

10 June 2025

Dr. Abhijit Mitra
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Via post and email: ahc-dadf@nic.in

Dear Dr. Mitra:

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 2 million members and supporters. We recently received alarming video footage, photographs and testimonials from insiders who were employed at Palamur Biosciences Pvt Ltd (CCSEA Registration Number: 1312/PO/RcBiBt-S/RcBiBt-L/09/CPCSEA) (hereinafter, "the Company"), located at Karvena (Village), Bhoothpur (Mandal), Mahabubnagar-District- 509001 Telangana, documenting the reported abuse and neglect of dogs, pigs, and monkeys used at the Company from 2021 to 2023. **You can see the referenced video footage, photographs, and more details [here](#).**

The details described below present a deeply troubling and persistent pattern of apparent noncompliance with The Prevention of Cruelty to Animals Act, 1960 (hereinafter, "the PCA Act, 1960"), The Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (hereinafter, "the Breeding of and Experiments on Animals Rules, 1998"), the Guidelines on the Regulation of Scientific Experiments on Animals, 2007 (hereinafter, "the CPCSEA Guidelines, 2007"), the CPCSEA Guidelines for Laboratory Animal Facility, 2015 (hereinafter, "the CPCSEA Guidelines, 2015"), and the Guidelines of CPCSEA for Reuse Rehabilitation of Large Animals 2020 (hereinafter, "the CPCSEA Guidelines, 2020").

Based on the information presented below, we request that the Committee for the Control and Supervision of Experiments on Animals (CCSEA) pursue the following immediate actions with respect to the Company due to serious and repeat apparent violations of the PCA Act, 1960, the Breeding of and Experiments on Animals Rules, 1998, the CPCSEA Guidelines, 2007, the CPCSEA Guidelines, 2015, and the CPCSEA Guidelines, 2020:

- **Permanently terminate the Company's CCSEA registration to conduct animal experiments now or in the future, and permanently close the company's breeding centre;**
- **Direct the Company to immediately cease to perform any experiment on any animal, or transfer any animal to any other laboratory or breeding centre, or acquire any new animal; and,**
- **Ensure care and protection of all surviving animals under the custody or control of the Company by rehabilitating them—at the Company's**

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expense—at loving homes and recognised sanctuaries, for which PETA India would offer to rally and work with NGOs to assist in animal placement and care.

Whistleblower Reported Facts

The aforementioned insiders reported the following details of apparent abuse and neglect of animals at the Company to PETA India:

1. Beagles:

- a. The Company kept more beagles than its facility could properly house or was licensed for—some nearly 1,500 dogs in a space designed for some only 800, forcing three to four dogs into cages meant for just two. Overcrowding was particularly pronounced in the Company's breeding facility. According to one insider, when auditors came to inspect the facility, representatives from the Company were careful to show them the research and other facilities, steering clear of the breeding facility.
- b. The Company begins breeding dogs when they are approximately 18 months of age. They are bred twice a year, and although the Company's policy is to breed the dogs for a maximum of five breeding cycles, the Company often ignores its own policy, exceeding that limit. Dogs as old as 13 years have been used for breeding. The Company's practice of breeding dogs too frequently—without allowing the mothers adequate time to rest and recover between pregnancies—placed immense physical strain on their bodies. This overbreeding significantly increased the risk of dystocia (difficult labor) and the need for cesarean (C-section) deliveries.
- c. The Company's overcrowding of dogs, coupled with a lack of socialisation, led to extreme frustration, food aggression, and frequent fights, often causing serious injuries, especially to the dogs' ears. Despite these wounds, the Company failed to provide basic care, neglecting both proper wound cleaning and pain management.
- d. The Company's animal care staff were seen handling dogs roughly, with some workers kicking the animals or carelessly closing cage doors on their legs. Workers would pick up dogs, some weighing as much as 15 kilograms, by the scruff of the neck or the skin on their backs. Although the Company offers some training, it fails to ensure workers follow proper handling methods, as captured on closed-circuit television (CCTV), where an employee slammed a cage door on a dog's leg, prompting the dog to yelp in pain.
- e. In some studies conducted by the Company, dogs were injected subcutaneously with test compounds. According to a whistleblower, animals developed abscesses, ulcers, and signs of severe pain following these injections. In several cases, the injection sites reportedly became inflamed or developed open wounds. Depending on the location of the abscess, there can be further health issues suffered by the dogs. For example, if the abscess is in the shoulder, that can inhibit the dog's ability to move. They can be in severe pain;

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they will lose their appetite and lose weight. These infections could spread, eating through the skin and damaging the underlying tissue, leaving the dogs with open, painful wounds.

- f. In the Company's other studies, dogs became very sick, and in one case, a dog vomited excessive quantities of blood before dying.
- g. Although the Company specifies "humane endpoints" in its protocols, that endpoint only exists on paper. Management at the Company will tell veterinarians to wait for the sponsor to give permission before euthanizing an animal who is suffering. Everything is decided by the sponsor. If the sponsor approves euthanasia or some other action, the veterinarians can pursue such actions. Otherwise, the animal is kept suffering.
- h. One insider reported that some animals suffered ulcers in their mouth and intestine from the oral dosing procedure—but they were kept alive unless the sponsor approved euthanasia.
- i. The Company kills dogs using thiopentone but fails to sedate them beforehand—a basic step that could reduce their fear and distress in their final moments of life.

2. Minipigs:

- a. The Company purchased Göttingen minipigs from a supplier in Denmark but the Company did not have a license to breed them. At one point, a minipig became pregnant, and the head veterinarian ordered the euthanasia of the eight to ten piglets born. The piglets were killed via intracardiac injection, but were not sedated first—a basic step that could have significantly reduced their fear and suffering.
- b. Despite a written policy requiring playtime and social enrichment for pigs, the Company routinely failed to provide either. Pigs would only be given access to enrichment when there were external visitors; otherwise, they remained confined to their cages and were only removed for experimental procedures.
- c. During a visit to the Company, representatives from the Danish company mentioned above in point 2.a. observed that pigs' feet were getting injured due to improper flooring.

3. Monkeys:

- a. The Company used rhesus macaques captured from the forest in the state of Rajasthan. The Company had permission from the Indian government to capture 12 monkeys, but it captured 14. The monkeys were approximately 1.5 years of age and weighed less than 4 kilograms. The monkeys were sedated and placed in plastic bags, with up to five monkeys in each bag.
- b. In Rajasthan, blood samples were taken from the monkeys captured by the Company and two of these monkeys tested positive for monkeypox, which is a zoonotic disease. The other monkeys tested negative for monkeypox. However, all of the monkeys were already on their way to the Company's facility in Telangana. When the monkeys arrived at the Company's facility, the two monkeys who had tested positive for monkeypox were killed, but the others were

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kept alive—even though they had been transported from Rajasthan with the positive monkeys and monkeypox can be transmitted between monkeys.¹ The 12 surviving monkeys were again tested for monkeypox one week after they arrived at the Company's facility, even though the incubation period for the virus can be longer. However, the Company needed the monkeys for a client-sponsored test and decided to go forward with using the monkeys for the test.

- c. Despite the public health risks to Company employees and the community-at-large, the Company kept the matter quiet and simply killed the monkeys.

Apparent Violations of Standards Under CCSEA Purview

These incidents *prima facie* point to serious lapses in the Company's adherence to the PCA Act, 1960, the Breeding of and Experiments on Animals Rules, 1998, the CPCSEA Guidelines, 2007, the CPCSEA Guidelines, 2015, and the CPCSEA Guidelines, 2020, overseen by CCSEA, including apparent violations of the following provisions:

APPARENT VIOLATIONS	LEGAL/REGULATORY REFERENCES
<p>Overbreeding and Housing Too Many Beagles Without Permission</p> <p>The Company held up to some 1,500 dogs severely overcrowding cages (e.g., 3–4 dogs in space meant for 2).</p> <p>(Refer to Whistleblower Reported Fact 1.a, 2.a and 3.a above.)</p>	<ul style="list-style-type: none"> • Rule 4, Rule 5, and Rule 8(a), Breeding of and Experiments on Animals Rules, 1998²
<p>Overcrowding, Lack of Veterinary Care, and Rough Handling</p> <p>Beagles were kept in overcrowded cages; animals suffered untreated injuries; employees reportedly kicked dogs and handled them roughly, including slamming cage doors on limbs.</p> <p>(Refer to Whistleblower Reported Fact 1.c, 1.d above.)</p>	<ul style="list-style-type: none"> • Rule 7(b), 7(d), 7(e), and 7(f), Breeding of and Experiments on Animals Rules, 1998³ • Paragraphs 11 and 16, CPCSEA Guidelines, 2015³

¹ According to the scientific literature, transmission of monkeypox can occur through direct contact with lesions, bodily fluids, or respiratory secretions; fomites, such as contaminated bedding or cages; aerosol transmission, especially in confined settings.

² Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, notified under the Prevention of Cruelty to Animals Act, 1960. Ministry of Environment and Forests, Government of India. Available at: <https://ccsea.gov.in/WriteReadData/userfiles/file/1998.pdf>

³ CPCSEA Guidelines for Laboratory Animal Facility, 2015. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of Environment, Forest and Climate Change, Government of India. Available at: <https://ccsea.gov.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf>

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	<ul style="list-style-type: none"> • Paragraph B.i.7, of the CPCSEA Guidelines, 2020⁴ • Principle 5, CPCSEA Guidelines, 2007⁵
<p>Excessive Whelping and Breeding</p> <p>Female dogs were reportedly bred twice a year and beyond the permitted five-litter limit, without rehabilitation.</p> <p><i>(Refer to Whistleblower Reported Fact 1.b above.)</i></p>	<ul style="list-style-type: none"> • Paragraph 9, CPCSEA Guidelines, 2015⁴ • Paragraph B.i.7, of the CPCSEA Guidelines, 2020⁵
<p>Unsanitary Housing Conditions</p> <p>Animals were kept in unclean enclosures and bedding; overcrowding also compromised hygiene.</p> <p><i>(Refer to Whistleblower Reported Fact 1.c and 2.c above.)</i></p>	<ul style="list-style-type: none"> • Rule 7, Breeding of and Experiments on Animals Rules, 1998³ • Paragraph 22, CPCSEA Guidelines, 2015⁴
<p>Unlicensed Breeding of Mini Pigs and Housing of Rhesus Macaques</p> <p>The Company allegedly bred Göttingen minipigs without CPCSEA license, and housed rhesus macaques without CCSEA or wildlife approvals.</p> <p><i>(Refer to Whistleblower Reported Fact 2.a and 3.a above.)</i></p>	<ul style="list-style-type: none"> • Rule 3 and Rule 10, Breeding of and Experiments on Animals Rules, 1998³
<p>Improper Quarantine Practices</p> <p>Monkeys were reportedly captured from the wild and killed after testing positive for zoonotic diseases, without following proper quarantine protocols.</p> <p><i>(Refer to Whistleblower Reported Fact above 3.a, 3.b and 3.c.)</i></p>	<ul style="list-style-type: none"> • Paragraph 4(b), CPCSEA Guidelines, 2015⁴

⁴ Guidelines of CPCSEA for Rehabilitation/Reuse of Large Animals Post-Experimentation, 2020. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of Environment, Forest and Climate Change, Government of India. Available at: <https://ccsea.gov.in/WriteReadData/userfiles/file/Guidelines%20of%20CPCSEA%20for%20Reuse%20Rehabilitation%20of%20Large%20Animals%202020.pdf>

⁵ Committee for the Control and Supervision of Experiments on Animals. (2021). *Compendium of CPCSEA*. Ministry of Fisheries, Animal Husbandry and Dairying, Government of India. Retrieved from <https://ccsea.gov.in/WriteReadData/userfiles/file/Compendium%20of%20CPCSEA.pdf> (p. 53)

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<p>Improper Euthanasia by Unqualified Personnel</p> <p>Dogs were killed using thiopentone without sedation; piglets born to an accidentally pregnant minipig were killed by intracardiac injection without sedation.</p> <p><i>(Refer to Whistleblower Reported Fact 1.g, 1.h and 2.a above.)</i></p>	<ul style="list-style-type: none"> • Rule 9(d), 9(ff), and 9(cc), Breeding of and Experiments on Animals Rules, 1998³ • Paragraphs 31 and 32, CPCSEA Guidelines, 2015⁴
<p>Failure to Report Adverse Reactions and Falsification of Records</p> <p>Deaths and zoonotic infections were allegedly concealed from Institutional Animal Ethics Committee (IAEC) and employees, risking public health and violating documentation protocols.</p> <p><i>(Refer to Whistleblower Reported Fact 1.e, 1.f, 3.b and 3.c above.)</i></p>	<ul style="list-style-type: none"> • Rule 11, Breeding of and Experiments on Animals Rules, 1998³ • Paragraph 27, CPCSEA Guidelines, 2015⁴
<p>Cruelty and Grievous Harm to Animals</p> <p>Beating, maiming, overcrowding, and unauthorised killing of animals constitute cruelty under Indian law.</p> <p><i>(Refer to Whistleblower Reported Fact 1.c, 1.d, 1.e, 1.g, 2.a, 3.a, 3.b and 3.c above.)</i></p>	<ul style="list-style-type: none"> • Section 11(1)(a), (b), (c), (e), (g), (h), (k), and (l), PCA Act, 1960 • Rule 9(ff), Breeding of and Experiments on Animals Rules, 1998³ • Section 117(2) (Voluntarily causing grievous hurt), 271 (Negligent act likely to spread infection of disease dangerous to life) and 291 (Negligent conduct with respect to animal) of the Bharatiya Nyaya Sanhita, 2023⁶

The alleged egregious conduct at the Company, described herein, represents a serious breach of both Indian law and basic ethical standards in animal welfare and compromises scientific integrity. We trust CCSEA will treat this matter with the utmost urgency and gravity it demands.

⁶ Government of India. (2023). *Bharatiya Nyaya Sanhita, 2023*. Sections 117(2) (Voluntarily causing grievous hurt), 271 (Negligent act likely to spread infection of disease dangerous to life) and 291 (Negligent conduct with respect to animal). Retrieved from https://www.mha.gov.in/sites/default/files/250883_english_01042024.pdf

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Global Regulatory Shifts Away From Animal Experimentation

We also wish to draw your attention to significant global developments concerning the growing shift away from the use of animals in experimentation. In April 2025, US federal agencies announced historic plans to phase out animal testing, in alignment with PETA US' Research Modernization NOW strategic framework for modernising research toward human-relevant methods⁷:

- The US Food and Drug Administration (FDA) announced on April 10, 2025, a "groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods", in an effort to "improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development (R&D) costs, and ultimately, drug prices".⁸
- The US National Institutes of Health (NIH) announced a major new initiative on April 29, 2025, "to expand the development and use of cutting-edge, non-animal models—such as organoids, tissue chips, computational models, and real-world data—to address long-standing translational challenges in biomedical research. This initiative reflects NIH's commitment to advancing innovative, translationally effective research while aligning with broader federal efforts to reduce reliance on animal models".⁹

Furthermore, specifically regarding experiments on dogs, the NIH announced on May 4, 2025, that it is "getting rid of all the beagle experiments on the NIH campus"¹⁰, and the US Secretary of the Navy announced that he is terminating all US Navy testing on dogs and cats.^{11,12}

I encourage CCSEA to take these groundbreaking shifts in the global animal testing landscape into consideration, as they likely will have an impact on the Company's

⁷ PETA US. Research Modernization NOW. November 2024.

<https://www.peta.org/wpcontent/uploads/2025/01/Research-Modernization-NOW-Biomedical.pdf>

⁸ US FDA. FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs. April 10, 2025. <https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs>

⁹ US NIH. NIH to prioritize human-based research technologies. April 30, 2025.

<https://oacu.oir.nih.gov/about-oacu/news-events/news/nih-prioritize-human-based-research-technologies>

¹⁰ NIH [@NIH]. May 4, 2025. [Watch @NIHDirector_Jay on @FoxNews with @RCamposDuffy where he discusses a new NIH initiative to expand innovative, human-based science while reducing animal use in research, including getting rid of all the beagle experiments on the NIH campus.] [Post]. X. <https://x.com/NIH/status/1919070337225855335>.

¹¹ Bedard P. May 28, 2025. Trump cheered as 'best friend of animals' after research grants nixed. Washington Examiner. Accessed May 29, 2025.

<https://www.washingtonexaminer.com/news/washington-secrets/3423973/trump-cheered-bestfriend-of-animals-after-research-grants-nixed/>.

¹² Secretary of the Navy [@SECNAV]. May 27, 2025. [Today it gives me great pleasure to terminate all Department of the Navy's testing on cats and dogs, ending these...] [Post]. X. <https://x.com/SECNAV/status/1927500765817393569?s=19>

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business model that is currently predicated on using animals in experiments. As the first step, the Company should be required to release all of its surviving animals to loving homes or recognised sanctuaries, and PETA India would be happy to work with other NGOs to assist in finding them good forever homes to live out the remainder of their lives in peace.

I can be reached at aagggarwal@petaindia.org or +91-9958840994. We stand ready to assist you further as needed. Thank you for your attention to this important matter, and we look forward to your response.

Sincerely,



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cc: **CCSEA Core Committee Members**

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CIN: U74899DL2000NPL103217

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General of India
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhavan, ITO, Kotla Road,
New Delhi -110002

10 June 2025

Via email and post: dcg@nic.in

Dear Dr. Raghuvanshi,

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 2 million members and supporters. We recently received alarming video footage, photographs and testimonials from insiders who were employed at Palampur Biosciences Pvt Ltd (CDSCO Medical Device Testing Laboratory Registration Number: TL/MD/2019/000006) (hereinafter, "the Company"), located at 401 Aikya, 4th Floor, H-no-10-3-32/9/23 Opp. to Faust High School, East Maredpally, Secunderabad, Hyderabad, Telangana – 500026, documenting the reported abuse and neglect of dogs, pigs, and monkeys used at the Company from 2021 to 2023. **You can see the referenced video footage, photographs, and more details [here](#).**

The details described below present a deeply troubling and persistent pattern of apparent noncompliance with Schedule Y of the Drugs and Cosmetics Rules, 1945 (hereinafter, "Schedule Y"), Medical Device Rules, 2017 (hereinafter, "the Medical Devices Rules"), and the Guidelines for Post Approval Changes in Biological Products (hereinafter, "the PAC Guidelines"). **Importantly, these reported serious non-compliances at the Company bring into question the large amount of data generated by the Company and submitted to your agency for various drug and other approvals, presenting an apparent danger to public health—a matter that is clearly within your agency's purview to take action.**

You'll recall that we sent you an earlier complaint regarding the Company dated 1 October 2024, in which we detailed serious concerns regarding apparently falsified data, use of non-approved species (rhesus macaques), and other violations under the Rules¹. We received no response from CDSCO regarding our 1 October 2024 complaint.

Based on the new information presented below, we request that the CDSCO exercise its powers under Rule 86 of the Medical Devices Rules to immediately

¹ People for the Ethical Treatment of Animals India. (2025, June). 2024-10-01 complaint letter to CDSCO [PDF]. Retrieved from <https://www.petaindia.com/wp-content/uploads/2025/06/2024-10-01-complaint-letter-to-cdscopdf>

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and permanently terminate the Company's Medical Device Testing Laboratory (MDTL) registration, and prohibit all future such applications from the Company regarding MDTL registration due to serious and repeat apparent violations of Schedule Y, the Medical Devices Rules, and the PAC Guidelines.

Whistleblower Reported Facts

The aforementioned insiders reported the following details of apparent abuse and neglect of animals at the Company to PETA India:

1. Beagles:

- a. The Company kept more beagles than its facility could properly house or was licensed for—some nearly 1,500 dogs in a space designed for only 800, forcing three to four dogs into cages meant for just two. Overcrowding was particularly pronounced in the Company's breeding facility. According to one insider, when auditors came to inspect the facility, representatives from the Company were careful to show them the research and other facilities, steering clear of the breeding facility.
- b. The Company begins breeding dogs when they are approximately 18 months of age. They are bred twice a year, and although the Company's policy is to breed the dogs for a maximum of five breeding cycles, the Company often ignores its own policy, exceeding that limit. Dogs as old as 13 years have been used for breeding. The Company's practice of breeding dogs too frequently—without allowing the mothers adequate time to rest and recover between pregnancies—placed immense physical strain on their bodies. This overbreeding significantly increased the risk of dystocia (difficult labour) and the need for cesarean (C-section) deliveries.
- c. The Company's overcrowding of dogs, coupled with a lack of socialisation, led to extreme frustration, food aggression, and frequent fights, often causing serious injuries, especially to the dogs' ears. Despite these wounds, the Company failed to provide basic care, neglecting both proper wound cleaning and pain management.
- d. In some studies conducted by the Company, dogs were injected with test compounds under the skin (subcutaneously). These injections sometimes were followed by infections at the injection sites that can be accompanied by inflammation, abscesses, and open wounds. Depending on the location of the abscess, there can be further health issues suffered by the dogs. For example, if the abscess is in the shoulder, that can inhibit the dog's ability to move. They can be in severe pain; they will lose their appetite and lose weight. These infections could spread, eating through the skin and damaging the underlying tissue, leaving the dogs with open, painful wounds.
- e. In the Company's other studies, dogs became very sick, and in one case, a dog vomited excessive quantities of blood before dying.

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- f. Although the Company specifies “humane endpoints” in its protocols, that endpoint only exists on paper. Management at the Company will tell veterinarians to wait for the sponsor to give permission before euthanizing an animal who is suffering. Everything is decided by the sponsor. If the sponsor approves euthanasia or some other action, the veterinarians can pursue such actions. Otherwise, the animal is kept suffering.
- g. One insider reported that some animals suffered ulcers in their mouth and intestine from the oral dosing procedure—but they were kept alive unless the sponsor approved euthanasia.
- h. The Company kills dogs using thiopentone but fails to sedate them beforehand—a basic step that could reduce their fear and distress in their final moments of life.

2. Minipigs:

- a. The Company purchased Göttingen minipigs from a supplier in Denmark but the Company did not have a license to breed them. At one point, a minipig became pregnant, and the head veterinarian ordered the euthanasia of the eight to ten piglets born. The piglets were killed via intracardiac injection, but were not sedated first—a basic step that could have significantly reduced their fear and suffering.

3. Monkeys:

- a. The Company used rhesus macaques captured from the forest in Rajasthan. The Company had permission from the Indian government to capture 12 monkeys, but it captured 14. The monkeys were approximately 1.5 years of age and weighed less than 4 kilograms. The monkeys were sedated and placed in plastic bags, with up to five monkeys in each bag.
- b. In Rajasthan, blood samples were taken from the monkeys captured by the Company and two of these monkeys tested positive for monkeypox, which is a zoonotic disease. The other monkeys tested negative for monkeypox. However, all of the monkeys were already on their way to the Company’s facility in Telangana. When the monkeys arrived at the Company’s facility, the two monkeys who had tested positive for monkeypox were killed, but the others were kept alive—even though they had been transported from Rajasthan with the positive monkeys and monkeypox can be transmitted between monkeys.² The 12 surviving monkeys were again tested for monkeypox one week after they arrived at the Company’s facility, even though the incubation period for the virus can be longer. However, the Company needed the monkeys for a client-sponsored test and decided to go forward with using the monkeys for the test.

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² According to the scientific literature, transmission of monkeypox can occur through direct contact with lesions, bodily fluids, or respiratory secretions; fomites, such as contaminated bedding or cages; aerosol transmission, especially in confined settings.

- c. Despite the public health risks to Company employees and the community-at-large, the Company kept the matter quiet and simply killed the monkeys.

Apparent Violations of Standards Under CDSCO Purview

These incidents *prima facie* point to serious lapses in the Company's adherence to the Medical Devices Rules, the PAC Guidelines and Schedule Y overseen by CDSCO, including apparent violations of the following provisions:

APPARENT VIOLATIONS	LEGAL/REGULATORY REFERENCES
Suppression of zoonotic disease outbreaks and failure to report adverse reactions (e.g., monkeypox in rhesus macaques). <i>(Refer to Whistleblower Reported Fact 3.b & 3.c above.)</i>	<ul style="list-style-type: none"> Paragraph 2.3.1 (Level I – Supplements: Safety and Efficacy) of the PAC Guidelines³
Unlicensed overbreeding of Göttingen minipigs and beagles without validated process controls. <i>(Refer to Whistleblower Reported Fact 1.b & 2.a above.)</i>	<ul style="list-style-type: none"> Paragraph 3.2.S.2 – Manufacture: Source, Identity, Control of Materials of the PAC Guidelines⁵
Failure to notify the use of new animal test systems like rhesus macaques without regulatory notification: Use of rhesus macaques without GLP or CDSCO approval for non-clinical studies. <i>(Refer to Whistleblower Reported Fact 3.a above.)</i>	<ul style="list-style-type: none"> Paragraph 2.3.2 (Level II – Risk/Harm Management Changes) of the PAC Guidelines⁵ Schedule Y and Rule 122 DAC, Drugs and Cosmetics Rules, 1945⁴

³ Post Approval Changes (PAC) Guidance for Biological Products – Quality, Safety and Efficacy, Version 1.2. Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India. Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTEyMzY

⁴ Good Clinical Practice Guidelines, including Schedule Y (Amended Version) as Annexure (Ministry of Health and Family Welfare, Government of India, n.d.), available at https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE5NTI.

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Fabrication of data and falsification of records to mislead regulatory audits. <i>(Refer to Whistleblower Reported Fact 1.f & 3.c above.)</i>	<ul style="list-style-type: none"> • Schedule Y⁷ • Rule 82(iii), Medical Devices Rules, 2017⁵
Non-compliance with Rule 82(iii) on animal house hygiene, quarantine, and recordkeeping; failure to isolate infected animals; overcrowding and untrained euthanasia practices. <i>(Refer to Whistleblower Reported Fact 3.b & 3.c above.)</i>	<ul style="list-style-type: none"> • Rule 82(iii)(a),(b),(c),(d),(e),(f),(g), Medical Devices Rules, 2017⁸

Supplementary Context: Pattern of Broader Regulatory Noncompliance

While the following matters fall outside CDSCO's direct regulatory jurisdiction, they underscore a broader institutional disregard for legal and ethical standards that affect the reliability and integrity of the Company's scientific operations.

The Company's aforementioned incidents also appear to constitute violations of multiple animal protection laws in India, including Sections 3 and 11 of the Prevention of Cruelty to Animals Act, 1960⁶, Rule 9(ff) of The Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998⁷ (hereinafter, "the Breeding of and Experiments on Animals Rules, 1998"), and Section 117(2) (Voluntarily causing grievous hurt), 291 (Negligent conduct with respect to animal), and 271 (Negligent act likely to spread infection of disease dangerous to life) of the Bharatiya Nyaya Sanhita (2023)⁸ (hereinafter, "the BNS, 2023").

As per Rule 82(iii)(g) of the Medical Devices Rules, 2017, the Company is obligated to ensure compliance with The Prevention of Cruelty to Animals Act, 1960 (hereinafter, "the PCA Act").

⁵ Good Clinical Practice Guidelines, including Schedule Y (Amended Version) as Annexure (Ministry of Health and Family Welfare, Government of India, n.d.), available at

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE5NTI.

⁶ Government of India. (1960). *The Prevention of Cruelty to Animals Act, 1960* (Act No. 59 of 1960). Ministry of Fisheries, Animal Husbandry and Dairying.

https://www.indiacode.nic.in/bitstream/123456789/11237/1/the_prevention_of_cruelty_to_animals_act%2C_1960.pdf

⁷ Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, notified under the Prevention of Cruelty to Animals Act, 1960. Ministry of Environment and Forests, Government of India. Available at: <https://ccsea.gov.in/WriteReadData/userfiles/file/1998.pdf>

⁸ Government of India. (2023). *Bharatiya Nyaya Sanhita, 2023*. Sections 117(2) (Voluntarily causing grievous hurt), 271 (Negligent act likely to spread infection of disease dangerous to life) and 291 (Negligent conduct with respect to animal). Retrieved from https://www.mha.gov.in/sites/default/files/250883_english_01042024.pdf

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However, the Company insiders' reported facts described above point to apparent violations of:

- Sections 11(1)(a), (b), (c), (e), (g), (h), (k), and (l) of the PCA Act⁹, which prohibit actions such as beating, kicking, overloading, mutilating, killing animals unnecessarily, housing animals in small receptacles that restrict movement, and denying animals exercise.
- Rule 9(ff) of the Breeding of and Experiments on Animals Rules, 1998¹⁰, which requires proper and humane euthanasia protocols.
- Sections 117(2), 291, and 271 of the BNS, 2023¹⁰, which criminalizes voluntarily causing grievous hurt to animals, negligent conduct with respect to animals, and negligent act likely to spread infection of disease dangerous to life, respectively, including acts resulting in fractures, maiming, or death through cruelty.

These statutory violations are reflected in whistleblowers' accounts described above.

Request for CDSCO Action to Address Reported Noncompliances

The alleged egregious conduct at the Company, described herein, represents a serious breach of both Indian law and basic ethical standards in animal welfare. We trust CDSCO will treat this matter with the utmost urgency and gravity it demands, and move to immediately and permanently terminate the Company's Medical Device Testing Laboratory (MDTL) registration, and prohibit all future such applications from the Company regarding MDTL registration. We also urge a critical look at any results from this laboratory and resulting end products.

You may reach me at aaggarwal@petaindia.org or +91-9958840994. We stand ready to assist you further as needed. Thank you for your attention to this important matter, and we look forward to your response.

Sincerely,



Anjana Aggarwal, PhD
Scientist and Research Policy Advisor
PETA India

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Dr. Ekta Kapoor
Scientist F and Head
National GLP Compliance Monitoring Authority
Department of Science and Technology
Technology Bhawan, New Mehrauli Road,
New Delhi-110016

10 June 2025

Via e-mail and post: ekta.kapoor@nic.in

Dear Dr. Kapoor,

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 2 million members and supporters. We recently received alarming video footage, photographs and testimonials from insiders who were employed at Palamur Biosciences Pvt Ltd (NGCMA Certificate No. GLP/C-229/2024, Validity Period 20-05-2024 to 19-05-2027) (hereinafter, "the Company"), located at SH-20, Karvina, Madigattla Village, Bhoothpur Mandal, Mahabubnagar, Telangana – 509382, documenting the reported abuse and neglect of dogs, pigs, and monkeys used at the Company from 2021 to 2023. **You can see the referenced video footage, photographs, and more details [here](#).**

The details described below present a deeply troubling and persistent pattern of apparent noncompliance with the Organisation for Economic Co-operation and Development (OECD) Principles on Good Laboratory Practice, revised 1997 (ENV/MC/CHEM(98)17) (hereinafter, "the OECD Principles").

You will recall that we sent you a complaint regarding the Company dated 1 October 2024, in which we detailed serious concerns regarding its apparent falsified data, use of non-approved species (rhesus macaques), and violations under the Rules.¹ We acknowledge your response—via your 20 December 2024 letter to us—regarding NGCMA's July 2023 study audits, subsequent surveillance inspections, the re-certification inspection in May 2024 of the Company, and the Company's responses through Corrective Action and Preventive Action (CAPA). However, despite our submission of publicly available admissions and video evidence indicating the Company's use of rhesus macaques in Good Laboratory Practice (GLP) studies without explicit approval by the National GLP Compliance Monitoring Authority (NGCMA) to use this species, it is disappointing that no suitable action appears to have been taken by your agency in response to our 1 October 2024 complaint.

¹ People for the Ethical Treatment of Animals India. 2024-10-01 complaint letter to NGCMA [PDF]. Retrieved from <https://www.petaindia.com/wp-content/uploads/2025/06/2024-10-01-complaint-letter-to-ngcma.pdf>

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Based on the disturbing new information presented below, we request that NGCMA exercise its power under Paragraph 3.2 (e) of GLP 113² Policies and Paragraph 30 of GLP 101³ to immediately revoke GLP certification of the Company and prohibit future applications from it due to serious and repeated apparent violations of OECD Principles.

Whistleblowers' Reported Facts

The aforementioned insiders reported the following details of apparent abuse and neglect of animals at the Company to PETA India:

1. Beagles:

- a. The Company kept more beagles than its facility could properly house or was licensed for—some nearly 1,500 dogs in a space designed for only 800, forcing three to four dogs into cages meant for just two. Overcrowding was particularly pronounced in the Company's breeding facility. According to one insider, when auditors came to inspect the facility, representatives from the Company were careful to show them the research and other facilities, steering clear of the breeding facility.
- b. The Company begins breeding dogs when they are approximately 18 months of age. They are bred twice a year, and although the Company's policy is to breed the dogs for a maximum of five breeding cycles, the Company often ignores its own policy, exceeding that limit. Dogs as old as 13 years have been used for breeding. The Company's practice of breeding dogs too frequently—without allowing the mothers adequate time to rest and recover between pregnancies—placed immense physical strain on their bodies. This overbreeding significantly increased the risk of dystocia (difficult labour) and the need for cesarean (C-section) deliveries.
- c. The Company's overcrowding of dogs, coupled with a lack of socialisation, led to extreme frustration, food aggression, and frequent fights, often causing serious injuries, especially to the dogs' ears. Despite these wounds, the Company failed to provide basic care, neglecting both proper wound cleaning and pain management.
- d. In some studies conducted by the Company, dogs were injected with test compounds under the skin (subcutaneously). These injections—either due to the compounds themselves or impurities in their formulation—sometimes caused infections at the injection sites. There can be inflammation, an abscess, and open wounds. Depending on the location of the abscess, there can be further health

² National Good Laboratory Practice (GLP) Compliance Monitoring Authority. (2022, May 9). *Policies and procedures of NGCMA for taking adverse and other decisions against test facilities* (Document No. GLP-113, Issue No. 03). Department of Science & Technology, Government of India. Retrieved from https://dst.gov.in/sites/default/files/GLP-113_0.pdf

³ National GLP Compliance Monitoring Authority. (2022, May 9). *Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility* (Document No. GLP-101, Issue No. 09). Department of Science & Technology, Government of India.

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issues suffered by the dogs. For example, if the abscess is in the shoulder, that can inhibit the dog's ability to move. They can be in severe pain; they will lose their appetite and lose weight. These infections could spread, eating through the skin and damaging the underlying tissue, leaving the dogs with open, painful wounds.

- e. In the Company's other studies, dogs became very sick, and in one case, a dog vomited excessive quantities of blood before dying.
- f. Although the Company specifies "humane endpoints" in its protocols, that endpoint only exists on paper. Management at the Company will tell veterinarians to wait for the sponsor to give permission before euthanizing an animal who is suffering. Everything is decided by the sponsor. If the sponsor approves euthanasia or some other action, the veterinarians can pursue such actions. Otherwise, the animal is kept suffering.
- g. One insider reported that some animals suffered ulcers in their mouth and intestine from the oral dosing procedure—but they were kept alive unless the sponsor approved euthanasia.
- h. The Company kills dogs using thiopentone but fails to sedate them beforehand—a basic step that could reduce their fear and distress in their final moments of life.

2. Minipigs:

- a. The Company purchased Göttingen minipigs from a supplier in Denmark but the Company did not have a license to breed them. At one point, a minipig became pregnant, and the head veterinarian ordered the euthanasia of the eight to ten piglets born. The piglets were killed via intracardiac injection, but were not sedated first—a basic step that could have significantly reduced their fear and suffering.
- b. Despite a written policy requiring playtime and social enrichment for pigs, the Company routinely failed to provide either. Pigs would only be given access to enrichment when there were external visitors; otherwise, they remained confined to their cages and were only removed for experimental procedures.
- c. During a visit to the Company, representatives from the Danish company mentioned above in point 2.a. observed that pigs' feet were getting injured due to improper flooring.

3. Monkeys:

- a. The Company used rhesus macaques captured from the forest in the state of Rajasthan. The Company had permission from the Indian government to capture 12 monkeys, but it captured 14. The monkeys were approximately 1.5 years of age and weighed less than 4 kilograms. The monkeys were sedated and placed in plastic bags, with up to five monkeys in each bag.
- b. In Rajasthan, blood samples were taken from the monkeys captured by the Company and two of these monkeys tested positive for monkeypox, which is a zoonotic disease. The other monkeys tested negative for monkeypox. However, all of the monkeys were already on their way to the Company's facility in Telangana. When the

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monkeys arrived at the Company's facility, the two monkeys who had tested positive for monkeypox were killed, but the others were kept alive—even though they had been transported from Rajasthan with the positive monkeys and monkeypox can be transmitted between monkeys.⁴ The 12 surviving monkeys were again tested for monkeypox one week after they arrived at the Company's facility, even though the incubation period for the virus can be longer. However, the Company needed the monkeys for a client-sponsored test and decided to go forward with using the monkeys for the test.

- c. Despite the public health risks to Company employees and the community-at-large, the Company kept the matter quiet and simply killed the monkeys.

Apparent Violations of Standards Under NGCMA Purview

These incidents *prima facie* point to serious lapses in the Company's adherence to the OECD Principles, overseen by NGCMA, including apparent violations of the following provisions:

APPARENT VIOLATIONS	LEGAL/REGULATORY REFERENCES
<p>Systemic animal welfare violations: Sick or injured animals (e.g., with fractures, abscesses) reportedly left untreated; veterinary care arranged only during inspections; euthanasia conducted without sedation; overcrowding causing violent fights; lack of isolation for unwell/aggressive animals.</p> <p><i>(Refer to Whistleblower Reported Fact 1.a, 1.c, 1.e, 1.g, 2.b & 2.c above.)</i></p>	<ul style="list-style-type: none"> • Part I, Section II, Subsection 5.2 of the OECD Principles⁵
<p>Improper housing and sanitation: Beagles overcrowded—3 to 4 per respective cages that are each designed for 2; dirty cages; bedding not cleaned; injured animals kept in unsanitary conditions; fights due to stress.</p> <p><i>(Refer to Whistleblower Reported Fact 1.a, 1.c, 2.b & 2.c above.)</i></p>	<ul style="list-style-type: none"> • Part I, Section II, Subsection 3.2 and 5.2(6) of the OECD Principles⁷

⁴ According to the scientific literature, transmission of monkeypox can occur through direct contact with lesions, bodily fluids, or respiratory secretions; fomites, such as contaminated bedding or cages; aerosol transmission, especially in confined settings.

⁵ National Good Laboratory Practice Compliance Monitoring Authority. (1998). *OECD Principles of Good Laboratory Practice* (as revised in 1997). New Delhi: Department of Science and Technology, Government of India. Retrieved from <https://dst.gov.in/sites/default/files/No1.pdf>

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<p>Improper euthanasia methods: Dogs and piglets killed using thiopentone or intracardiac injection without sedation; no oversight by trained personnel.</p> <p><i>(Refer to Whistleblower Reported Fact 1.f, 1.g, 2.a, 2.b, 3.b and 3.c above.)</i></p>	<ul style="list-style-type: none"> Part I, Section II, Subsection 5.2(2) and 5.2(3) of the OECD Principles⁷
<p>Non-approved research on rhesus macaques: The Company admitted to conducting pharmacokinetic (PK) studies and vaccine efficacy studies using rhesus macaques without GLP certification for that species.</p> <p><i>(Refer to Whistleblower Reported Fact 3.a above.)</i></p>	<ul style="list-style-type: none"> Part I, Section II, Subsection 1.1, 5.2, 6.2, 8.1, 8.2.5, 9.1.4 of the OECD Principles⁷
<p>Attempts to mislead audits—indicating possible falsification and obstruction of quality assurance processes.</p> <p><i>(Refer to Whistleblower Reported Fact 1.f & 2.b above.)</i></p>	<ul style="list-style-type: none"> Part I, Section II, Subsection 1.2.e, 1.4.3, 2.2.1, 9.1 and 9.2 of the OECD Principles⁷
<p>Breeding Göttingen minipigs without license and unlawful capture of rhesus macaques—indicating unapproved acquisition and lack of facility registration or licensing for such animals</p> <p><i>(Refer to Whistleblower Reported Fact 2.a & 3.a above.)</i></p>	<ul style="list-style-type: none"> Part I, Section II, Subsection 1.1.2(b), 5.1 and 5.2 of the OECD Principles⁷

Supplementary Context: Pattern of Broader Regulatory Noncompliance

While the following matters fall outside NGCMA's direct regulatory jurisdiction, they underscore a broader institutional disregard for legal and ethical standards that may affect the reliability and integrity of the Company's scientific operations.

The Company's aforementioned incidents also appear to constitute violations of multiple animal protection laws in India, including Sections 3 and 11 of the Prevention of Cruelty to Animals Act (PCA), 1960⁶; Rule 9(ff) of The Breeding of

Entities:

- PETA US
- PETA Asia
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (UK)

⁶ Government of India. (1960). *The Prevention of Cruelty to Animals Act, 1960* (Act No. 59 of 1960). Ministry of Fisheries, Animal Husbandry and Dairying.
https://www.indiacode.nic.in/bitstream/123456789/11237/1/the_prevention_of_cruelty_to_animals_act%2C_1960.pdf

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and Experiments on Animals (Control and Supervision) Rules, 1998⁷ (hereinafter, "the Breeding of and Experiments on Animals Rules, 1998"); and Sections 117(2) (Voluntarily causing grievous hurt), 291 (Negligent conduct with respect to animal), and 271 (Negligent act likely to spread infection of disease dangerous to life) of the Bharatiya Nyaya Sanhita (2023)⁸ (hereinafter, "the BNS, 2023").

Since GLP certification in India operates under the umbrella of Indian law, a facility's GLP status does not exempt it from statutory compliance with the PCA Act and Rules framed under it.

However, the Company insiders' reported facts described above point to apparent violations of:

- Sections 11(1)(a), (b), (c), (e), (g), (h), (k), and (l) of the PCA Act⁹, which prohibit actions such as beating, kicking, overloading, mutilating, killing animals unnecessarily, housing animals in small receptacles that restrict movement, and denying animals exercise.
- Rule 9(ff) of the Breeding of and Experiments on Animals Rules, 1998¹⁰, which requires proper and humane euthanasia protocols.
- Sections 117(2), 291, and 271 of the BNS, 2023¹¹, which criminalizes voluntarily causing grievous hurt to animals, negligent conduct with respect to animals, and negligent act likely to spread infection of disease dangerous to life, respectively, including acts resulting in fractures, maiming, or death through cruelty.

These statutory violations are reflected in whistleblowers' accounts as described above.

Request for NGCMA Action to Address Reported Noncompliances

The alleged egregious conduct at the Company, described herein, represents a serious breach of both Indian law and basic ethical standards in animal welfare. We trust NGCMA will treat this matter with the utmost urgency and gravity it demands, and move to immediately and permanently terminate the Company's NGCMA's GLP certification, and prohibit all future such applications from the Company regarding NGCMA's GLP Certification.

You may reach me at aaggarwal@petaindia.org or +91-9958840994. We stand ready to assist you further as needed. Thank you for your attention to this important matter, and we look forward to your response.

Sincerely,

⁷ Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, notified under the Prevention of Cruelty to Animals Act, 1960. Ministry of Environment and Forests, Government of India. Available at: <https://ccsea.gov.in/WriteReadData/userfiles/file/1998.pdf>

⁸ Government of India. (2023). *Bharatiya Nyaya Sanhita, 2023*. Sections 117(2) (Voluntarily causing grievous hurt), 271 (Negligent act likely to spread infection of disease dangerous to life) and 291 (Negligent conduct with respect to animal). Retrieved from https://www.mha.gov.in/sites/default/files/250883_english_01042024.pdf

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