparation of a list of essential medicines for animal use. The composition of the Committee shall be as follows:

1.	Dr. B. K. Singh	Director, Indian Veterinary Research Institute, Meerut	Chairperson
2.	Dr. A.R. Nandi	Head, Standardization Division, Indian Veterinary Research Institute, Meerut	Member
3.	Director	Chemistry Chander Singh National Institute of Animal Health, Baggpat, Meerut	Member
4.	Dr. Himanshu Barn	Scientist, Veterinary Sciences, Central Drugs Research Institute, Lucknow	Member
5.	Dr. Gaurinder	Asst. Prof. Lala Lajpat Rai University of Veterinary and Animal Sciences, Hisar	Member
6.	Dr. Anil Sanyal	Joint Director, Indian Veterinary Research Institute, Meerut, Meerut	Member

1	Representative from Veterinary Council of India	Member
2	A representative of Department of Animal Husbandry & Dairying, Ministry of Animal Husbandry, Dairying and Fisheries	Member
3	A representative of FSSAI	Member
4	A representative of CDSCO	Member
5	A representative of IFC, Gurgaon	Member
6	A representative of NBE, Delhi	Member

The Terms of Reference of the Committee will be as follows:

1. The Committee shall prepare detailed guidelines and proceedings for preparation of list of Essential Medicines for animal use;
2. Before finalizing the list, the Committee shall obtain views from experts/ stakeholders by organizing consultative workshops or meeting.
3. If considered necessary, the Committee can interact with the stakeholders like Civil Society, voluntary drug manufacturers, academics, individual experts on the subject, etc.
4. The Committee shall submit its report within 06 months from the date of its 1st meeting.
5. TA/DA/honorarium for non-official members and other logistic support will be paid / provided from the budget of the Indian Pharmaceutical Commission, Gurgaon (U.P.) as per rules.
6. The members / experts should sign prior declaration on conflict of interest.

(R.S. Singh)

Under Secretary to the Govt. of India

Telex: 25083019

To

The Chairperson and all members of the Committee