# GOVERNMENT OF INDIA MINISTRY OF FISHERIES, ANIMAL HUSBANDRY & DAIRYING DEPARTMENT OF ANIMAL HUSBANDRY & DAIRYING LOK SABHA

UNSTARRED QUESTION NO. 2002 TO BE ANSWERED ON  $3^{RD}$  MARCH, 2020

### QUALITY MEDICINES TO ANIMAL HUSBANDRY SECTOR

#### 2002. SHRIMATI DARSHANA VIKRAM JARDOSH

Will the Minister of FISHERIES, ANIMAL HUSBANDRY & DAIRYING मत्स्यपालन, पशुपालन और डेयरी मंत्री

be pleased to state:

- (a) whether the Ministry has proposed to formulate a concrete policy for providing quality medicines to animal husbandry sector in coordination with the Department of Animal Husbandry;
- (b) if so, the details thereof;
- (c) whether the Ministry has proposed to formulate a concrete policy for enhancing research and developmental activities in animal husbandry sector;
- (d) whether the Government complies with international norms for providing quality medicines to animal husbandry sector; and
- (e) If not the concrete reasons therefor?

#### **ANSWER**

## THE MINISTER OF STATE FOR FISHERIES, ANIMAL HUSBANDRY & DAIRYING (DR. SANJEEV KUMAR BALYAN)

- (a) and (b) Drugs, including veterinary drugs, are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules made there-under. Central Drug Standards Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is administering the Drugs and Cosmetics Act, 1940 and Rules made there-under. CDSCO issues license for manufacture, marketing and import of drugs including veterinary drugs.
- (c) The Indian Council of Agricultural Research (ICAR) under the Department of Agricultural Research and Education (DARE), Ministry of Agriculture and Farmers Welfare, Government of India is mandated to work in the area of agricultural research and development including animal husbandry. ICAR has 19 Animal Science Institutes working in the area of livestock and poultry production including species specific institutes carrying out research in various species for improvement in Animal Health Management and conservation of elite germ plasm for better progeny.

All India Coordinated Research Projects (AICRP)/All India Network Project (AINP)/Outreach Programme (ORP)/Consortium Research Platform (CRP) are coordinated by ICAR for breed improvement and management of Animal Health through development of specific point of care diagnostics and vaccines including prophylactics.

- (d) and(e) As per information received from the Central Drugs Standard Control Organization (CDSCO), Government has taken the following regulatory measures to ensure quality of drugs in the country—
- i) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
- ii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.
- iii) States / UTs have been requested to set up special Courts for speedy disposal in respect of offences under Drugs and Cosmetics Act.
- iv) On 27/10/2017, the Drugs and Cosmetics Rules, 1945 were amended vide Gazette notification no. G.S.R. 1337 (E) making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drug Inspectors of the Central Government and the State Governments.
- v) The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government to verify the compliance with the conditions of license and the provisions of the Drugs & Cosmetics Act and Rules for not less than once in three years or as needed as per risk based approach.
- vi) On 10/04/2018, the Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification no. G.S.R. 360 (E), making it mandatory that the applicants shall submit evidence of stability, safety of excipients, etc. to the State Licensing Authority, for all drugs, before grant of product manufacturing license by the authority.