Report:
Inspections of Indian Equine Facilities

Inspections authorised by: The Animal Welfare Board of India (AWBI) with letter No 9-1/2015-16/PCA/IR. The authorisation letters are enclosed as **Annexure 1**. The following people were authorised by the AWBI to participate in various inspections:

- Dr Binu K Mani, Assistant Professor of Veterinary Microbiology, College of Veterinary & Animal Sciences, Kerala Veterinary and Animal Sciences University, Mannuthy, Thrissur, Kerala

- Dr Ashok V Bhonsle, Assistant Professor, College of Veterinary & Animal Sciences, Maharashtra Animal & Fishery Sciences University, Udgir, Maharashtra

- Dr S Anoop, Assistant Professor, Department of Veterinary Surgery and Radiology, College of Veterinary &Animal Sciences, Mannuthy, Kerala

- Dr JB Rajesh, Assistant Professor, Department of Veterinary Medicine, College of Veterinary Sciences & Animal Husbandry, Central Agricultural University, Selesih

- Dr Chaitanya Koduri, Co-Opted Member, AWBI, and Science Policy Adviser, People for the Ethical Treatment of Animals (PETA) India

- Dr ManilalValliyate, Co-Opted Member, AWBI, and Director of Veterinary Affairs, PETA India

- Dr Naresh Chandra Upreti, Honorary Animal Welfare Officer, AWBI, and Chief Operating Officer, Animal Rahat

- Dr Rakesh Chittora, Senior Veterinary Trainer, Animal Rahat

Inspection period: July 2015 to September 2015

Equine Facilities Inspected

- Serum Institute of India (SII)
- VINS Bioproducts Ltd (VBL)
- Haffkine Bio-Pharmaceutical Corporation Limited (HBPCL)
- Premium Serums and Vaccines Pvt Ltd (PSVPL)
- Biological E Limited (BEL)
- Mediclone Biotech Pvt Ltd (MBPL)
- King Institute of Preventive Medicine & Research (KIPMR)
- Bharat Serums and Vaccines Ltd (BSVL)
- Raut Serum IndiaPvt Ltd (RSIPL)

Relevant Acts, Rules, Notifications and Guidelines

- The Prevention of Cruelty to Animals Act, 1960
- Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998
- Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2001
- Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006

- Honourable Supreme Court judgement dated 23 September 2002 on Writ Petition (Civil) No 216/ 2001 on OP Tehlanv Union of India &Ors
- Guidelines for the "Care and Management of Equines Used in the Production of Biologicals" issued by the Committee for the Purpose of Control and Supervision of Experimentation on Animals (CPCSEA) of the Ministry of Environment, Forest and Climate Change
- CPCSEA Guidelines for Laboratory Animal Facility, 2005
- CPCSEA Standard Operating Procedures (SOP) for the Institutional Animal Ethics Committee (IAEC)
- Guidelines on the Regulation of Scientific Experiments on Animals, 2007
- The Prevention of Cruelty to Animals (Licensing of Farriers) Rules, 1965

Purpose of the Inspection

To inspect the equines and assess their mental and physical welfare, their upkeep, and their housing and maintenance; to check for any incidences of cruelty or violations of animal-protection laws; and to scrutinise relevant records and reports

Report submitted on: 6April 2016

I. Executive Summary

Laboratory	Number of Equines in Each Laboratory	CPCSEA Registration
Serum Institute of India	0	N/A
VINS Bioproducts Ltd	763	Not registered
Haffkine Bio-Pharmaceutical Corporation Limited	845	Registered
Premium Serums and Vaccines Pvt Ltd	876	Not registered
Biological E Limited	1335	Not registered
Mediclone Biotech Pvt Ltd	91	Registered
King Institute of Preventive Medicine & Research	47	Not registered
Bharat Serums and Vaccines Ltd	587	Registered
Raut Serum IndiaPvt Ltd	1243	Registered
Total Number of Equines	**5787**	

A scientific welfare assessment of equines in all the aforementioned laboratories–based on the Standardised Equine Based Welfare Assessment Tool (SEBWAT) developed by the University of Bristol in the UK and The Brooke, an international animal welfare organisation, after extensive studies on working equines in India and other developing countries–using a sample size of the equine population at each institute large enough to be meaningfully representative of the total population, revealed the following averages:

- Sixty-three per cent of the equines at these facilities display negative reactions indicative of poor mental health.
- Forty-eight per cent have eye abnormalities.
- Fifty-five per cent have an abnormal mucous membrane colour.
- Forty-eight per cent are over 15 years of age or under 3½.
- Eight per cent have wounds or lesions on some part of the body.
- Fifty-seven per cent are thin and have a below-average body condition score.
- Sixteen per cent have swelling of the superficial flexor tendon (SFT) and fetlock joint of one or both of the forelimbs.
- Thirty per cent have swelling of the SFT and fetlock joint of one or both of the hind limbs.
- Forty-nine per cent have an abnormal hoof shape in either their forelimbs or hind limbs.
- Forty-four per cent have an abnormal hoof horn quality in both forelimbs and hind limbs.
- Sixty per cent have a frog which is diseased or missing.
- Forty-six per cent have an abnormal gait and are showing signs of lameness.

		VBL	HBCPL	PSVPL	BEL	KIPMR	MBPL	BSVL	RSIPL	Average
Observer approach – negative response		85%	54%	46%	91%	60%	60%	56%	54%	63%
Avoids chin contact		35%	35%	10%	24%	20%	27%	28%	32%	26%
General attitude – negative		65%	31%	63%	85%	60%	60%	32%	44%	55%
Eye abnormalities		65%	46%	34%	29%	80%	47%	52%	32%	48%
Abnormal mucous membrane colour		80%	58%	51%	48%	47%	67%	36%	49%	55%
Over 13 years of age or under 3½		50%	46%	59%	62%	67%	40%	24%	32%	48%
Body lesions	Head/ neck	65%	73%	71%	20%	20%	47%	80%	78%	57%
	Withers/ spine	5%	5%	5%	44%	20%	N/A	5%	N/A	11%
	Ribs/ flanks	5%	5%	5%	26%	N/A	N/A	5%	N/A	6%
	Forelimbs	5%	5%	5%	6%	54%	27%	5%	10%	15%
	Hind limbs	5%	5%	5%	20%	27%	67%	5%	27%	20%
	Knees	30%	15%	7%	11%	N/A	N/A	8%	10%	10%
Firing lesions		100%	100%	100%	93%	0%	100%	16%	49%	80%
"Thin" body condition score		45%	35%	54%	69%	60%	80%	68%	46%	57%

Ectoparasites	30 %	N/A	N/A	13 %	N/A	13 %	N/A	N/A	7%
Swelling of the SFT and fetlock joint – forelimbs	20 %	4%	24 %	22 %	7%	33 %	8%	10 %	16%
Swelling of the SFT and fetlock joint – hind limbs	25 %	4%	49 %	17 %	47%	33 %	40 %	27 %	30%
Abnormal hoof shape	5%	22%	46 %	95 %	33%	60 %	28 %	61 %	49%
Abnormal hoof horn quality	5%	20%	40 %	89 %	74%	60 %	16 %	46 %	44%
Abnormal frog health	N/ A	70%	54 %	51 %	47%	79 %	60 %	61 %	60%
Abnormal gait	20 %	12%	32 %	89 %	73%	87 %	28 %	32 %	46%
Capped elbow	N/ A	N/A	12 %	N/ A	13%	26 %	12 %	3%	8%

The low body condition score of many animals could be caused by poor nutrition, poor dental care, digestive tract diseases and other protozoal diseases. The animals with several body lesions had a negative reaction to human touch, likely because of pain or fear. Lesions on the hind legs indicate that horses were forced to roll on the hard floor and endured prolonged lateral recumbency because of weakness, severe lameness (chronic laminitis) and improper care. Ectoparasites, especially ticks, are carriers of potentially life-threatening protozoal blood diseases, and a heavy infestation may also lead to anaemia. The presence of ectoparasites on animals indicates that regular de-ticking is not being practised, and ectoparasite bites cause the animals constant irritation and distress.

Osteoarthritis is a degenerative joint disease, most frequently involving the knee, hock, fetlock, pastern and coffin joints, caused by repeated stress or trauma on the joints because of overexertion and improper farriery. Several equines were suffering from osteoarthritis or tenosynovitis (inflammation of the lining of the sheath surrounding a tendon), were in severe pain and had an abnormal gait, even when walking. These conditions are permanent, as they cannot be reversed if not treated in their early stages. Swollen joints indicate that the animal is lame and will continue to be lame, as these disorders cause permanent anatomical and functional damage. Once the animal loses function in a joint, he or she compensates by putting more strain on other joints and on tendons and ligaments. Thus, the healthy parts of the legs are subjected to undue wear and tear, leading to inflammation of those joints, tendons and ligaments.

Abnormal hoof shape puts additional pressure on flexor and extension tendons, ligaments and joints and causes inflammation and swelling. If there are permanent changes in tendons, ligaments and joints, the animal becomes permanently lame. An improper toe-to-heel ratio seen in several equines indicates that hoof trimming is not being done on a regular basis. Dumping of the hoof wall observed in many equines is a predisposing factor for painful conditions such as seedy toe and laminitis. A diseased frog or the absence of a frog indicates a complete lack of hoof care. A diseased frog is usually caused by thrush (an infection of the frog, which is predisposed by moist, damp, dirty ground or stable conditions) or canker (a serious infectious process that results in the development of a chronic hypertrophy of the horn-producing tissues) and often results in continuous severe pain, discomfort and lameness in equines. Another

condition, capped elbow, develops from continually keeping equines on hard floors.

None of the animals suffering from dermatitis was isolated for treatment. Skin diseases such as ringworm infestation can easily spread to humans and other animals.

Many of the equines were also suffering from eye diseases such as corneal ulcers, cataracts, keratitis, swelling and injuries on the eyelid, uveitis and blindness. Numerous equines were also branded. All methods of branding (hot or cold) are painful.

The equines were not subjected to routine examination of teeth and rasping. The staff at the majority of the laboratories inspected were not aware of the specific purposes of a curry comb or body brush or the techniques of using them for grooming. The dirty skin and coat of equines indicated that no regular individual grooming is practised.

The veterinarians did not follow the basic steps of wound management. They were not aware of the treatment protocol to be followed for thrush and canker conditions in feet. They were also unaware of the importance of recognising and managing pain and of the neuroleptanalgesia protocol to be followed prior to any invasive and painful veterinary procedure. Euthanasia is not practised by most laboratories, and the veterinarians are not aware of its necessity or the protocols to be followed.

Recently born foals and the presence of mares among stallions indicate that laboratories do not have effective control over breeding. The housing conditions were poor and

severely crowded, and the sheds were dirty and waterlogged. The equines were forced to stand in mud. The fencing of old paddocks at some laboratories was rusted and damaged in many places. There are no dedicated sand pits– a space ideally should be filled with soft sand for the animals to roll in. The feeding practices are unscientific and do not meet the nutritional requirements of the animals as is evident by the fact that many are very thin. In group feeding, often the weak and diseased are deprived of adequate food. Healthy and sick animals are housed together, and the quarantine practices are inadequate, as the quarantined animals live in close proximity to other animals and no regular disease surveillance is practised to detect the prevalence of infectious diseases, such as glanders, equine influenza, equine herpes virus or others.

The medications and equipment were inadequate and failed to meet quality criteria. There was no procurement, storage or disbursement system in place. Some of the essential drugs and chemicals, such as liquid paraffin, which is stocked by some of the facilities, were in such low quantities that there was not even enough to treat one or two cases of colic. There was no stock of barbiturates, which is essential for the euthanasia of suffering animals, even though a few of the facilities have an SOP for euthanasia. Only one stomach tube (of medium size) was available in many laboratories, making it difficult to use for equines of different sizes, including foals, ponies and large Thoroughbreds. The foot-trimming kits were not maintained properly, and equipment was not as sharp as it should be. The foot-care kits also lacked many essential types of equipment such as a drawing knife, a searching knife and an abscess knife.

Laboratory analyses of blood samples collected from equines in the different laboratories indicated that, on average, 36 per cent of the animals suffer from some form of anaemia and 19 per cent suffer from some form of infection.

	VBL	HBCPL	PSVPL	BEL	KIPMR	MBPL	BSVL	RSIPL	Total
Anaemia	52%	23%	40%	60%	40%	6%	24%	39%	36%
Sub-acute inflammatory reaction/ chronic infection	24%	12%	7%	21%	13%	20%	44%	13%	19%

A look at the records and reports showed that the majority of the laboratories were not maintaining the feed and stock registers or the daily diary of the veterinarians, as mandated by the CPCSEA's guidelines for the "Care and Management of Equines Used in the Production of Biologicals". In the majority of the facilities, the inspectors were not given any documents relating to permission for procuring new equines, indicating that the equines procured at least in recent years were done so without permission from the CPCSEA's central committee.

There were apparent violations of the PCA Act for not providing the severely lame and injured animals and those who were thin and emaciated with adequate veterinary treatment and care, and there were apparent violations of the Breeding of and Experiments on Animals (Control and Supervision) Amendment Rules, 2006, for allowing the breeding of equines without authorisation. There are also apparent violations of the CPCSEA's guidelines for the

"Care and Management of Equines Used in the Production of Biologicals" for not equipping facilities with necessary equipment and skilled caretakers, not following procedures for the pre-purchase screening of animals and their quarantine and management, and not practising necessary animal husbandry procedures, such as providing adequate nutrition, foot care, dental care, grooming and so on.

The inspections prove that the equines kept by several laboratories are suffering because of negligence and inadequate management and care and that numerous provisions of animal-protection laws and the honourable Supreme Court of India's directives are being violated. The AWBI-authorised inspection team recommends that the AWBI request that the CPCSEA cancel the registration of all the laboratories that have violated the regulations and not renew the registrations of those laboratories whose registrations have expired and which are waiting for renewal. The AWBI should also advise the Central Drugs Standard Control Organization to cancel the licences of all the laboratories to manufacture biological products and advise the Ministry of Science & Technology to produce antitoxins without using animals and to develop more such non-animal technology in India. The inspection team also recommends that the needs of those equines who require euthanasia, rehabilitation or care be immediately addressed.

II. Introduction

Once the inspection team arrived at the laboratories, the inspectors met with the resident veterinarians. During that meeting, the inspectors informed the laboratory staff about the purpose of the inspection and gave them a copy of the AWBI authorisation letter. The staff were also given a list of

documents that needed to be produced by the end of the day, as per the CPCSEA's norms.

Using a sample size of the equine population large enough to be meaningfully representative of the total population at each laboratory, the inspectors randomly selected equines and subjected them to a detailed welfare assessment using the SEBWAT. The assessment helped to interpret the physical and mental health of the equines being kept by these laboratories.

Required copies of the records and reports were photocopied. Following an inspection of the records and reports, the team checked the physical stock and quality of medication in the clinic and store and inspected the instruments used for veterinary treatment and the equipment used for routine management and care practices such as grooming, dental care and foot care.

Except for HBPCL, which obtains venom from its own snake farm, the Indian snake venom for infecting the equines in the laboratories is obtained from the Irula Cooperative Venom Centre in Tamil Nadu. Also, the laboratories which use the equines for the production of anti-venin for African snakes, scorpions and so on import the venom from other countries.

III. Findings of the Inspections

A. Behavioural Observations

1. Response to Observer Approach

On average, 63 per cent of the equines in these facilities responded negatively when the observer

approached them from a distance of approximately 3 metres at an angle of approximately 20 degrees. These reactions include non-reactive negative responses, such as being apathetic or dull, and negative reactions, such as being nervous, frightened or aggressive.

2. **Chin Contact**
   On average, 26 per cent of the equines in these facilities avoided contact when the observer tried to touch their chin using his hand, meaning that these animals are afraid of people and prefer to avoid human contact.

3. **General Attitude**
   On average, 55 percent of the animals in these facilities showed negative reactions throughout the assessment. These include negative reactions and non-reactive negative responses (apathetic or dull).

B. Physical Health

1. **Eye Abnormalities**
   On average, 45 percent of the equines in these facilities had eye abnormalities, including blindness; chronic corneal opacity and discharge from either one or both eyes, which attracted flies and further distressed the animals; swelling of either one or both eyelids; lesions on the medial canthus of either eye; and signs of habronemiasis (a condition characterised by pruritic, reddish-brown granulomatous lesions in the medial canthus of the eye caused by aberrant intradermal migration of the

larvae of stomach worms). Other eye abnormalities detected included a missing eyeball and enophthalmos (the sinking of the eyeball into the socket).

Horse 53 (left) at MBPL suffers from partial blindness, and horse 5 has corneal opacity.

Horse 853 (left) from HBPCL has swelling and a wound on the medial canthus and lower eyelid, suggestive of habronemiasis. Horse gelding 341 from HBPCL has corneal opacity in the left eye.

Discharge, which attracts flies, can be seen coming out of these animals' eyes at BSVL.

This pony at BEL has a purulent discharge from the right eye.

Horse 48 (left) is blind in the left eye (chronic uveitis with vascularisation). Mule 327 has corneal opacity in the right eye. Both animals are from KIPMR.

Horse 106from KIPMR has swelling of the lower eyelids of both eyes (right and left).

2. **Mucous Membrane Colour**
   On average, 55 per cent of the equines in these facilities had an abnormal mucous membrane colour. These animals include those who had a paler than normal (pink and moist) mucous membrane and those who had a dark, congested mucous membrane. The mucous membrane colour was confirmed by examining the conjunctival mucous membrane of their eyes, in addition to looking at their gums. An abnormal mucous membrane colour is suggestive of anaemia or a systemic infection.

This horse from MBPL has a paler than normal mucous membrane on the upper gums.

Horses 9 (left) and 2 from KIPMR have a pale mucous membrane on their gums.

At PSVPL, this animal's mucous membrane on the upper gums and conjunctiva are paler than normal.

3. **Age**
   On average, 48 per cent of the equines are over 13 years of age or under 3½. Even so, they are still used for bleeding. Often, their ages are

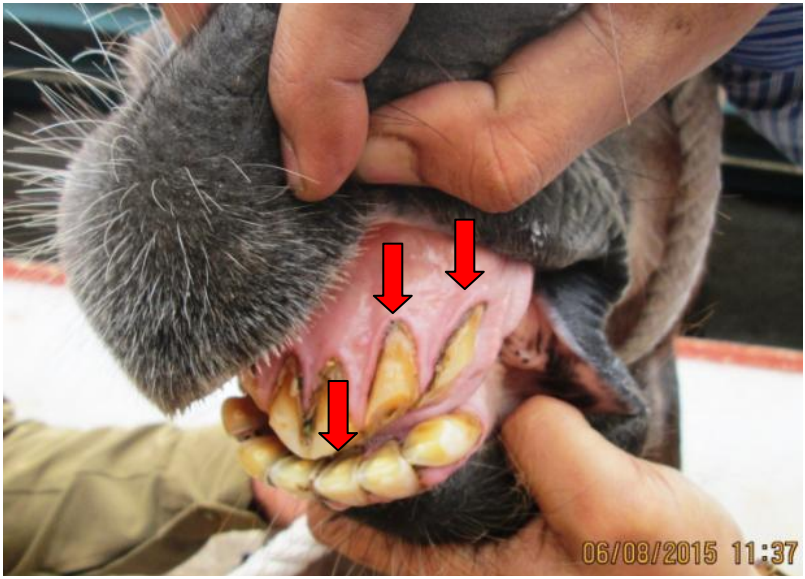
misrepresented in the facilities' records, possibly because veterinarians have not been trained to estimate the age of animals by checking their dentition.

Pony R11, who is under 3 years of page (the lateral and corner incisors are milk teeth and are still present), was being used for serum extraction. VBL's records list the animal's age as 9 years.

Mule A28 from VBL is over 25 years of age (the Galvayne's groove is worn out more than halfway from the top of the corner incisor, and the table surface of the incisors has only a dental star), but in records furnished by VBL, the animal's age was listed as 9 years old on 10 October 2014.

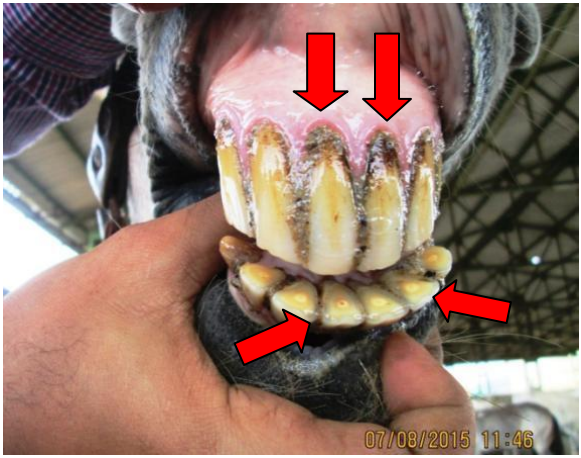
Horse 474, a 2½-year-old pony (lateral and corner incisors are milk teeth and are still present), is being used for serum production. RSIPL's records list his age as 5 years old.

Horse B1, a 3½-year-old pony (lateral and corner incisors are milk teeth and are still present), is being used for serum production. RSIPL's records list his age as 6½ years old.



In mule 138, the Galvayne's groove is worn down more than halfway from the top of the corner incisor and the table surface of the incisors has only dental stars, showing that this animal is over 25 years of age. But records furnished by HBPCL list the animal's age as 21 years.

Mule 190, who is over 25 years of age and still being used for serum production, is identified by PSVPL as being 14 years old.



In the records furnished by PSVPL, mule 158's age is listed as 12 years. But the animal is actually over 25 and is still being used for serum production.

4. **Body Lesions**
   a. **Head and ears:** Some of the equines have injuries on the head which could have been caused by fighting among the animals. Biting each other is an indication of severe crowding and the mental distress caused by continuous confinement. All the equines are tied most of the time with a short rope inside the stables of BSVL and RSIPL.

A deep lesion exposing muscle can be seen on the head of horse stallion 984 at RSIPL.

The skin and immediate subcutaneous layers are broken on horses A 248 (left) and A 540 at BSVL.

This horse from HBPCL has a puncture hole in the left ear for tagging for identification purposes.

b. Neck: Fifty-seven per cent of the equines had lesions on their necks. These lesions include superficial or healed lesions, and the skin and immediate subcutaneous layers are broken on others. The animals did not allow anyone to touch them, possibly because of severe pain and fear.

Geldings 28 and A11 from VBL have severe neck lesions.

Pony UF 1 at BEL has a deep lesion on the neck.

Horse 237's skin and immediate subcutaneous layer are broken. The animal, from MBPL, also has phloebitis (inflammation of the walls of a vein).

This mule (left) from PSVPL has a deep lesion involving muscle and tendon, and a wound on the neck of this horse (right) at PSVPL is oozing pus.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The skin and immediate subcutaneous layersare broken on mule 442 (left) and horse gelding T 42 at PSVPL.

c. **Knees:** Many equines have superficial or healed lesions on the knee, injuries caused by being forced to live on a hard concrete floor.

Horse 550 (top) and mule 341 from HBPCL have healed lesions on their knees.

d. **Withers and spine:** Many equines have lesions on the withers and spine – superficial healed lesions or lesions with the skin and immediate subcutaneous layers broken.

The skin and immediate subcutaneous layers are broken on donkey 817 (left). A lesion can be seen on the animal's withers and spine. At right, healed lesions can be seen on this

horse's withers and spine, ribs and flank area. Both animals are from HBPCL.

Mule 219 (left) has a wound (score 2) over the croup region. Mule 4 has a wound (score 2) over the back region. Both of the animals are from KIPMR.

e. **Ribs and flanks:** Many equines have lesions on the ribs and flanks –both superficial healed lesions and also some with the skin and immediate subcutaneous layers broken.

A healed lesion can be seen near this animal's ribs and flank at PSVPL.

f. Girth/stomach: Some of the equines have lesions on the girth and stomach. The skin and immediate subcutaneous layers are broken on all of them.

Mule 22 from KIPMR has a wound (score 2) on the stomach (left) and the girth (right).

g. **Forelimbs:** Fifteen per cent of the equines have severe lesions on their forelimbs – the skin and

immediate subcutaneous layers are broken on some of them, while others have deep lesions involving muscles and bones.

Horse 9 (left) has a wound (score 2) at the fetlock joint of the left leg. Mule 10 has a wound (score 2) just below the knee joint. Both of the animals are from KIPMR.

Mule 219 (left) has a wound over the fetlock joint. Horse 106 has a wound over the cannon bone. Both of the animals are from KIPMR.

At MBPL, horse 80 (left) is bleeding from the right foreleg and horse 53 has a deep elbow wound.

h. Hind limbs: On average, 20 per cent of the equines had lesions on the hind limbs. Some of them had superficial or healed lesions, while the skin and immediate subcutaneous layers are broken on others.

The skin and immediate subcutaneous layers are broken on horse 2 at BEL.

Horse 299 (left) has severe wounds on the hind legs. Mule22 has a wound on the left hind leg. Both of the animals are from KIPMR.

Horse 76 (left) from MBPL has a deep lesion (with a score of 3) on both hind legs.

i. **Hindquarters:** Some of the equines have lesions on the hindquarters – a few have

superficial or healed lesions, while the skin and immediate subcutaneous layers are broken on others.

The skin and immediate subcutaneous layers are broken on mule 567 at BEL.

Horses 80 (left) and 45 from MBPL have lesions on their hindquarters.

j. **Firing lesions:** On average, 80 per cent of the equines in these facilities have either fresh, infected or healed lesions on different parts of the body from hot and cold branding – some of them have firing lesions on one area of the body, while others have firing lesions on two or three areas.

Both of these equines from VBL have healed lesions caused by hot branding for identification purposes.


A 26


A 32
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All four of these equines from VBL have open wounds caused by hot branding.

Horse 173 at BEL has multiple firing/branding marks.

Horse gelding 80 from MBPL has three identification marks – two on his left side and one on his right side.

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The animal on the left from HBPCL has a healed firing lesion caused by hot branding for identification. The skin and immediate subcutaneous layers are broken on the animal on the right from HBPCL. The lesions were caused by hot branding.

The skin and immediate subcutaneous layers have been broken on these animals. The lesions were caused by hot branding at PSVPL.

k. **Hobbling:** Some of the equines have superficial or healed lesions caused by hobbling.

Pony 16 at BEL has hobbling lesions on the forelegs.

l. **Bite wounds and injuries:** Many equines were found with bruises on different parts of their body, bite wounds on their lips and serious damage to the hoof wall because of fighting among the animals as a result of severe crowding and poor animal-housing practices. There is no system to keep the dominant and active animals separate.

Horse 177 at BEL has a hit wound that damaged the hoof wall of the left foreleg.

An injury from being bitten can be seen on the left upper eyelid of pony 193 at BEL.

Horse 80 at MBPL has extra incisors in the lower mandible, which has caused a cut on the lip. The animal was not given any treatment.

5. **Ectoparasites**
   Equines from VBL, BEL, RSIPL and MBPL had tick infestations, either inside the ear or under the base of the tail. Ectoparasites, especially ticks, are carriers of potentially life-threatening protozoal blood diseases, and a heavy infestation may also lead to anaemia. The biting also causes the animals constant irritation and distress. The presence of ectoparasites on animals indicates that regular de-ticking is not being practised by the caretakers at these laboratories, even though screening of ectoparasites is required by the CPCSEA's guidelines for the "Care and Management of Equines Used in the Production of Biologicals".

Ticks were found under the tail base and inside the ears of these equines atVBL.

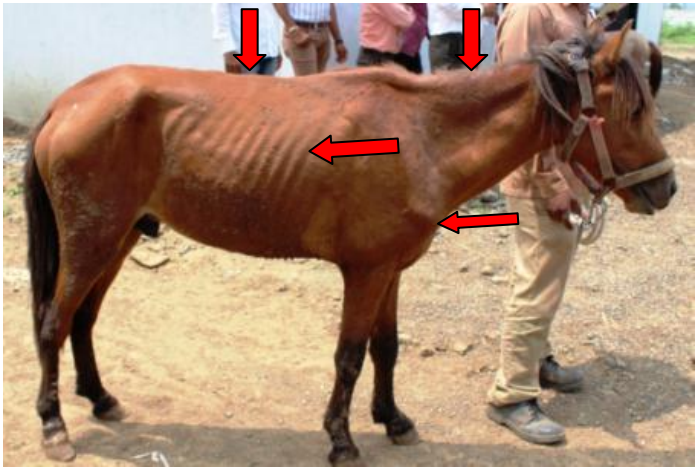
Lice eggs have infested the forelock and mane of horse gelding B 52 at RSIPL.

Ticks can be observed under the tail base and inside the ear on this animal at MBPL.

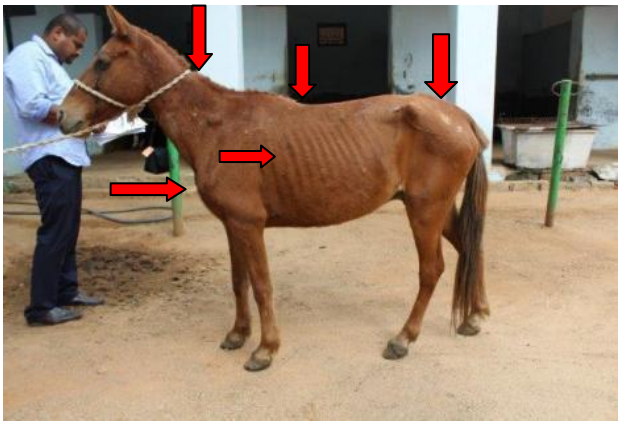
6. **Body Condition Score**
   On average, 57 per cent of the equines in these facilities are thin or very thin and have a below-average body condition score when assessed on a 9-point body condition scoring system, from 1 (very thin) to 5 (very fat) with half scores in

between. A low body condition score could be because of malnutrition, poor dental care, digestive tract diseases and other infectious protozoal diseases.

This horse from MBPL has a body condition score of 1 (very thin): neck concave/straight, point of shoulder prominent, spine prominent, ribs prominent, pelvis hollow/flat, pinbone prominent and tail head prominent.



This animal from RSIPL has a body condition score of 1 (very thin).



Pony 103 at BEL has a “very thin” body condition score.

Mule329 from KIPMR has a body condition score of 1.

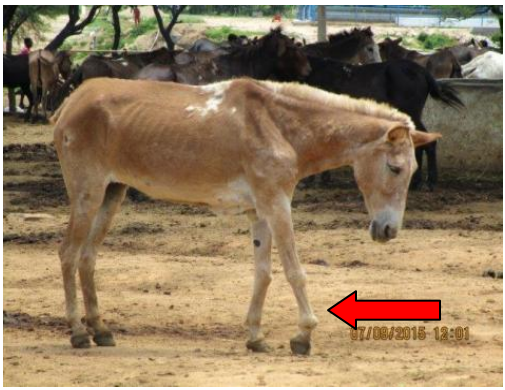
7. **Limb and Gait Indicators**
   a. **Swelling on the superficial flexor tendon and fetlock joint:** On average, 16 per cent of

the equines in these facilities have swelling on one or both of the forelimbs when observed from the side and rear. Thirty per cent have swelling on one or both of the hind limbs when observed from the side and rear.

Mule 556 at BEL has osteoarthritis and ringbone in the pastern joints of both hind limbs.

Mule22 (left) has swelling on both hind legs. Mule327 has swelling on both fetlock joints (hind legs). Both of the animals are from KIPMR.

This animal (left) has swelling of the fetlock joint in both forelimbs. The animal on the right has swelling of the superficial flexor tendon and fetlock joint on the left hind limb. Both of these animals are from HBPCL.



This mule at BEL has osteoarthritis in the fetlock joint of the right forelimb and a contracted flexor tendon.

At MBPL, horse 412 (left) has a swollen fetlock joint on the right hind leg. Horse 80 has a swollen flexor tendon on the right hind leg.

b. Hoof shape: On average, 49 per cent of equines in these facilities have an abnormal hoof shape on either their forelimbs or their hind limbs or on both.

Horse stallions B 1 (left) and 980 at RSIPL have an abnormal hoof shape in one of their forelimbs.

Gelding 602 from HBPCL has an abnormal hoof shape in both of the forelimbs (left) and both of the hind limbs.

On mule 22's right hind hoof, the toe is too short and the heel is too high (left). Horse 270's right hind hoof is concave. Both of the animals are from KIPMR.

At MBPL, the animal on the left has a toe that is too long on the right leg and a heel that is too high on the left leg. The animal on the right has a heel that is too high on the left leg and a toe that is too long on the right leg.

c. **Hoof horn quality:** On average, 44 per cent of equines in these facilities have an abnormal hoof horn on both forelimbs and hind limbs.

Horse 176 at BEL has a damaged hoof wall and an abnormal hoof horn.

The hoof walls of both of horse 296's forelegs have cracks and seedy toe (left). The hoof walls of both of mule 4's forelegs are dumped and have seedy toe. Both of the animals are from KIPMR.

At MBPL, the animal on the left has seedy toe and separation of the hoof wall at the toe. The animal on the right has damage to the hoof walls in all four hooves as the result of dumping.

Horse 56 at MBPL suffers from canker.

d. Frog health: On average, 60 per cent of the equines in these facilities suffer from poor frog health. Several equines have a diseased frog (ie, thrush and a foul-smelling discharge). Some of them don't have a frog –it might have been removed by a foot trimmer or eroded from disease. The frog acts as a shock absorber for the foot when it hits the ground, decreasing the pressure put on the bones and joints of the leg. If the frog is diseased or missing, there is a high probability that the horse or mule may become lame, causing the animal a lot of pain and suffering.

Mule 4's hoof (left) is missing a frog, maggots are crawling on it and it is infected with thrush. Mule 219's hoof is missing a frog. Both of the animals are from KIPMR.

Horse stallions 614 (left) and 980 and horse gelding 801 at RSIPL have a frog with thrush.

Horse 152 at BEL is missing a frog.

The frog is missing on the right foreleg hoof of mules 341 (left) and 260 from HBCPL.

Mule 22's hoof (left) has a diseased frog. Horse 2 has a flat foot, and the hoof wall has not been trimmed in a long time. Both of the animals are from KIPMR.

The frog is absent on the right foreleg hoof of horse 951 (left) and mule 190 at PSVPL.

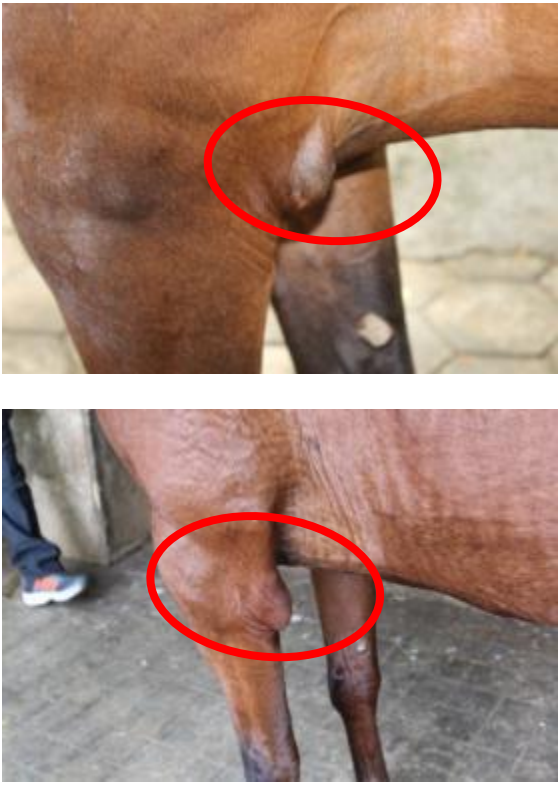
e. Gait: On average,46 per cent of the equines in these facilities have an abnormal gait and show signs of lameness. The ability of several of them to walk is moderately to severely compromised, and some of them are unable to bear their full weight on their limbs.

This mule from KIPMR is unable to bear weight on the left foreleg and is severely lame.

f. Capped elbow, or bursitis: Many equines have "capped elbow" condition. Capped elbow is an inflammatory swelling of the subcutaneous

bursae (acquired bursitis) located over the olecranon process and tuber calcaneus of horses and mules. Causes include kicks, falls, iron shoes projecting beyond the heels, prolonged recumbency and trauma from lying on poorly bedded, hard floors. The inspectors did not see any bedding for the animals, and the floor of the stable is concrete, which is quite hard.

Horse gelding 974 at RSIPL has a capped right elbow.



Horses 296 (left) and 243 from KIPMR have capped elbows.

A right capped elbow can be seen in mules 262 (left) and 158 at PSVPL.

g. **Chronic and painful leg conditions:** Many equines are suffering from painful leg conditions that have been caused mainly from a lack of standard foot-care practices and inadequate trimming and rasping of the hooves. These conditions include osteoarthritis with exostosis of the knee joints (sometimes with a conformational defect like “cow hock”), bursitis on elbow joints and severe lameness.

Mule 601 at BEL has arthritis in the knees of both forelegs as well as an abnormal gait associated with the arthritis.

Horse 337 at BEL suffers from cow hock.

Horse 101 at BEL suffers from capped hock.

Mule 466 at BEL has osteoarthritis with exostosis in the knee joint of the right forelimb.

Mule 556 at BEL has osteoarthritis in the pastern joint of all four legs.

At PSVPL, mule P2 (left) has osteoarthritis in the left knee, and mule 361 has osteoarthritis in both knees.

g. **Chronic and painful hoof diseases:** Many equines suffer from chronic and painful hoof diseases, such as canker, which are caused by serious negligence and inadequate foot care. They also suffer from maggot infestations and damaged, broken heels.

Horse 103 at BELsuffers from canker.

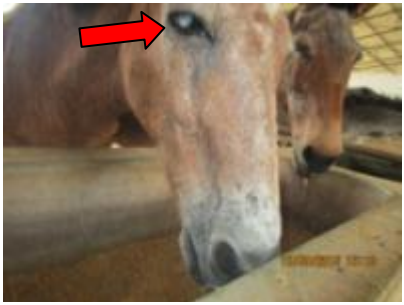
Horse 111 at BEL suffers from canker in the right hind limb.

Mule 22 from KIPMR has an abscess that is draining through the coronet.

Horse 83 at MBPL has a hoof abscess that is draining through the coronet.

8. **Chronic and Painful Eye Conditions**
   Many equines suffer from incurable and neglected eye diseases, complete or partial blindness, microphthalmia, corneal opacity, injury or swelling of eyelids, recurrent uveitis and infections with discharge.

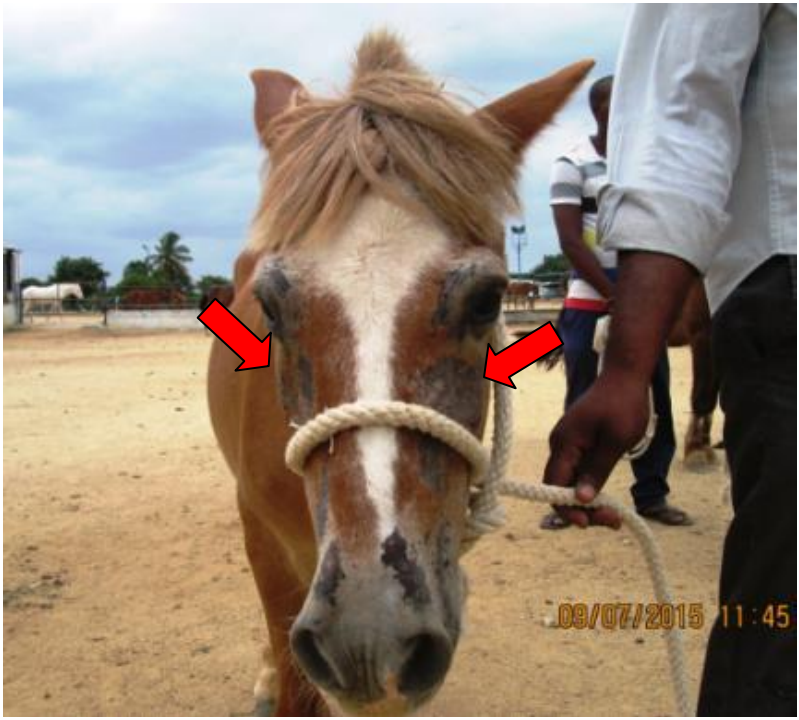
At KIPMR, horse 2 (left) and mule 10 suffer from epiphora (an overflow of tears onto the face) from the right eye.



At MBPL, two equines (left and centre) are blind and suffer from complete corneal opacity, and another has swelling above the upper eyelid – which might be the result of continually rubbing the area against a hard surface in an effort to relieve irritation.

9. **Dermatitis**
   Some animals suffered from dermatitis on the head, particularly on the face, around the eyes and on both sides of the nasal bridge. None of these animals was isolated for treatment – they were kept with other animals. Skin diseases such as ringworm infestation can easily spread to humans and other animals.

Mare A9 from VBL has dermatitis around both eyes.



Gelding D52 from VBL has dermatitis on the face.

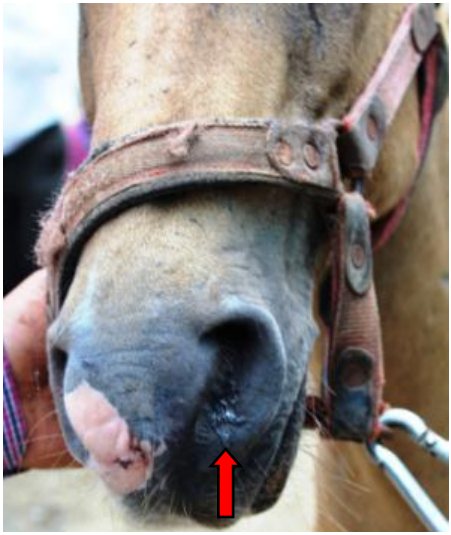
Horse 48 (left) and mule 22 from KIPMR have dermatitis around the eyes.

Horse 106 from KIPMR has dermatitis around the scrotum.

These animals from MBPL have dermatitis lesions on their backs.

10. Nasal Discharge

Some of the equines have a purulent nasal discharge. This is indicative of a respiratory tract infection, and these animals need to be segregated and treated for the infection. But it was observed at RSIPL that they are allowed to be kept with other animals, risking the spread of the infection to the other equines.



Horses B 59 (left) and 801 at RSIPL have a purulent discharge coming from their nostrils.

11. Abnormal Oral and Dental Conditions

One of the equines at MBPL has extra incisors on the lower jaw, which caused injuries to the lower lip. No corrective dental procedures had been done, and the wound had not been dressed. This condition prevents the animal from being able to eat grass easily. At MBPL, horse 27 has a severe overshot bite (the upper jaw is physically longer than the lower jaw), and mule 45 suffers from an undershot bite (the lower jaw is physically longer than the upper jaw). In both conditions, the incisors are not apposed properly, which prevents the animals from being able to grasp or cut grass easily. The majority of the equines at MBPL also have dark, stained teeth with tartar deposition, indicating that they are not given the appropriate food to eat.

Horse 27 (left) has an overshot bite. Mule 45 has undershot bite. Both of the animals are at MBPL.

These equines at MBPL have stained teeth.

12. Protozoal Infections

Many equines had corneal opacity, petaechial haemorrhages over their third eyelid or flies on their body – all of which likely indicate clinical or sub-clinical protozoal infections, particularly trypanosomiasis. The majority of the laboratories inspected do not routinely screen for such diseases, as required by regulations. Findings of

high neutrophilia in equines from some of the laboratories support the suspicion that there is a high a prevalence of protozoal infection amongst animals at those facilities.

Horse 27 (left) has petaechial haemorrhages on the third eyelid. This animal's leg is bleeding after being bitten by a fly. Both animals are at MBPL.

This fly is on the body of one of the equines at MBPL.

C. Other Observations

1. Staff Safety

At the majority of the laboratories visited, animal handlers did not wear appropriate shoes, and some of them were barefoot – even the veterinarians. This puts the safety of the staff at risk.

Some handlers wear slippers at MBPL.

Some handlers are barefoot at MBPL.

2. **Improper Bio-Medical Waste-Management System**

MBPL does not have a bio-medical waste-management system in place. All the waste, including used and non-sterile syringes and dressing materials, is dumped at one corner of the farm, where animals are allowed to roam freely and where the workers' accommodations are located. Inspectors also observed that used syringes and needles are kept on the veterinarian's table. Not disposing of the used needles and syringes indicates that the staff might be reusing them to administer medication to the animals.

Bio-medical waste is improperly disposed of at one side of the farm at MBPL, and used syringes and needles are left on the veterinarian's table

3. **Breeding of Animals**
In many sheds, very young foals were found with their mothers, a mare and a stallion were found together and pregnant animals were also found, indicating that there is uncontrolled breeding taking place at various facilities. At many of the laboratories, only a physical barrier separates the males and the females, and animals are not sterilised. At MBPL, mares and stallions roam together freely and actively breed, and 15 foals have been born at the facility since March 2013.

A newborn foal lies on the ground at BEL.

The horse on the left gave birth to a foal on 28 August 2015. Mare 412 is seven months pregnant.

4. **Housing**
   The majority of the laboratories have crowded paddocks. Many times, when more equines are purchased, the housing areas, number of caretakers, material resources for the animals, etc, remain the same. The aforementioned bruises, bite wounds and other injuries were caused by internal

fighting, which is the result of extreme crowding and poor animal-housing practices.

The fencing of many of the old paddocks in these facilities is damaged and rusted. Animals are severely crowded and forced to stand in mud caused by water logging. The animals are fed in a common manger, and often, the dominant and healthy ones eat most of the food, starving the unhealthy and diseased equines. There is no dedicated sand pit available – a space ideally should be filled with soft sand for the animals to roll in. Instead, they are forced to roll on the hard ground, with gravel and stones, or on hard concrete.

The healthy equines and those with injuries and diseases are generally kept in the same sheds. A few equines with serious illnesses – such as chronic osteoarthritis, bilateral blindness, thrush and canker – and behavioural issues are housed with healthy animals and denied adequate exercise. The sheds for equines kept under quarantine are very close to paddocks where other animals are housed, calling into question the very purpose of quarantine, which is to prevent the spread of disease.

Equines at VBL were stabled on the hard concrete floor without any bedding.

Animals at HBPCL are stabled on a hard concrete floor without any bedding.

Horses are forced to stand amidst their own faeces and urine at RSIPL.

Severely crowded, barren paddocks do not supply enrichment or offer the equines an opportunity to graze at RSIPL.

Equines are severely crowded in one shed at BEL.

Equines are forced to stand in mud and waterlogged areas at BEL.

This paddock (left) at KIPMR does not contain grass. Standing water in this paddock (right) allows mosquitoes to breed at KIPMR.

Small pipes with sharp edges are installed in the paddock at MBPL.

Rusted horizontal pipes with sharp edges are located in many places at MBPL.

Animals at PSVPL are stabled on the hard concrete floor without any bedding.

5. **Routine Preventive-Management Practices**
   Although officials from all the laboratories claimed that they have staff to check the animals'

feet regularly and clean and trim/rasp them, many of the equines have either overgrown hooves or abnormally short hooves. The foot-care practices in general are so inadequate that many equines suffer from a serious cancerous condition known as canker, which is untreatable. The animals with canker are severely lame, and often, the affected area becomes infested with maggots, as seen in some of the equines. Some facilities have a few, one or no foot trimmers for hundreds of animals, and in cases when they are employed, the staff lacked training or licencing. The equines are not subjected to routine dental examinations or rasping. Staff members did not know how to use the curry comb or body brush for grooming, and equines' dirty skin and coats indicated that regular grooming is not practised.

Mule 211 at BEL has matted hair and dandruff, indicating a lack of grooming.

This horse at MBPL has matted hair, indicating a lack of grooming.

6. **Improper Medical and Equipment Storage**
   Many of the laboratories do not follow a procurement, storage and disbursement protocol, and the quantity of medication was wholly inadequate considering the number of animals who are injured and diseased and the huge population of equines. Monthly audits are not being conducted to check the quality and quantity of drugs or the serviceability of the equipment. Some laboratories, including MBPL, do not maintain an emergency medical kit and do not have barbiturates, an essential drug for euthanising suffering animals. MBPL has an ample stock of injectable Ivermectin (Hi Tech), although the use of this drug is contraindicated in equines. In the majority of the laboratories, inspectors found teeth rasps and stomach tubes that have not been properly maintained. Stocks of

emergency medication, such as liquid paraffin (a laxative used for treating colic),were so low that there wasn't enough to treat even one or two cases of colic. Although the facilities have equines of different sizes, including foals, ponies, donkeys and large horses, they usually have stomach tubes in only one size, raising questions about their ability to handle equine emergency situations, such as colic, effectively. The foot-trimming kits are not maintained properly, and the equipment was not sharp enough. The foot-care kit also lacked many essential tools, such as a drawing knife, a searching knife, an abscess knife, etc.

Medication is stored in open boxes and unhygienic conditions at MBPL.

At KIPMR, damaged head collars are used, and temporary repairs have been made using sharp synthetic materials.

MBPL does not have appropriate farriery tools, and it uses a damaged face halter, which is being held together with iron wires.

At MBPL, the trevis is rusted and has pipes with rust and sharp edges.

7. **Pre-Purchase Screening Procedures/Approval and Post-Purchase Quarantine and Management**

   The majority of the laboratories do not follow their own SOP or the CPCSEA's guidelines regarding pre-purchase screening of animals, as many horses at the facilities are suffering from

chronic conditions, such as osteoarthritis, canker, blindness, etc, and officials claimed that most of these conditions existed when they purchased these animals. However, officials failed to explain why they procured injured and diseased animals who were physically and mentally unfit for serum production. If some of these clinical conditions manifested after the animals were purchased, it shows a serious failure on the part of veterinarians to identify the problems and treat them before irreversible and irreparable damage was done and the conditions became increasingly harder to treat. In addition, many laboratories were flouting post-purchase quarantine and management procedures. The observations made during the inspection, including the ineffective separation of newly purchased equines from the existing healthy population, indicate that laboratories were not complying with regulations. The majority of the facilities do not have permission from the CPCSEA's central committee to procure animals, and instead they procure them illegally based on the demand for serum.

Ponies recently procured by RSIPL are weak and emaciated.

8. Quality of Veterinary Services and Adherence to Pain Management

Veterinarians from various laboratories did not follow the basic steps of wound management, such as clipping hair from wounds, flushing wounds with plenty of water ("dilution is the solution to pollution") and using antiseptics and fly repellents appropriately. Often, the wounds were found to have been sprayed with an herbal antiseptic and fly repellent without first clipping the hair and cleaning the area. The veterinarians were not aware of the treatment protocol to be followed for thrush and canker conditions in feet. They also did not know about the importance of recognising and managing pain and of the

neuroleptanalgesia protocol (giving a combination of a sedative and an analgesic such as xylazine and butorphanol) to be followed prior to any invasive and painful veterinary procedure, such as dressing a severe injury on the upper eyelid or treating a foot abscess, canker, etc. It is well known that colic is a common emergency medical condition in equines. However, inspectors observed that the majority of the laboratories do not have a functional colic box.

The CPCSEA's guidelines recommend that bleeding be done with a disposable needle with a cannula. Laboratories should use 14- to 16-gauge needles that are 25 to 40 millimetres long, with suitable silicon tubing. However, the needles used for bleeding by all the laboratories were found to be larger than a 14-gauge needle and longer than 100 millimetres, which could be very painful and stressful for the equines.

An 8-gauge needle is used for bleeding at RSIPL, which is in apparent violation of the CPCSEA's guidelines.

The bleeding needle used by BEL is larger than a 14-gauge needle and is 150 millimetres long.

Pony 498 at VBL was observed to be in a recumbent condition, and inspectors were told that

the animal had been under treatment for the previous two weeks. According to the treatment record furnished by VBL, this animal had been receiving treatment since 20 June 2015 for problems with coordination. The pony was forced to lie on the hard, bare floor without any bedding, adding to the animal's pain and suffering.

Pony 498 is in a recumbent position (left).The animal has unclean eyes that attract flies.

9. **Death Rate**
   The death rate, as seen from the death records from the majority of the laboratories, is very high. This could be because of poor veterinary care, unskilled staff who completely failed to provide animals with basic veterinary care, over bleeding anaemic animals, and unregulated procurement of immature, already sick and old animals.

10. **Ending the Suffering of Animals Through Euthanasia**
    Although the CPCSEA's guidelines clearly state that equines with incurable diseases, those in severe pain and distress, and those who are terminally ill must be euthanised after obtaining the necessary permission from the CPCSEA, the laboratories are not doing this. Many equines are suffering from painful osteoarthritis in the legs with exostosis (formation of new bone on the surface of a bone) and are severely lame. Some equines are blind in both eyes, and others are suffering from painful foot conditions such as canker.

    The equines listed below are recommended for immediate euthanasia. They are among those who were examined by the inspectors during the welfare assessment. There could be many more animals with severe, chronic and painful disease conditions in the laboratories, but the inspectors couldn't identify them because of time limitations. The veterinarians are vested with the responsibility of identifying them immediately

and taking necessary action to relieve their suffering through euthanasia.

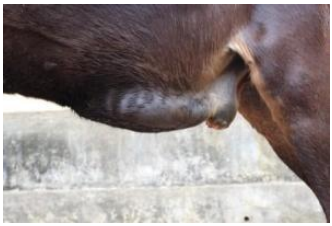
Animals at BEL Who Need to Be Euthanised Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Requires Euthanasia	Photograph
1	601	Mule, Gelding	This animal has osteoarthritis with exostoses in both forelimb joints.	
2	176	Horse, Gelding	This animal was purchased from a Chettinad stud farm in 2011 with canker in his right hind foot.	
3	103	Horse, Mare	This animal has recurrent uveitis and partial blindness in both eyes. She also has canker in both hind feet and her right forefoot, and her left forefoot has maggots. In addition to having bursitis in her right elbow, she is not able to bear weight on her limbs and has a "thin" body condition score.	

4	111	Horse, Gelding	This animal has severe canker in his right hind foot and a “very thin” body condition score. He is also unable to bear weight on his limbs as a result of severe lameness.	
5	466	Mule, Gelding	This animal has osteoarthritis with exostoses in both forelimb joints and is severely lame.	
6	264	Horse, Mare	This animal has osteoarthritis in the fetlock and pastern joints of all four legs.	
7	463	Mule, Mare	This animal has arthritis in her left knee joint (probably from a previously healed fracture), and the frog is missing as a result of thrush. She is also severely lame.	

Animals at KIPMR Who Need to Be Euthanised Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Euthanised	Photograph
1	299	Horse, Gelding	This horse cannot bear weight on either hind limb because of laminitis in the hooves, so he has shifted his whole body weight onto both forelegs ("camped under" condition), which have become swollen from the shoulder to the knee. He lies down more than normal, so bedsores (wounds) can be seen all over his extremities and other parts of his body, such as the pelvic girdle, point of shoulder and head. He has been suffering like this for a long time. He has untreatable chronic laminitis and does not allow any of his legs to be lifted. His body condition score is 1 (very thin). His ribs are visible, and the point of shoulder, tail base and spine are too prominent.	   

2	329	Mule, Gelding	This mule is over 25 years of age and suffers from a suspected protozoal disease. His body condition score is 1 (very thin). There is oedema over his abdomen, and he has petaechial haemorrhages in both eyes. According to the facility's veterinarians, he is not responding to treatment. He also has hoof problems, is missing a frog and cannot walk.	  
3	4	Mule, Mare	This mule cannot bear weight on her forelimbs because of laminitis. Maggots are crawling in the area where a frog is missing. Her hoof walls are collapsed, and other parts of her body have deep wounds. She is over 20 years of age. She cannot walk normally and has to be forced to walk.	  

Animals at MBPL Who Need to Be Euthanised Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Euthanised	Photograph
1	83	Horse, Gelding	This animal suffers from chronic laminitis and cannot bear weight on his forelegs. He has a body condition score of 1 (very thin), and his ribs, shoulders, pelvis and spine are prominent. He has wounds on all of his extremities. His hoof walls are collapsed, and he has seedy toe. He has swelling in the fetlock joints of both forelegs, and an abscess is draining through the coronet. He also suffers from dermatitis and ulcers in his oral cavity.	   

2	80	Horse, Gelding	This animal suffers from chronic laminitis and cannot bear weight on his forelegs. He has a body condition score of 1 (very thin), and his ribs, shoulders, pelvis and spine are prominent. He has wounds on his extremities, and his hoof walls are damaged. His fetlock joints on both forelegs are swollen. He also suffers from canker, bleeding from a frog, a deep wound over his pastern and a fresh, bleeding wound. He was not given any treatment for these conditions. He has extra incisors in his lower mandible, which have injured his upper lip and make it difficult for him to eat.	    

3	45	Mule, Mare	This animal cannot walk or stand on her forelegs, both of which have abnormal conformation. Because of this, she lies down on the concrete floor frequently, which has caused wounds to develop on her body. She has a body condition score of 1 (very thin), corneal opacity, no frog in one of her hooves, dermatitis and an undershot bite, which makes it difficult for her to pick up grass.	  

4	237	Horse, Stallion	This animal has a problem with his left stifle joint, which hinders his ability to walk. When he was forced to walk, he fell down. He also has corneal opacity in his right eye and a wound on his neck.	   

5	53	Horse, Gelding	This animal suffers from chronic laminitis and has laminitis rings over his hoof wall. His hoof wall has collapsed, and he has seedy toe. He also has sole ulcers, moderate lameness and a capped elbow on his right foreleg with a deep wound over it. He does not have a left eyeball.	   

Animals at VBL Who Need to Be Euthanised Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Euthanised	Photograph
1	498	Horse, Gelding	According to the treatment record furnished by VBL, this pony has been under treatment since 20 June 2015 for problems with gait coordination. He was lying on the bare ground without any bedding on 9 July 2015. He was struggling to get up and had been recumbent for the previous two days.	

11. Rehabilitation of Retired Animals and Young Foals

The equines many laboratories claim to have retired and rehabilitated continue to live in the same sheds and paddocks as other animals used for bleeding, irrespective of their age, physical condition or ailments. Just like any other animal there, they have to compete for their food and drinking water. Most of the retired and rehabilitated equines suffer from chronic and painful foot diseases and need special care with respect to having easily digestible food, exercise, grooming, dental care, etc. The AWBI should recommend that these animals be moved to a genuine AWBI-approved sanctuary where they

can receive the treatment, care and freedom from suffering that they need. Many foals under 3½ years of age are used for bleeding. The AWBI should recommend that they be rehabilitated at a suitable sanctuary.

The equines listed below are recommended for immediate rehabilitation. They are among those who were examined by the inspectors during the welfare assessment. Many more animals could be in such need, but the inspectors couldn't identify them because of time limitations. The veterinarians of the concerned laboratories are vested with the responsibility of identifying them immediately and taking necessary action.

Animals From PSVPL Who Need to Be Rehabilitated Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Rehabilitated	Photograph
1	361	Mule, Mare	This animal has osteoarthritis in both knee joints.	
2	295	Horse, Gelding	This animal is over 25 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
3	190	Mule, Gelding	This animal has swollen flexor tendons and fetlock joints of all four limbs. He is also over 25 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	

4	P2	Mule, Gelding	This animal has osteoarthritis in the left knee of the foreleg.	
5	T 40	Mule, Mare	This animal is over 25 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
6	158	Mule, Gelding	This animal has an abnormal hoof shape in the right hind hoof. He is also over 25 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	

7	951	Horse, Gelding	This animal is over 25 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	

Animals at RSIPL Who Need to Be Rehabilitated Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Rehabilitated	Photograph
1	801	Horse, Gelding	This animal is over 19 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
2	B 1	Horse, Stallion	This animal is under 3½ years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	

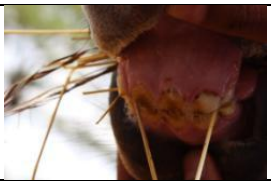
3	474	Horse, Stallion	This animal is under 3 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
4	614	Horse, Stallion	This animal is around 2 years old. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
5	447	Horse, Stallion	This animal is under 3 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
6	B 59	Horse, Stallion	This animal is under 4 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	

Animals at BSVL Who Need to Be Rehabilitated Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Rehabilitated	Photograph
1	A 373	Horse, Gelding	This animal is over 18 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
2	A 548	Horse, Stallion	This animal is under 3 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
3	A 311	Horse, Stallion	This animal is under 3 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	
4	P 135	Horse, Stallion	This animal is under 3 years of age. Per the CPCSEA's guidelines, he should not be used in the bleeding programme.	

Animals at BEL Who Need to Be Rehabilitated Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Rehabilitated	Photograph
1	177	Horse, Stallion	This animal is beginning to develop canker in the hooves of his forelegs, the lateral wall of his left foreleg heel is damaged, the frog is missing and he has a "thin" body condition score.	
2	16	Horse, Mare	This animal is over 25 years of age and has a "very thin" body condition score.	
3	567	Mule, Mare	This animal is over 25 years of age and has a "thin" body condition score. She also has swelling on her left lower eyelid.	
4	506	Mule, Gelding	This animal is over 25 years of age and has a "thin" body condition score.	
5	403	Horse, Stallion	This animal is approximately 2½ years old and has a "thin" body condition score. Per the CPCSEA's guidelines, he should not be used for bleeding.	

6	502	Horse, Stallion	This animal is approximately 2½ years old and has a “thin” body condition score. Per the CPCSEA’s guidelines, he should not be used for bleeding.	
7	260	Horse, Stallion	This animal is approximately 2½ years old and has a “very thin” body condition score. Per the CPCSEA’s guidelines, he should not be used for bleeding.	
8	UF 3	Horse, Mare	This animal is approximately 2½ years old and has a “very thin” body condition score. Per the CPCSEA’s guidelines, she should not be used for bleeding.	
9	UF 2	Horse, Mare	This animal is the foal of mare 122. She is approximately 2½ years old and has a “thin” body condition score. Per the CPCSEA’s guidelines, she should not be used for bleeding.	
10	UF 1	Horse, Stallion	This animal is approximately 2½ years old and has a “very thin” body condition score. Per the CPCSEA’s guidelines, he should not be used for bleeding.	

Animals at VBL Who Need to Be Rehabilitated Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Rehabilitated	Photograph
1	A 28	Mule, Gelding	This animal is over 25 years of age. Per the CPCSEA's guidelines, he should not be used for bleeding.	
2	A 32	Mule, Mare	This animal is over 25 years of age. Per the CPCSEA's guidelines, she should not be used for bleeding.	
3	142	Horse, Gelding	This animal is over 25 years of age. Per the CPCSEA's guidelines, he should not be used for bleeding.	
4	R 11	Horse, Mare	This animal is under 3 years of age. Per the CPCSEA's guidelines, she should not be used for bleeding.	
5	Foals	Horse	There are a few foals at the facility who need to be rehabilitated at a better facility after they have been weaned from their mother.	

Animals at HBPCL Who Need to Be Rehabilitated Immediately

Serial No	Animal ID No	Species and Sex	Condition for Which Animal Needs to Be Rehabilitated	Photograph
1	138	Mule, Mare	This animal is over 25 years of age. Per the CPCSEA's guidelines, she should not be used for bleeding.	
2	481	Horse, Gelding	This animal is under 2 years of age. Per the CPCSEA's guidelines, he should not be used for bleeding.	

12. Laboratory Analysis

The inspection team collected whole blood samples from all the equines who were assessed. The samples were collected in EDTA (anti-coagulant) vials and sent to laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories for analysis. The results of the laboratory analyses and the interpretation of the results are enclosed as **Annexure 3**.

The laboratory analyses revealed that, on average, 36 per cent of the equines are suffering from anaemia and 19 per cent are suffering from sub-acute, acute, chronic or active inflammatory reaction. Several equines have a complex/mixed pathological condition, like anaemia, accompanied by a sub-acute, acute, chronic or active inflammatory reaction.

13. Records and Reports

A look at the records revealed that all the laboratories have been procuring animals after receiving permission from the IAEC and not the CPCSEA's central committee, as required by the regulations. The majority of the laboratories do not have copies of annual inspections by the IAEC, and those that had these reports didn't accurately record veterinary findings in the animals. The inspectors also did not find any documents that farriers are licensed, as is required by the provisions of the Prevention of Cruelty to Animals (Licensing of Farriers) Rules, 1965,at any of the laboratories.

Bleeding records indicate that many animals are bled several times in a month and that more blood is removed than is permitted. Also, there was a wide variation in the bodyweight measurements of the same animal in the same month, indicating that veterinarians failed to calculate the proper bodyweight and, in many cases, ended up collecting more blood than is allowed.

Post-mortem records show a high death rate at several laboratories, indicating poor veterinary care and general physical condition of the animals used for bleeding. There are also a few laboratories, such as MBPL, that do not have any records, and others, such as BEL, which have all the necessary SOPs but not the records that the SOPs require.

IV. Discussion

Antitoxins are commercially prepared by repeatedly exposing large mammals – usually equines – to repeated doses of a toxin, often in conjunction with an adjuvant to stimulate the immune response. This process causes the horses' immune systems to produce abnormally large quantities of antibodies against the toxin, while also leading to a host of local adverse effects. Horses frequently develop injection site oedema, thrombosis, phloebitis, abscesses, fistulas, fibrosis and other problems, even when all relevant guidelines are complied with. To isolate these antitoxin antibodies for human use, the hyper-immunised animals are repeatedly bled of large volumes of blood over an essentially indefinite period. The CPCSEA's guidelines from 2001 require that horses be bled up to only 1 per cent of their bodyweight, or 10 per cent of their circulating blood volume, once every four weeks – a figure that can variably translate to up to 8litres of blood per bleeding – and the horses are supposed to be rested for at least three months a year. In 2005, this was increased to 1.5 per cent of their bodyweight or 15 per cent of their circulating blood volume.

Apart from the aforementioned negative impacts of antitoxin production on the welfare of the horses who are used essentially as production machines, there are recognised safety issues associated with human use of the final products. Equine antitoxins may cause hypersensitivity and serum sickness, and the equine immunoglobulin subclass IgGT is highly immunogenic in humans. Horses, like all mammals, can harbour communicable diseases (including Creutzfeldt-Jakob disease) that may compromise the safety of final antitoxin products.

Fortunately, non-animal antibody production techniques can be used in place of production methods that use equines. In one well-described approach, immune cells from individuals who have suffered from venomous bites or other forms of toxin exposure can be used to construct human immune libraries.[1,2,3] Once these libraries have been prepared, antibody phage display provides a technology to generate toxin-neutralising antibodies against multiple toxin types. Phage display facilitates the production of antibodies from human sources without the need for a long process of animal immunisation (or housing, feeding and veterinary care) while also eliminating concerns over a final product that itself can

[1]Chassagne S, Laffly E, Drouet E *et al*. 2004. A high-affinity macaque antibody F_{ab} with human-like framework regions obtained from a small phage display immune library. Mol Immunol. 41(5):539–546.
[2]Pelat T, Hust M, Laffly E *et al*. 2007. High-affinity, human antibody-like antibody fragment (single-chain variable fragment) neutralizing the lethal factor (LF) of *Bacillus anthracis* by inhibiting protective antigen-LF complex formation. Antimicrob Agents and Ch.51(8):2758–2764.
[3]Pelat T, Hust M, Hale M *et al*. 2009. Isolation of a human-like antibody fragment (scF_v) that neutralizes ricin biological activity. BMC Biotechnol. 9:60.

cause illness in humans who receive it during treatment.[4] This approach has been demonstrated in the development of human antibodies against the toxic components of the venom of scorpions, snakes, puffer fish and other organisms.[5,6,7]

V. Interpretations

Many of the animals showed negative reactions such as fear and apathy during "observer approach" and "chin contact" assessments, indicating that they are actively avoiding human contact or the suffering associated with the process of bleeding, firing, etc.

Eye lesions showing signs of habronemiasis, blindness, corneal opacity and swelling as well as injuries to the eyelids indicate poor veterinary care or that the staff responsible for such care are not adequately trained.

Pale mucous membranes indicate anaemia, which may be from poor nutrition – the result of group feeding, in which only dominant animals get to feed. The anaemia may also be caused from more bleeding than permitted or repeated

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[4]Lanzavecchia A, Corti D, Sallusto F. 2007. Human monoclonal antibodies by immortalization of memory B cells. CurrOpinBiotechnol. 18(6):523–528.

[5]Amaro I, Riaño-Umbarila L, Becerril B, Possani L. 2011. Isolation and characterization of a human antibody fragment specific for Ts1 toxin from *Tityusserrulatus* scorpion. Immunol Lett. 139(1-2):73–79.

[6]Roncolato E, Pucca M, Funayama J *et al*. 2013. Human antibody fragments specific for *Bothropsjararacussu* venom reduce the toxicity of other *Bothrops sp*. venoms. J Immunotoxicol. 10(2):160–168.

[7]Chulanetra M, Bangphoomi K, Sookrung N *et al*. 2012. Human ScF_v that block sodium ion channel activity of tetrodotoxin. Toxicon. 59(2):272–282.

bleeding with less than four weeks between successive bleeds. This is also supported by blood reports which showed that 36 per cent of equines used in these facilities are suffering from some form of anaemia.

An examination of animals' teeth revealed that very young and very old animals are being used for bleeding, and the misrepresentation of their age in the records indicates either a lack of veterinary training or the falsification of data. It also indicates that proper rehabilitation of animals is not being done, and instead of being rehabilitated, old animals are continually bled until they die. The lack of dental care and treatment records as well as instruments used for dental care indicates that such treatments are not being done at all. Animals, such as those at MBPL, have stained teeth, which indicates that the appropriate type and amount of grass is not being given to the animals.

Body lesions indicate poor wound-management practices by caretakers, and wounds on the point of the knee indicate slippery floors and the lack of required bedding. Bite lesions indicate crowding and can also result from housing sick, old and aggressive animals together.

The majority of the equines are thin and malnourished. This shows serious negligence on the part of the management at these facilities with respect to important and routine management practices, such as providing the animals with adequate and balanced nutrition, checking their teeth and floating, and adopting effective deworming strategies, as explained in the CPCSEA's guidelines.

Even though the CPCSEA doesn't recommend hot branding for the identification of equines, the majority of the laboratories use this method for the identification of animals. This hot branding plays a major role in inducing fear and pain in these animals. Some of the firing lesions became infected as the result of fly infestation, and the wounds were not properly managed, causing the animals severe discomfort.

Nearly 60 percent of the equines have issues with frog health, and this, in turn, results in other foot conditions, such as contracted heel, that cause lameness and disorders in gait. This also reflects poor foot care, either the result of a lack of training or of not understanding the importance of equine foot care. Hard concrete floors and the lack of soft bedding have made the animals' foot- and hoof-related issues worse.

A high death rate indicates that there is gross negligence in the care and management of equines, sick and injured animals are not being provided with quality veterinary treatment services and, apparently, there is serious violation of the CPCSEA's guidelines.

The majority of the laboratories ignored the CPCSEA's guidelines by purchasing unfit animals, perhaps because they were available at a cheaper price than healthy ones. Many foals have been born at the facilities which indicates that pregnancy screenings are not being done prior to purchase and that there is no control over breeding at the facilities.

VI. Violations

There are numerous apparent violations of the following animal-protection laws and guidelines by these laboratories:

A. Section 3 of The Prevention of Cruelty to Animals Act, 1960, states, “It shall be the duty of every person having the care or charge of any animal to take all reasonable measures to ensure the well-being of such animal and to prevent the infliction upon such animal of unnecessary pain or suffering”. Also, CPCSEA Guidelines for Laboratory Animal Facility, 2005, states, “Adequate veterinary care must be provided and is the responsibility of a veterinarian or a person who has training or experience in laboratory animal sciences and medicine”. The majority of animals at these laboratories are suffering unnecessarily, are neglected and are denied basic veterinary treatment and care.

B. Section 4(a) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states, “No establishment shall perform any experiment on animals unless it is registered”. VBL, BEL and PSVPL were not registered with the CPCSEA, while BSVL, MBPL and HBPCL need to renew their registration to continue to use animals.

C. Section 3(b) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states, “Every breeder/establishment carrying on the business of breeding animals or trade of animals for the purpose of experiments, shall apply for

registration within sixty days from the date of commencement of these rules and stop breeding of animals if registration is subsequently refused to it by the Committee". With the exception of BSVL and SII (which does not require one), the laboratories did not have renewed registrations. Staff admitted that the procurement and use of animals continued despite not having approval from the CPCSEA's central committee.

D. Section 6(a) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states, "Every registered establishment shall maintain a register as per the specified format and keep complete particulars about the kind of animal to be used for conducting any experiment, the health of the animal, the nature of experiment to be performed, and the reasons necessitating the performance of such an experiment on particular species". The majority of the laboratories do not have records of annual inspections by the IAEC. MBPL does not have any proper records at all. A few of the laboratories, including BEL, do not have full records of the minutes of the IAEC meetings.

E. Section 7(d) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states that "animals' attendants must be suitably trained and experienced in the duties allotted to them". The majority of the laboratories used an 8-gauge needle to extract blood despite the CPCSEA's Guidelines for "Care and Management of Equines Used in the Production of Biologicals", which

requires that laboratories use a 14-gauge needle for bleeding. Healed lesions on animals' limbs, hoof-related lesions, the use of older and younger animals who require rehabilitation, the lack of soft bedding, the presence of systemic infections, the lack of grooming, improper wound and pain management, the lack of dental care, improper equipment and poor body condition scores in many of the equines indicate that the staff are not adequately trained to take care of the animals or to carry out their other duties.

F. Section 7(e) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states that "animals shall be looked after, before and after the experiments by a trained and experienced attendant". Accidental births, the continued use of animals with incurable conditions, the lack of euthanasia, and the procurement of unfit, lame and pregnant animals indicate that animals are not looked after before or after bleeding.

G. Section 9(f) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states that when there is reason to believe that an animal is suffering from abnormal or severe pain at any stage of a continuing experiment, the animal "shall be painlessly destroyed at that stage without proceeding with the experiment". Inspectors found several animals with foot problems, including canker, chronic arthritis, exostosis, etc. All these animals should ideally be euthanised to relieve them from pain and suffering.

H. Section 10(b) of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, states, "An establishment shall not acquire any animal by sale or otherwise except from a registered breeder/establishment". All animals are procured from unlicenced breeders. Animals are procured despite being pregnant and having untreatable conditions such as blindness, degenerative joint disorders and infections.

I. Rule 3 of The Prevention of Cruelty to Animals (Licensing of Farriers) Rules, 1965, states, "No person shall, after the commencement of these rules, begin to carry on the business of a farrier, and no person carrying on the business of a farrier at the commencement of these rules, shall, after the expiration of three months from such commencement, continue to carry on such business, except under a licence". Some of the laboratories do not have a full-time farrier, and farriers who were present were untrained and likely unlicenced, as the inspectors couldn't find the licencing records for any of them.

J. A 2006 amendment in rule 9 of the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, (1) clause (b)(bb), states that "replacement alternatives not involving experiments on animals should be given due and full consideration and sound justification must be provided in case alternatives, though available, are not used". None of the laboratories that use animals for bleeding have explored the availability of non-animal methods of antitoxin production.

K. The Honourable Supreme Court judgement dated 23 September 2002 on Writ Petition (Civil) No 216/2001 on *OP Tehlan v Union of India &Ors* states, "In view of the action taken by the CPCSEA pursuant to the orders which were issued by this Court, no further action is called for. But the Ministry of Environment & Forests will continue to be vigilant and take appropriate action whenever and wherever necessary. Accordingly, the writ petition is disposed of". The findings of the AWBI-authorised inspections reveal failure to implement and monitor the existing regulations and guidelines and adhere to the Supreme Court judgement.

VII. Recommendations

A. The AWBI should request that the CPCSEA not renew the registration of the equine facilities that have apparent violations of animal-protection laws.

B. All the seriously sick and injured animals and those who suffer from incurable diseases or injuries must be immediately euthanised to end their suffering.

C. All other sick and injured animals should be rehabilitated at a sanctuary recognised by the AWBI.

D. All the equines must be immediately sterilised to prevent breeding.

E. The AWBI should advise the Central Drugs Standard Control Organization to cancel the licences of all the facilities that violate animal-protection laws to manufacture biological products, as the serum is obtained from animals who are sick and whose welfare is poor, thereby compromising the quality of the biological product.

F. The CPCSEA should recommend euthanasia for those equines the inspectors noted in the aforementioned charts as well as any others who suffer from irreparable, irreversible and painful conditions in order to relieve their suffering.

G. The CPCSEA should recommend rehabilitation of the young and aged animals and those who are physically unfit for bleeding, as noted in the aforementioned charts, in order to prevent any further suffering of those animals.

H. The AWBI should request that the CPCSEA improve its existing guidelines for the "Care and Management of Equines Used in the Production of Biologicals" by making the following amendments:

1. The guidelines should be modified to make them *rules* under the law for stronger implementation.
2. A screening mechanism should be put in place to identify animals who are pregnant, under 5 years of age or over 14 prior to procurement.
3. Horses under 5 or over 14 should not be procured and used for blood extraction. Also,

the veterinarians of the equine farms owned by serum institutes should be trained to determine the age of equines using dentition in order to prevent bleeding of equines in age groups prohibited by the law.

4. Equines must be procured only from CPCSEA-registered breeders and suppliers.
5. Montanide adjuvants could be a safer alternative to the conventional adjuvants (Freund's) for the primary phase of immunisation in antivenin production.
6. Even when all the guidelines are implemented, immunisation and extraction of blood are very painful procedures, and horses should not be subjected to a lifetime of torture. So the CPCSEA should implement the 2001 recommendation not to use a horse for serum extraction for more than three years.
7. Body condition scores should also be checked, along with bodyweight, to determine whether the animals can be used for bleeding. Only animals with a body condition score of 3 (on a 1–5 scale, with 1 being very thin and 5 being very fat) should be used.

I. The AWBI should advise the National Research Centre on Equines and the Ministry of Agriculture & Farmers Welfare to carry out regular disease surveillance of equines at serum institutes in India.

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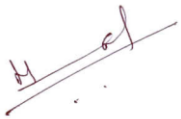

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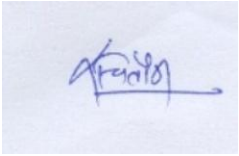

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