Checklist for submission of dossier in uniform and Concise format by the firms for import/manufacture of drugs/vaccines/biologicals

The checklist for submission of dossier in Summary/Concise format by the firm for import/manufacture of drugs/vaccine/biological is as follows (Data/proof for all claims to be included)

1. Name of the product (details in case of microbes like serovars, strains, variants)
2. Manufacture/Import from Country (In case of import – Place of manufacture & name of the country/source)
3. Justification/reasons for import
4. **General Requirement**

    i. Target species

    ii. Composition

    iii. Active ingredient(s)

    iv. Indications for use

    v. Dose

    vi. Potency/Titer

    vii. Route of administration

    viii. Onset and duration of immunity

    ix. In case of combo vaccines/drugs advantages over single product

    x. In case of change in drug composition or vaccine Strain-reasons to be given (with proof for justification)

    xi. Contradictions/precautions if any (Special warning/precaution for each target species)

    xii. Adverse reaction (frequency and seriousness)

    xiii. Use during lactation/pregnancy/layers/Broiler Breeder

    xiv. Overdose reactions/ margin of safety

    xv. Shelf life (Specify Temperature)

    xvi. Storage (Temperature)

    xvii. Vaccines -

    Live/ Attenuated/inactivated/Killed/ Recombinant

5. **Data required**

i. Summary on Efficacy claims and study data
ii. Laboratory efficacy claims
iii. Summary on studies of safety
iv. Pharmacological properties
v. Studies/publications/ homology related to prevalence of strain(s) in the country against which intended to be used
vi. Clinical trial data
vii. In case of change in drug composition or vaccine Strain-safety/efficacy studies related to the proposal

6. Use in other Countries, if used/registered/patented (Patent details) along with names of countries

7. Rejected/ banned by any country

8. Narcotics /any banned substance.

9. Whether it is GM product, give details.

10. Environmental impact/shedding period and mode

11. Novel strain, first time Import-Advantage over present vaccine strains available in India.

12. Labelling –withdrawal period in case of drugs/any other safety requirement /precaution, indication, contraindication.

13. Excretion in milk in livestock/ eggs in poultry

14. Maximum residual effects in case of animal drug; time withdrawal recommended if any (with details)

15. Is the firm /trader able to monitor the usage through retailers or is it possible for them to trace back or recall in case of any problem

16. Whether the product is as per standards given in Indian Pharmacopea-2018 **(Latest edition) or any other standard(specify)**

17. What is the utility of the product is for the Indian animal health sector and how this product is novel.

18. Any publications to support the claims on the product (If yes, please provide the reference)
19. Impact of drugs/vaccine on environment / human/animal