Regulatory Status of Veterinary Medicinal Products (VMPs)- An Indian Perspective

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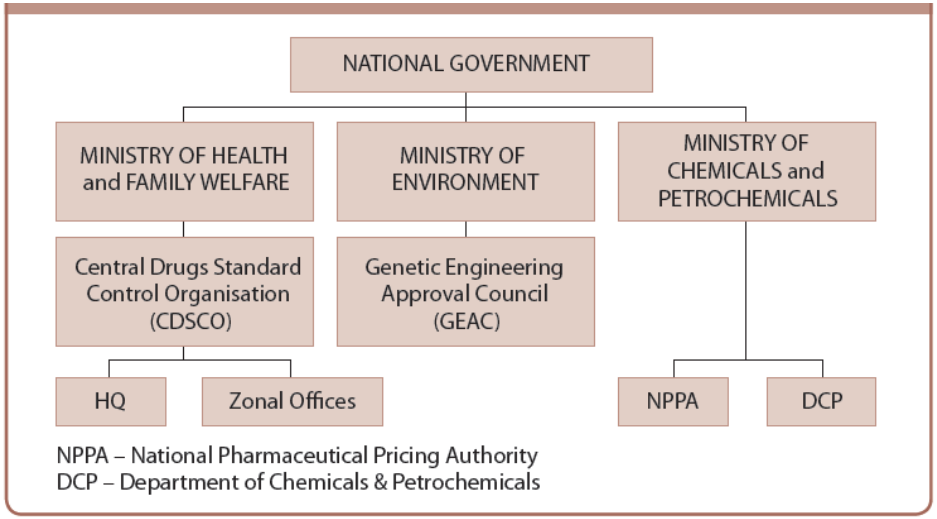
Regulatory Structure in India

- India is a federal form of government and the medical regulatory structure is divided between National and State Authorities .
- The principal national drug authority based in New Delhi is the Central Drug Standards Control Organization (CDSCO). CDSCO is controlled by the Drug Controller General India (DCGI).

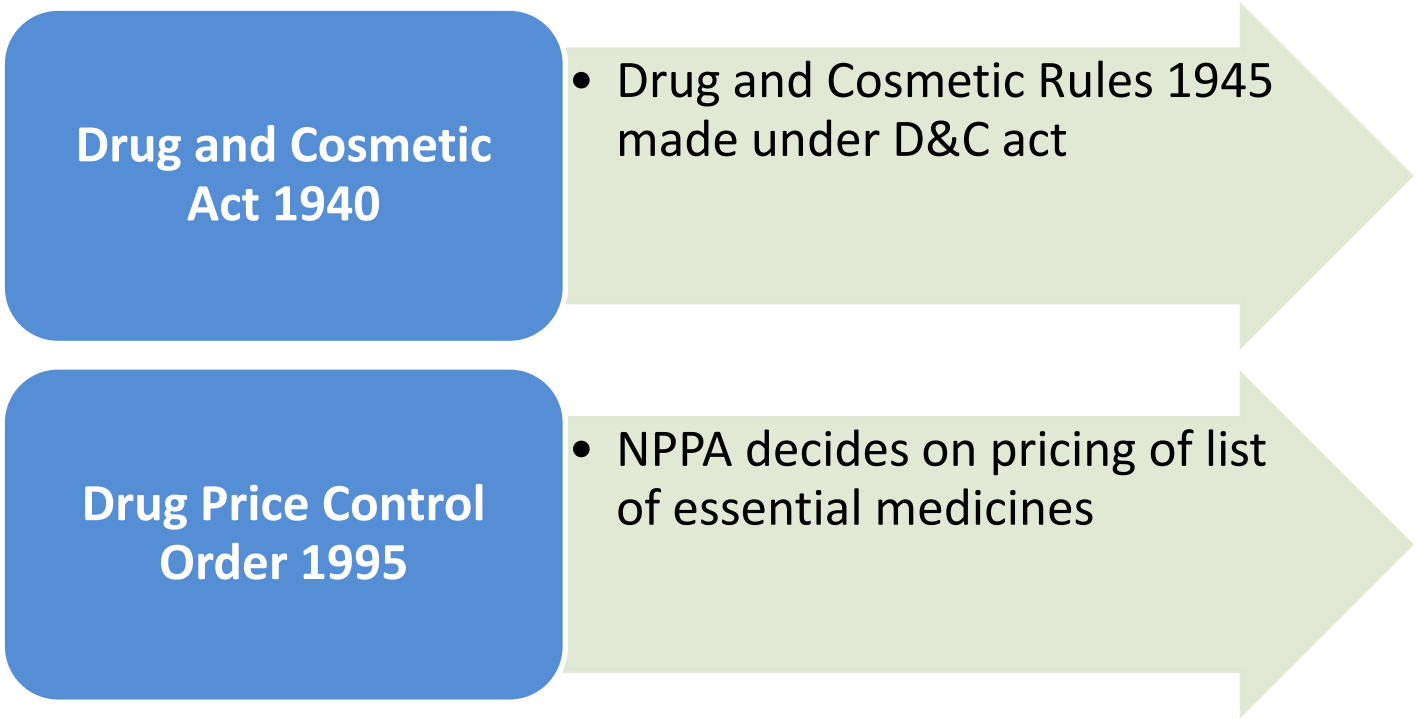
Regulatory Structure in India

- There are also 35 state-level Food and Drug Administrations, one for each of India's states and territories.
- The DCGI registers all imported drugs, new drugs, biologicals and drugs in selected categories.
- It also has responsibility for medical devices, clinical trials and quality standards.
- The state FDAs register all other products, accredit manufacturing plants, and conduct the bulk of quality monitoring and inspections.

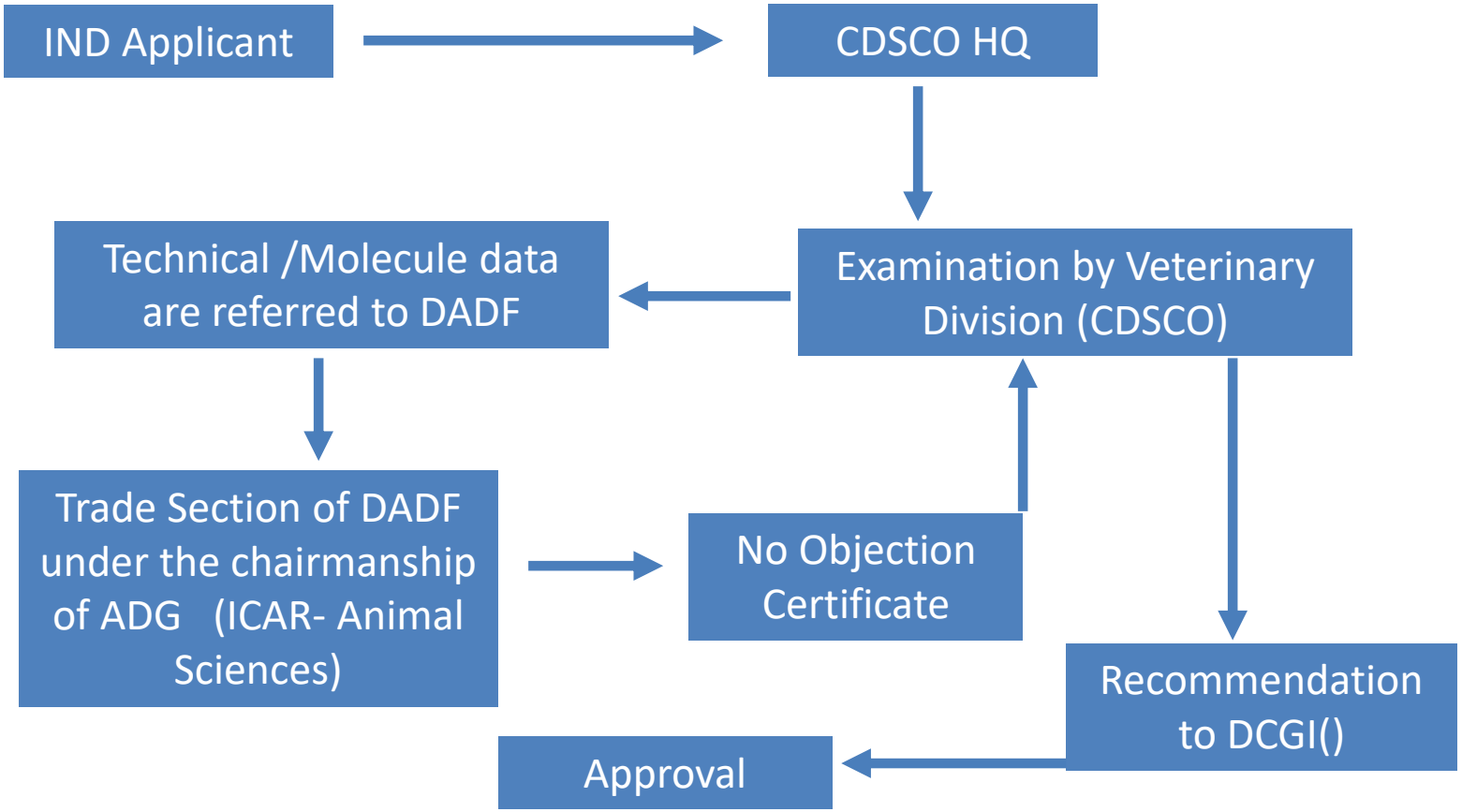


Regulatory body	Approval
Drug Controller General of India (DCGI)	Import registration approval
Drug Controller General of India (DCGI)	New drug registration approval
Drug Controller General of India (DCGI)	Medical device application and approval

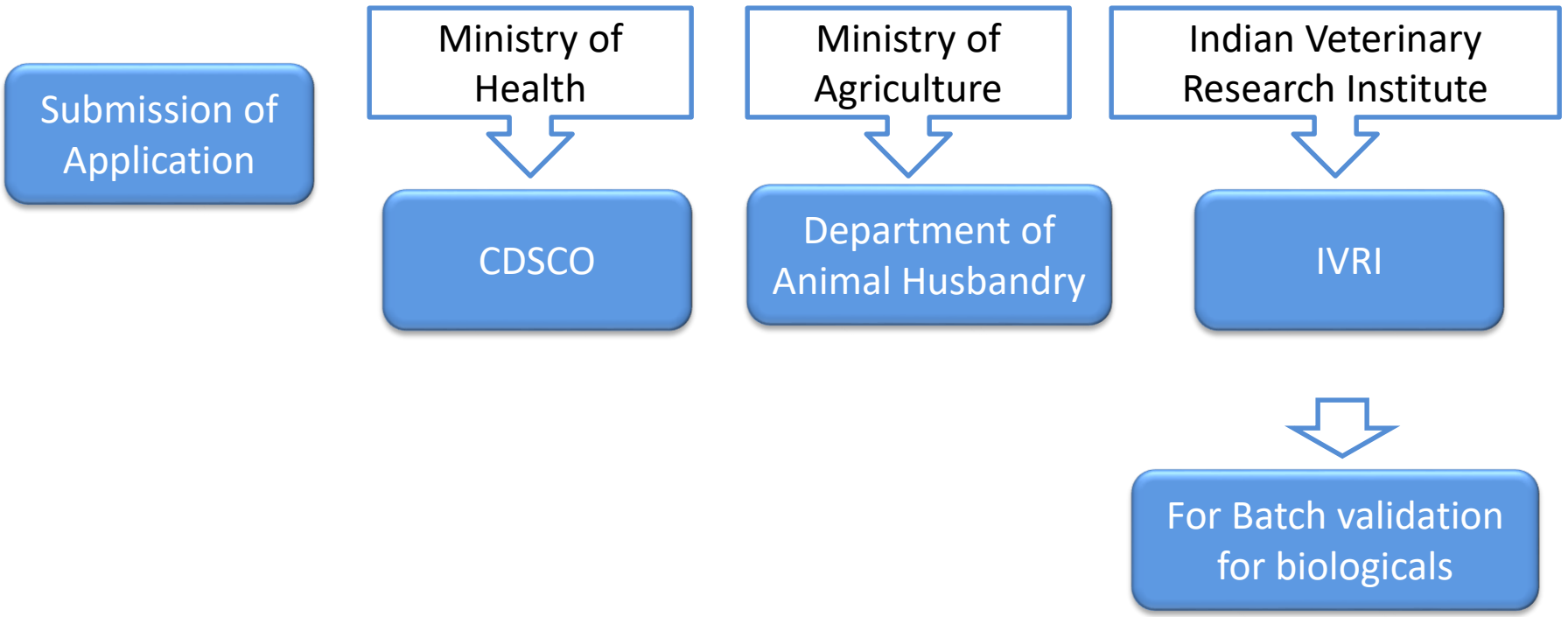
Drug Regulations applicable for India



VMPs Approvals in India



Registration of Veterinary Drugs



Import, Registration and Licencing

TYPE-1
Drug containing
Molecules Already available in India

- Registration certificate
- Import Licence

TYPE-2
New Drugs, Biologicals and Medical Devices

- Import Permission
- Registration certificate
- Import Licence

RC and IL are valid for 3 years and there after needs to be renewal regularly

US/EU/IND- Regulatory bodies

Requirements	US	EU	INDIA
Agency	One Agency USFDA	Multiple Agencies • EMEA • CHMP • National Health Agencies	One Agency DCGI
Registration Process	One Registration Process	Multiple Registration Process • Centralized (European Community) • Decentralized (At least 2 member states) • Mutual Recognition (At least 2 member states) • National (1 member state)	One Registration Process
TSE/BSE Study data	TSE/BSE Study data not required	TSE/BSE Study data required	TSE/BSE Study data required
Braille code	Braille code is not required on labelling	Braille code is required on labelling	Braille code is not required on labelling
Post-approval changes	Post-approval changes in the approved drug: • Minor changes • Moderate changes • Major changes	Post-variation in the approved drug: • Type IA Variation • Type IB Variation • Type II Variation	Post approval changes: Major quality changes Moderate quality changes

US/EU/IND- Finished Product Requirements

Requirements	US	EU	INDIA
Justification	ICH Q6A	ICH Q6A	ICH Q6A
Assay	90 - 100 %	95 - 105 %	90 - 110 %
Disintegration	Not Required	Required	Required
Colour Identification	Not Required	Required	Required
Water Content	Required	Not Required	Required

US/EU/IND- Manufacturing & Control Requirements

Requirements	US	EU	INDIA
Number of batches	1	3	1
Packaging	A minimum of 1,00,000 Units	Not Required	Not addressed
Process Validation	Not required at the time of submission	Required	Required
Batch Size	1 pilot scale or minimum of 1 lakh units whichever is higher.	2 pilot scale plus 1 lab batch or minimum of 1 lakh units whichever is higher.	Pilot scale batch

US/EU/IND- Stability Requirements

Requirements	US	EU	INDIA
Number of batches	3 Pilot Batch or 2 Pilot Batch & 1 Small scale	2 Pilot Scale (If API Stable) 3 Primary Batches (If API unstable)	2 Pilot Scale/Production scale(If API Stable) 3 Primary Batches (If API unstable)
Condition: Long term stability, Accelerated stability,	Long term: 25°C/60%RH Accelerated: 40°C/75%RH(0,3,6 months); Intermediate: 30°C/65%RH	Long term: 25°C/60%RH Accelerated: 40°C/75%RH(0,3,6 months) Intermediate: 30°C/65%RH	Long term: 30°C/70%RH Accelerated:40°C/75%RH (0,3,6 months)
Minimum time period at Submission	6 Months Accelerate & 6 Months long term	6 Months Accelerate & 6 Months long term	6 Months Accelerate & 6 Months long term
Container orientation	Inverted & Upright	Do not address	upright and inverted
Clause	21 CFR part 210 & 211	Volume 4 EU Guidelines for medicinal products	ICH Q1F
QP Certification	Not Required	Required	Required

Regional Organizations and Mutual Recognition in Animal Health Strategy

Vaccine ,Diagnostics, Antigen, Antisera, Mab etc.

Global Economic order under WTO/OIE/IP/FAO/EU/CDC/WHO/NIH guidelines

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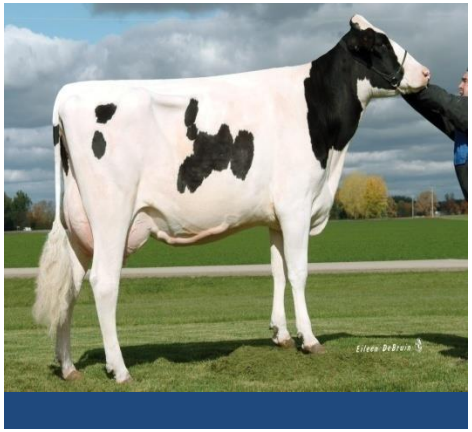
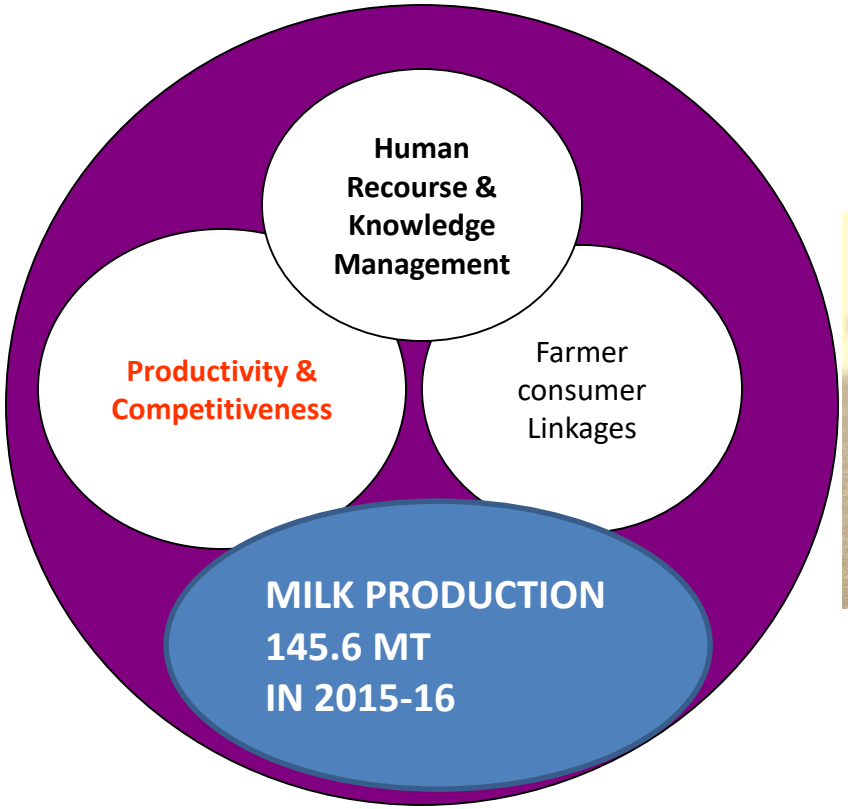
Facility & Biosafety/USFDA/DCGI/CPCSEA/ISO/QMS

ASIAN LIVESTOCK REVOLUTION

MISSION MILK: *DAILY INCOME GENERATING ACTIVITY*





Improving the competitiveness of small holder/milk producers to provide more & better quality milk & dairy products in Asian consumers

NETWORKING, COOPERATION AND COORDINATION

भाकृअनुप
ICAR

सत्यमेव जयते

WRL
INSURANCE • ANNUITIES

WORLD TRADE ORGANIZATION

OIE

PD-FMD

Dream or Reality?

FAO
FIAT PANIS

RIIDFA
Argentine Inter-Institutional Network for R&D in FMD

National Research Council
Ministry of Science and Technology
CEVAN – ICT MILSTEIN

National Institute of Agriculture Tecnology
Ministry of Agriculture
VIROLOGY and BIOTECHNOLOGY CENTERS

National Service for Agrifood Health Quality
OIE –FMD- REFERENCE LABORATORY

Vaccine Company
FMD Vaccine and Antigen Bank

COOPERATION
1+1>2

Regulatory & Development

BAIF
BAIF DEVELOPMENT RESEARCH FOUNDATION

Gaon Se Global

रापजासूविसं
NIVEDI

GMP & ProductionEconomic Impact

Gaon Se Global

Netpeoplekart Pvt Ltd.

NETPEOPLEKART PRIVATE LIMITED

Private Sectors and MNC

EFFLUENT TREATMENT PLANT

Environment clearance by Govt. of Karnataka and India






INDIAN PHARMACOPIA VETERINARY 2014

Are we serious??????

- Cell cultures for the production of veterinary vaccines
- Evaluation of efficacy of veterinary vaccines and immunosera
- Evaluation of safety of each batch of veterinary vaccine and immunosera
- Evaluation of safety of veterinary vaccines and immunosera

Cell cultures for the production of veterinary vaccines

- Cell line
- Characteristics of culture
- Karyotypes
- Identification
- Sterility
- Mycoplasma
- Absence of contaminating viruses
- Detection of heamadsorption viruses
- Detection of specified viruses
- Tumorigenicity Assay

- ❖ Management of Master seed
- ❖ Working Seed
- ❖ Production Continuous Cell Culture in Bioreactor

Recent Strategy in Vaccinology – FMD

Extremely contagious, viral disease

95% of exposed animals become infected

Loss due to highly contagious - morbidity and mortality

Virus variations

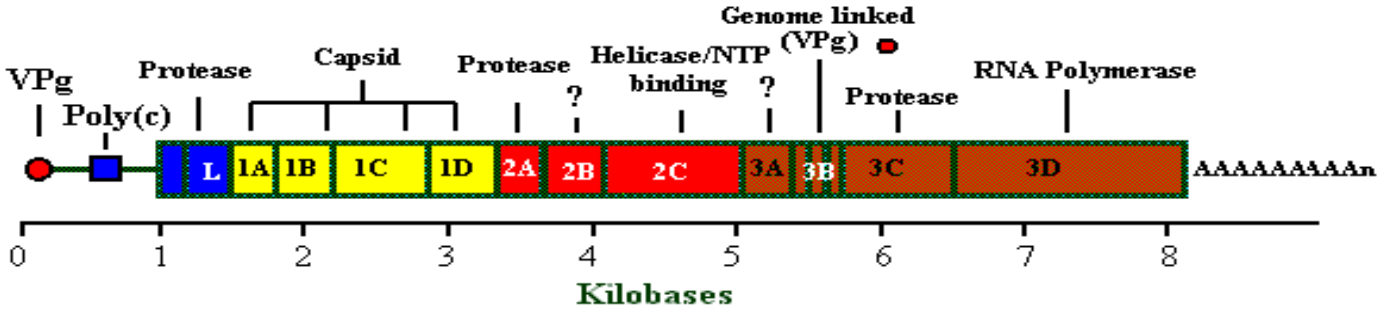
7 Strains (In India – A, O, C, Asia-1)

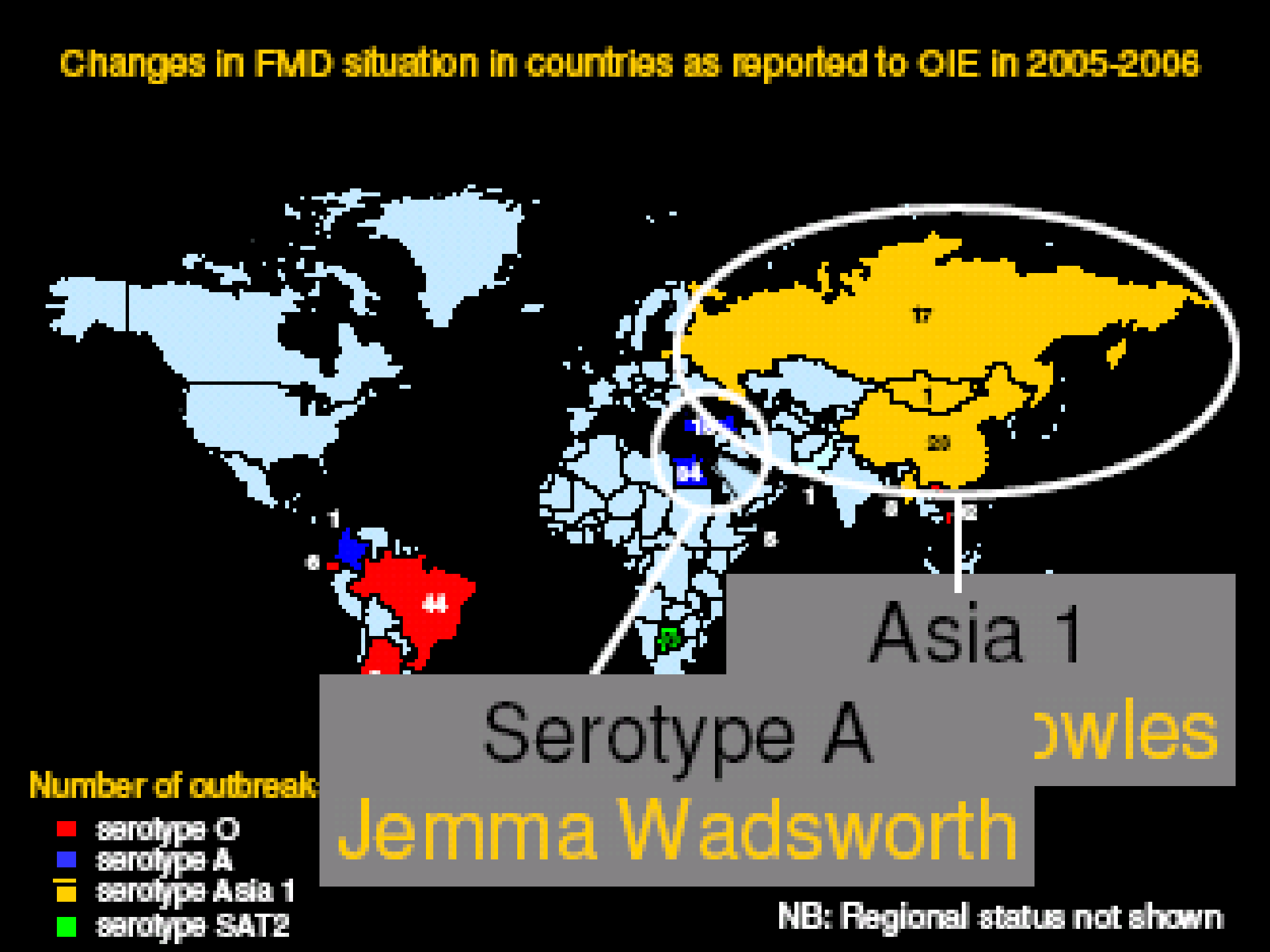
60 total serotypes

Picornaviridae

Apthovirus genome map

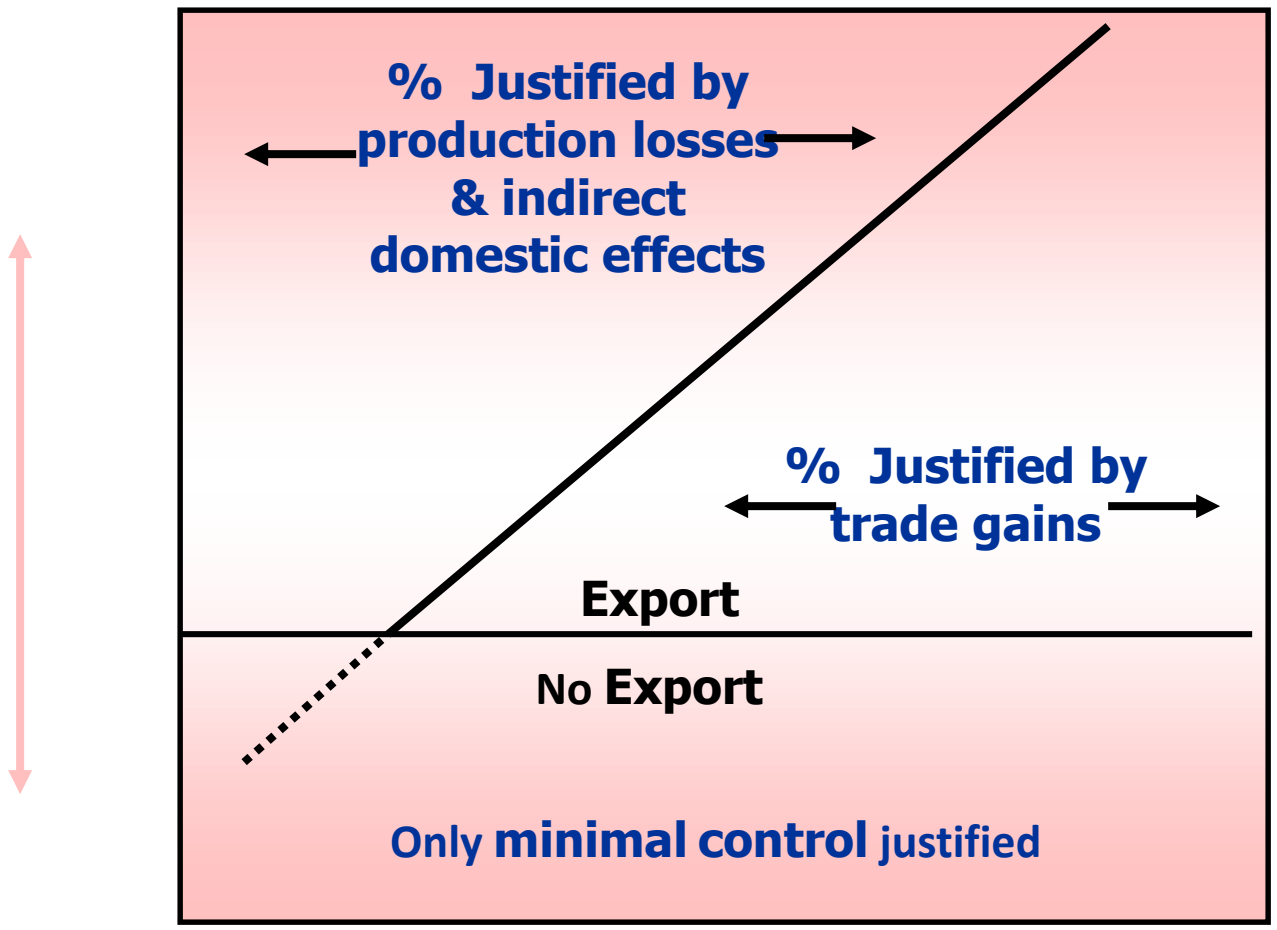
a single strand of positive sense RNA of 8000 nucleotide bases



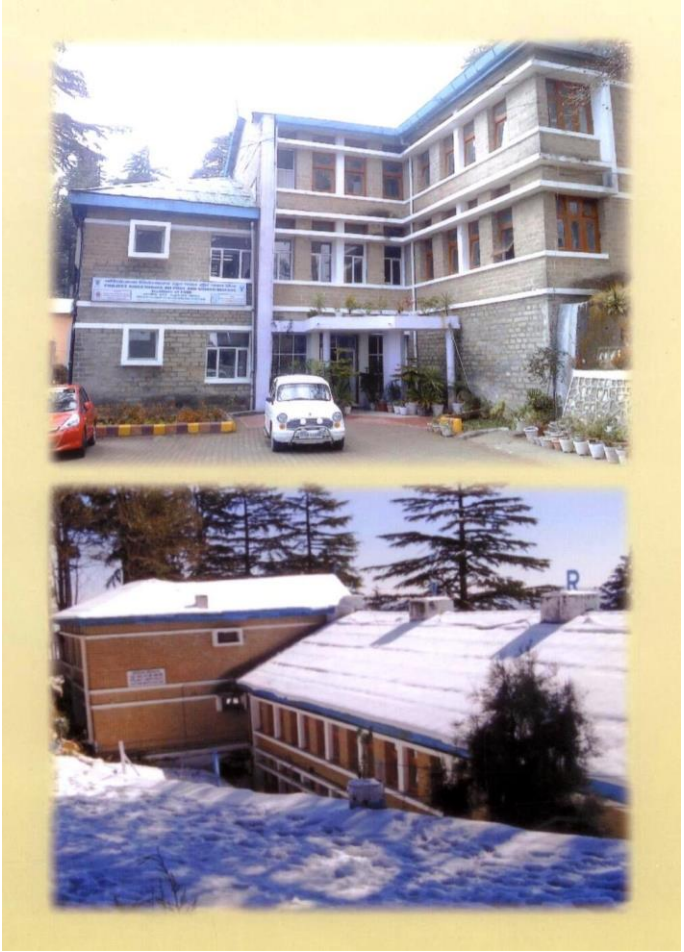

Changes in FMD situation in countries as reported to OIE in 2005-2006
17
1
39
1
6
2
6
1
44
Asia 1
Serotype A
owles
Jemma Wadsworth
Number of outbreak
serotype O
serotype A
serotype Asia 1
serotype SAT2
NB: Regional status not shown

FMD Control Program

- Justification



PD FMD MUKTESWAR



OIE/FAO/WRL GLOBAL –REF. LAB. SAARC COUNTRIES
FMD VACCINE STRAIN MATCHING

REMARKS

1. VACCINATION IS A VALID AND IMPORTANT TOOL TO CONTROL FMD WITHOUT THE RISK OF DISEASE SPREADING

2. HERD IMMUNITY SURVEYS ARE RELEVANT FOR MONITORING THE EFFECTIVITY OF THE VACCINATION PROCESS

3. MAbs ARE VALUABLE TOOLS FOR FIELD STRAIN IDENTIFICATION AND VACCINE CONTROL

4. INDIRECT METHODS ARE A RELIABLE ALTERNATIVE TO IN VIVO POTENCY TESTING

5. IT IS IMPORTANT TO BUILD AND MAINTAIN INTERNATIONAL REFERENCE BANKS OF SERA, INCLUDING MAbs

6. CONSOLIDATE AND EXPAND VACCINE AND Ag. BANKS AND PROMOTE NETWORKING ACTIVITIES