OBJECTION TO THE DRAFT PREVENTION OF CRUELTY TO ANIMALS

(CONTROL AND SUPERVISION OF EXPERIMENT, BREEDING AND TRADING OF LABORATORY ANIMALS) RULES, 2026

Overall objection

Medicine Without Cruelty objects to the Draft Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026 because they continue to authorise and facilitate animal experimentation rather than establish a clear and decisive direction towards ending it.

The consequences for animals are profound. These Rules perpetuate an entire system in which animals are deliberately bred, traded, captured, transported, confined and ultimately subjected to experimentation and slaughter – this is barbaric. Laboratory breeding itself raises serious concerns: animals are brought into existence to supply experiments and may spend their lives in restrictive, controlled environments, often in close proximity to other animals. Maintaining these breeding populations creates continuing demand for animals and sustains an infrastructure built around their exploitation. It also raises significant One Health concerns, including the risks of infectious disease transmission within confined animal populations and through the movement of animals between breeding establishments, suppliers and research facilities. The consequences are not limited to animals subjected to individual experiments; they extend to the entire breeding and supply chain that makes animal experimentation possible.

The Draft Rules also create routes through which animals from wild, stray, feral and other unregistered sources may enter experimental establishments, while continuing to permit the use of non-human primates. These provisions risk drawing further animals into an established system of breeding, capture, trade, confinement and experimentation. This is not simply a question of how animals are sourced or managed. It is the continuation of a system that treats animals as a supply of experimental material, with serious consequences for animal lives, biodiversity and human health.

This direction is increasingly at odds with international scientific and regulatory developments. The UK Government published its *Replacing Animals in Science Strategy* in November 2025, setting out a programme to develop, validate and adopt non-animal methods, with the stated long-term ambition of phasing out animal use. The US Food and Drug Administration published its roadmap to reduce animal testing in preclinical safety studies in April 2025 and reported progress against its first-year goals in April 2026. In June 2026, the European Commission adopted its roadmap towards phasing out animal testing for chemical safety assessments. These developments demonstrate growing international recognition that scientific progress requires a transition towards more human-relevant, non-animal approaches. India should be accelerating this transition, not creating a regulatory framework that entrenches animal experimentation.

Of particular concern is the provision allowing foreign organisations to commission animal research through establishments registered in India. This risks making India a loophole for animal experimentation that organisations in other countries may be seeking to move away from. Rather than ending animal testing, it could displace it across borders, creating further demand for animals, breeding and supply networks, and the capture and movement of animals for experimental use.

There is also a fundamental scientific question. Around 95% of drug candidates are commonly reported to fail during clinical development (Ineichen *et al*., 2024). Nevertheless, the continued reliance on animal models has not prevented substantial failures when candidate medicines are tested in humans. India has an opportunity to invest in scientific approaches based on human biology, including human cells and tissues, organoids, organ-on-chip systems, computational modelling and other advanced non-animal methods.

India has the opportunity to become a global leader in animal-free science. It can build scientific capacity, attract investment, support innovation and contribute to a future in which research and testing are based on human-relevant methods rather than the continued use of animals. The Draft Rules move in the opposite

direction. They risk expanding the infrastructure, supply chains and international market for animal experimentation at precisely the time when other jurisdictions are developing plans to move away from it.

These concerns are interconnected. The retention of the 3Rs framework, the broad permitted purposes for experimentation, institutional approval and self-reporting, routes for sourcing animals, and the possibility of foreign-commissioned research collectively risk entrenching and expanding animal experimentation in India.

Medicine Without Cruelty therefore calls for the Draft Rules to be withdrawn in their entirety. India should instead pursue a clear, time-bound transition towards ending animal experimentation, ending the breeding and sourcing of animals for experimental purposes, and directing scientific investment, research infrastructure and regulatory development towards modern, human-relevant non-animal methods.

Rule 3: Rejection of the 3Rs and the need to end animal experimentation

The inadequacy of the 3Rs framework is not merely theoretical. It has been criticised for diverting scientific attention away from the development of research based on human biology. In *The Rat Trap*, Pandora Pound highlights that the 3Rs "divert attention away from the need for a science based on human biology." This is a fundamental concern: rather than challenging the scientific rationale for animal experimentation, the 3Rs framework permits its continuation while prioritising measures to reduce animal numbers or suffering.

Evidence also demonstrates that the existence of a non-animal method does not necessarily result in the discontinuation of the corresponding animal test. Hutchinson, Owen and Bailey (2022) reported that 452 skin sensitisation tests were conducted on mice in the UK in 2020 despite the availability of a validated non-animal method. Similarly, Cruelty Free International's *Replace Animal Tests (RAT) List* identified ten animal tests that were still being conducted despite valid non-animal methods being available. The organisation estimated that ending these ten tests could save approximately 750,000 animals each year in Europe.

These examples expose a central weakness of the 3Rs approach: the principle of Replacement has not ensured that animal tests are discontinued when scientifically appropriate non-animal methods are available. Reduction and Refinement, meanwhile, continue to accommodate animal experimentation rather than requiring its cessation. A regulatory framework that retains all three principles therefore risks perpetuating animal use, even in circumstances where non-animal methods have already been established.

Rule 3 must move beyond this framework. It should establish a clear requirement for establishments to identify, assess and adopt scientifically appropriate non-animal methods, rather than allowing animal experimentation to continue through a discretionary interpretation of whether an alternative is "possible".

Rule 4: The excessively broad purposes permitted for animal experimentation

Rule 4 – The excessively broad purposes permitted for animal experimentation

Medicine Without Cruelty objects to the extensive range of purposes for which animal experimentation is permitted under Rule 4. The provision encompasses basic research; research into human, animal and plant health; environmental protection; species preservation; forensic investigations; testing of drugs, food, feed and other substances; higher education and professional training; and processes involving blood and blood products.

These categories cover an exceptionally broad range of scientific activity. In particular, the inclusion of basic research creates an extensive scope for animal experimentation, potentially encompassing almost any area of biological or biomedical investigation. The provision does not establish a requirement to demonstrate that the scientific objectives can be achieved through non-animal methods, nor does it direct research towards the development and adoption of these methods.

Animal experimentation in education: reversing progress towards animal-free learning

Medicine Without Cruelty (MWC) strongly objects to provisions in the proposed *Prevention of Cruelty to Animals (Control and Supervision of Experiment, Breeding and Trading of Laboratory Animals) Rules, 2026* that permit animal experimentation for higher education and professional training. In particular, Rule 4(6) identifies higher education and professional training as purposes for which experiments may be conducted, while Rule 11(11) provides for institutional approval of repetitive or curriculum-based teaching experiments for periods of up to five years.

These provisions risk entrenching animal experimentation in educational institutions when India has already taken important steps towards animal-free learning.

In notification No. F.14-6/2014 (CPP-II), issued in July 2014 under Section 12(j) of the University Grants Commission Act, 1956, the University Grants Commission directed that, in undergraduate and postgraduate programmes in Zoology, Life Sciences and allied disciplines, no animal of any species should be dissected by teachers or students for any purpose. It directed teachers to demonstrate anatomy using digital alternatives, models, charts and similar educational resources. The notification's stated scope also refers to research programmes.

This was a significant step towards ending the use of animals in university education and recognising that students can learn anatomy and biological sciences through animal-free alternatives to dissection. Subsequent educational initiatives in India have developed digital teaching resources, models, cell culture and in-vitro toxicology training, alongside other non-animal approaches.

The proposed rules risk moving policy in the opposite direction. By expressly providing for animal experiments in higher education and professional training, and by enabling approvals for curriculum-based experiments lasting up to five years, they create a route for continued animal use in teaching without establishing a binding transition to animal-free education. This risks undermining the direction of earlier educational initiatives and normalising animal experimentation for successive generations of students.

MWC rejects the 3Rs framework of Replacement, Reduction and Refinement as an appropriate policy endpoint. Reducing the number of animals used or refining experimental procedures does not end animal experimentation; it permits it to continue. Education should not perpetuate animal use on the basis that experiments involve fewer animals or are conducted under improved procedures. Instead, universities and professional training institutions should adopt scientifically appropriate non-animal methods, including human cell and tissue models, organoids, organ-on-chip systems, computational approaches, simulations, digital resources and other relevant technologies.

We urge the Government of India to reconsider and remove provisions that facilitate animal experimentation for educational and training purposes. The rules should establish a clear direction towards ending animal use in education and advancing non-animal methods throughout university curricula and professional training. The progress represented by the 2014 UGC notification should be protected and advanced, not placed at risk by a regulatory framework that could facilitate renewed or continued animal experimentation.

We further request explicit clarification of the legal relationship between the proposed rules and the 2014 UGC notification. The Government should confirm whether the notification remains applicable, explain how any apparent conflict between the two frameworks will be resolved, and ensure that the proposed rules cannot be used to circumvent existing directions intended to end animal use in education.

Rule 11: Institutional approval, self-reporting and inadequate independent scrutiny

MWC is concerned that Rule 11 places substantial responsibility for approving animal experiments with Institutional Animal Ethics Committees (IAECs) within the establishments conducting the research, without sufficiently demonstrating how independent scrutiny and effective oversight will be ensured. Under Rule 11, a significant category of experiments can be approved by institutional committees without prior approval from CCSEA. Although reporting requirements apply, these arrangements rely substantially on information generated and submitted by the researchers and establishments undertaking the experiments.

The risks associated with over-reliance on institutional reporting and inadequate independent oversight are demonstrated by recent experience in the United Kingdom. In January and February 2026, two Westminster Hall parliamentary debates examined serious non-compliance incidents in British animal testing laboratories, drawing on the Animals in Science Regulation Unit's (ASRU) 2024 annual report. MPs raised cases of animals drowning in cages, dying through lack of food or water, being kept alive beyond authorised humane endpoints and being accidentally disposed of as waste. During the February debate, Ruth Jones MP highlighted that 69% of reported non-compliance incidents in 2024 were self-reported by licence holders. She also raised concerns that only 68 establishments had been inspected during the year, with just 10 inspections unannounced, while the regulator had 8.2 full-time equivalent inspectors responsible for overseeing 15,626 licences. Irene Campbell MP specifically raised concerns about the regulator's over-reliance on self-reporting. The Government Minister undertook to examine whether sufficient unannounced inspections were taking place.

These parliamentary debates demonstrate the limitations of relying on institutional reporting as a means of identifying failures and ensuring compliance. The fact that incidents are reported does not establish that all failures are detected, particularly where independent inspections are limited. The proposed Indian framework must therefore provide clear and effective mechanisms for independent verification, rather than relying primarily on institutional assurances and reporting.

The proposed reliance on institutional approval and reporting also raises serious concerns about what may happen to animals within experimental establishments when independent scrutiny is insufficient. Where institutions conducting experiments are also responsible for approving significant categories of procedures, classifying their severity and reporting compliance to the central authority, there is a risk that serious failures or harmful practices may not be identified or independently challenged. Reliance on institutional self-reporting cannot provide the assurance that animals are protected from abuse, suffering or unacceptable treatment. The consequences of inadequate oversight may extend beyond the harms inherent in experimentation itself. Animals should not be left dependent on the internal decisions and reporting of the institutions responsible for conducting experiments on them. MWC rejects a framework that places animals in this position while continuing to authorise their use.

A further fundamental concern is whether IAECs will have the necessary scientific expertise to identify, assess and recommend viable non-animal methods before approving animal experiments. The 2023 Rawle Report, commissioned by the UK National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs), examined the role of ethical review and regulatory approval processes in animal research. It found that institutional review committees rarely challenged the use of animals itself, and that committee members often lacked sufficiently detailed specialist knowledge to identify whether appropriate and practicable non-animal methods were available. The report also found that committees could assume researchers and funders had already considered alternatives, while veterinary expertise was predominantly focused on animal methods. These findings demonstrate a structural weakness in relying on institutional committees to determine whether animal experiments are necessary without ensuring access to the specialist expertise needed to assess non-animal scientific approaches.

This raises a fundamental question about the proposed IAEC approval process: what guarantees are there that committees will have access to independent scientific expertise in human-relevant, non-animal methods, and that every viable non-animal approach will be properly investigated before an animal experiment is approved? It

is not sufficient to ask researchers to justify their proposed use of animals if the committee reviewing that justification lacks the knowledge or resources to challenge it.

MWC therefore objects to a regulatory framework that continues to authorise animal experimentation while placing substantial reliance on institutional approval and reporting, without clear guarantees of independent scrutiny or the scientific expertise required to identify non-animal approaches. The objective must not be to improve the oversight of animal experiments so that they can continue, but to ensure that research and education move towards modern, human-relevant non-animal methods and bring animal experimentation to an end.

- Michael Wheeler MP, Animal Testing, Westminster Hall debate, 28 January 2026. Hansard.

- Seamus Logan MP, Animals in Science Regulation Unit annual report 2024, Westminster Hall debate, 3 February 2026. Hansard.

- Rawle, F. (2023). The role of review and regulatory approvals processes for animal research in supporting implementation of the 3Rs. NC3Rs.

Local approval and severity self-classification

The proposed rules make significant changes to the approval and sourcing of animals for experimentation. Taken together, these changes risk reducing independent scrutiny while expanding the routes through which animals can enter the experimental supply chain.

Removal of central approval based on animal species

Under the existing regulatory framework, experiments involving animals higher on the phylogenetic scale, including dogs, pigs, goats, cattle and non-human primates, are subject to consideration by the Institutional Animal Ethics Committee (IAEC) and approval by the central Committee (CCSEA). This requirement applies irrespective of whether the proposed procedure is considered mild or severe.

The 2026 draft fundamentally changes this approach. Rule 7 introduces four severity classifications: non-recovery, mild, moderate and severe. Under Rule 11(2), severe and non-recovery experiments involving animals above rodents and lagomorphs require CCSEA approval following IAEC recommendation. However, Rule 11(3) allows mild and moderate experiments involving all animal species to be approved by the IAEC without referral to CCSEA.

Consequently, experiments involving highly sentient animals, including pigs, dogs and non-human primates, could proceed without prior central approval simply because the procedure has been classified as mild or moderate.

The severity classification framework is closely modelled on the EU's Directive 2010/63/EU. However, there is a fundamental difference in how the classification and approval process operates. Under Articles 36 and 38 of the EU Directive, projects require prior authorisation and the competent authority is responsible for project evaluation, including assessment and assignment of the severity classification. In contrast, the Indian draft places the approval of mild and moderate experiments with the IAEC, without referral to CCSEA.

This is particularly concerning because the severity classification determines whether central approval is required. Where the establishment undertaking the research is responsible for classifying the proposed experiment, there is a risk that procedures involving significant pain, suffering or distress could be assigned an insufficiently high category, thereby avoiding central scrutiny. The draft does not provide an equivalent requirement for independent central assessment of every experiment involving animals above rodents and lagomorphs.

MWC objects to this removal of central oversight. The use of a sentient animal should not escape central scrutiny simply because an experiment has been assigned a mild or moderate classification. Furthermore, no animal experiment should be permitted merely because its expected severity is classified as mild or moderate.

Rules 5 and 21: Wild, stray and unregistered animal sourcing – One Health implications

Rules 5 and 21 raise related concerns about permitting animals from the wild, stray or feral populations, and unregistered sources to enter the experimental supply chain. From a One Health perspective, the health of humans, animals and ecosystems is interconnected. The World Health Organization, World Organisation for Animal Health and United Nations Environment Programme have highlighted the risk of zoonotic disease transmission associated with the capture, movement and mixing of animals whose infection status and exposure histories may be unknown.

Animals obtained from unregistered sources may have incomplete records of their origin, movement, previous contacts and health status. This can make it more difficult to assess disease risks, identify the source of an infection and trace potential transmission between animals and people. Capture, transport, confinement and contact with animals from different sources can introduce further opportunities for pathogen transmission. These concerns are particularly relevant to wild-caught animals, for which previous exposure to infectious agents may be difficult to establish.

These risks should not be overstated: an animal obtained from an unregistered source is not necessarily infected, and sourcing alone does not establish that transmission will occur. Nevertheless, exceptions that permit animals with uncertain provenance or health histories to be used in experiments require careful scrutiny. Veterinary examination, quarantine and testing may reduce particular risks but cannot guarantee that all relevant pathogens will be detected or that all previous exposures will be identified.

Importantly, this is not an argument for substituting purpose-bred laboratory animals as an acceptable source. Controlled breeding and health monitoring may reduce some uncertainties, but they do not eliminate all infectious risks and do not resolve the scientific and ethical objections to animal experimentation itself. Medicine Without Cruelty opposes the use of animals in experiments regardless of whether they are wild-caught, stray, obtained from an unregistered source or bred specifically for laboratory use.

We therefore ask the Government to reconsider provisions that facilitate the sourcing of animals for experimentation and to explain how the proposed framework addresses zoonotic risks, animal traceability and disease surveillance across the relevant supply chains. The regulatory response should not be to expand or legitimise alternative sources of experimental animals, but to accelerate the development and adoption of scientifically appropriate non-animal methods.

The definition of an establishment in Rule 2(i) is also concerning because it expressly includes premises that are not wholly enclosed or covered, as well as mobile facilities. This raises questions about the transparency, traceability and effective oversight of locations in which animals may be bred, housed, traded or used for experiments. It is particularly important where work may involve infectious agents or other biological hazards.

The draft rules must be considered in the context of risks to animal health, occupational health and public health. Facilities handling biological hazards require clearly designated and appropriate containment arrangements, supported by documented risk assessments and effective monitoring. The inclusion of partially enclosed and mobile premises makes it essential to establish how such risks will be identified and controlled, and how effective inspection and accountability will be assured.

These concerns are not an argument for permitting animal experimentation in better-equipped facilities. No level of containment or accreditation removes the fundamental scientific and ethical objections to using animals in experiments. Rather, the potential for inadequate oversight and exposure to biological hazards reinforces the need to move away from animal experimentation and towards modern non-animal methods. Protecting animals, laboratory personnel and the wider public must be central to a genuine One Health approach.

Unregistered animal sources and the risk of stolen or unlawfully obtained animals

Rule 5 provides for exceptions to restrictions on the experimental use of wildlife, wild-caught animals and stray or feral animals. These exceptions risk exposing animals who should be protected from experimental use to capture, procurement and experimentation.

Separately, Rule 21(1) requires animals to be acquired from CCSEA-registered breeders, establishments or traders. However, Rule 21(2) creates an exception where particular livestock and farm animals above the level of lagomorphs, fish or birds are unavailable from registered breeders or traders. In these circumstances, animals may be obtained from non-registered establishments or open markets, subject to prior IAEC approval, documentation and veterinary-certified quarantine and stabilisation.

MWC objects to the creation of this route into the experimental supply chain. Unregistered sources and open markets may not provide the same assurance of traceability, lawful ownership or reliable records of an animal's origin and movement history. This raises serious concerns about the potential for lost, abandoned or stolen animals to be acquired and sold for experimentation, particularly where effective checks on ownership and origin are absent.

Although Rule 21(2) does not expressly authorise the procurement of stolen pets or stray dogs and cats, the absence of robust sourcing controls creates a risk that animals obtained unlawfully could enter supply chains through which their history and ownership are difficult to verify. Veterinary quarantine and examination cannot establish lawful ownership or retrospectively guarantee an animal's origin.

These provisions must also be considered alongside the zoonotic disease risks associated with animals of unknown origin, health status and exposure history. The capture, movement, transport and mixing of animals from different sources can create opportunities for pathogen transmission. These are concerns for animal health, laboratory personnel and wider public health.

MWC calls for the removal of the exceptions permitting the use of wildlife, wild-caught, stray and feral animals in experiments, and for the removal of provisions allowing animals to be acquired from unregistered sources and open markets. No animal should be exposed to experimentation because it is available through an inadequately controlled supply chain.

The combined effect of these provisions is to reduce central scrutiny of animal experiments while permitting additional routes for animals to enter the experimental system. This is contrary to the direction required for modern science and a genuine One Health approach. India should be moving decisively towards human-relevant non-animal methods and the end of animal testing, not weakening the safeguards and controls governing the use of animals in research.

Rules 5 and 6: Continued authorisation of non-human primate experimentation

Medicine Without Cruelty raises serious concerns about the relationship between Rules 5 and 6, which create an unclear and inconsistent framework for the protection and experimental use of non-human primates. These provisions also fail to adequately address the scientific limitations of non-human primate models or the potential zoonotic and occupational health risks associated with keeping, breeding and using these animals in research facilities.

1. Inconsistent provisions and continued authorisation of non-human primate experimentation

Rule 5(1) establishes that specimens of animals protected under the Wildlife (Protection) Amendment Act, 2022 shall not be used in experiments, subject to specified exceptions. However, Rule 5(1)(c) states that this sub-rule shall not apply to any species of non-human primates. This provision therefore expressly excludes all non-human primates from the prohibition established under Rule 5(1).

Rule 6 then addresses experiments on non-human primates separately. It states that, subject to Rule 5, non-human primates shall not be used in experiments except where specified research purposes are met and scientific justification establishes that the purpose cannot be achieved using species other than non-human primates. Rule 6(2) subsequently states that non-human primates listed under the Wildlife (Protection) Amendment Act, 2022 shall not be used in experiments.

These provisions raise questions about the consistency and intended operation of the Rules. In particular, Rule 5(1)(c) excludes all non-human primates from its prohibition, while Rule 6(2) prohibits only those non-human primates listed under the wildlife legislation. This creates a distinction between listed and unlisted species, leaving the latter potentially available for experimentation under the exceptions in Rule 6(1).

The Government must clarify why non-human primates are treated separately from other protected wildlife and why the proposed framework permits their experimental use where specified conditions are met. The requirement to demonstrate that another species cannot achieve the research purpose does not establish that experimentation on non-human primates is scientifically necessary or that their use is an appropriate means of addressing human disease.

Rule 5(1)(d), which refers to the Committee reviewing the sourcing of non-human primates from self-sustaining colonies, raises an additional concern. The existence of a self-sustaining captive population does not establish the scientific suitability of these animals as models of human biology, nor does it justify their continued breeding and use in experiments. Research has demonstrated genetic variation between populations of cynomolgus macaques used in biomedical research, with potential implications for disease susceptibility and drug metabolism (Kanthaswamy et al., 2013).

2. Scientific limitations of non-human primate models

The proposed justification for permitting experiments on non-human primates is particularly concerning. Rule 6 requires scientific justification that the purpose of an experiment cannot be achieved using species other than non-human primates. However, this requirement does not establish that non-human primates are reliable predictors of human biological responses, nor does it consider whether the research objective could be achieved through scientifically appropriate non-animal methods.

Genetic similarity between humans and non-human primates is frequently used to justify their use in biomedical research. However, genetic similarity alone does not establish functional equivalence or predictability. Differences in gene expression, physiology, immune responses and drug metabolism can produce substantially different responses to the same substance (Bailey, 2014).

Furthermore, the conditions in which non-human primates are captured, transported, confined and used in laboratories can themselves affect their biological responses. Stress associated with restraint, social deprivation and experimental procedures can alter immune function, metabolism and susceptibility to illness, potentially introducing confounding variables into research findings (Bailey, 2018).

The limitations of non-human primate models are also illustrated by the TGN1412 clinical trial incident in 2006. Despite preclinical testing in cynomolgus macaques, the first-in-human trial resulted in life-threatening reactions in six healthy volunteers. The incident demonstrated the limitations of relying on animal studies to predict potentially severe human adverse reactions.

Meanwhile, human-relevant approaches, including human cell-based models, organoids, organ-on-chip technologies and computational methods, offer opportunities to investigate biological processes and drug responses using human-specific systems. These methods should be developed and assessed on their scientific merits rather than being required to demonstrate equivalence to an animal model.

The requirement in Rule 6 to establish that another animal species cannot achieve the research purpose is therefore inadequate. It continues to frame scientific necessity in terms of selecting an animal species, rather

than asking whether the research objective can be achieved through scientifically appropriate non-animal methods.

3. Zoonotic disease and occupational health risks

The continued breeding, housing and use of non-human primates in research facilities also raises significant One Health and occupational health concerns. Non-human primates can carry infectious agents capable of transmission to humans, sometimes without displaying obvious signs of infection themselves. Direct contact with animals, their bodily fluids, tissues and secretions, as well as procedures involving their handling and post-mortem examination, can create occupational exposure risks for veterinarians, animal-care personnel, laboratory researchers and other workers.

A particularly serious example was documented by the Chinese Center for Disease Control and Prevention in 2021. Its report, *First Human Infection Case of Monkey B Virus Identified in China, 2021*, described a 53-year-old veterinary surgeon working at a Beijing institute specialising in non-human primate breeding and experimental research. Following the dissection of two dead monkeys, he developed a fatal infection with Macacine alphaherpesvirus 1, commonly known as Monkey B virus or B virus. The virus was confirmed in his cerebrospinal fluid. The report noted that approximately 60 human cases of pathogenic zoonotic B virus infection had previously been documented and reported a case fatality rate of 70–80% among zoonotic infections (Wang et al., 2021).

The China CDC specifically identified this case as evidence of a potential zoonotic threat to occupational workers and highlighted the need for surveillance in laboratory macaques and occupationally exposed personnel.

This incident demonstrates that the risks associated with non-human primate research are not confined to the animals themselves. The breeding, housing and experimental use of these animals can also expose people working in these facilities to potentially life-threatening infections. Such risks must be considered within a One Health framework that recognises the interconnected health of humans, animals and the environment.

Although the documented risk of human B virus infection is rare, its potential severity makes it an important occupational health concern. The possibility of reducing infection risks through surveillance, screening and protective procedures does not eliminate the underlying hazard or justify the continued use and breeding of non-human primates for experimentation.

4. Recommendations

Medicine Without Cruelty rejects the continued use of non-human primates in experimentation, irrespective of whether a species is listed under wildlife legislation or sourced from a self-sustaining colony.

Their genetic similarity to humans does not guarantee reliable predictions of human responses, and the availability of captive-bred animals does not establish scientific necessity. Furthermore, the potential for zoonotic disease transmission creates risks extending beyond the animals themselves to veterinarians, animal-care personnel, researchers and wider public health.

We therefore call for:

- The removal of provisions permitting experiments on non-human primates under Rules 5 and 6, including the exceptions based on research purpose, species classification and sourcing arrangements.
- An unequivocal prohibition on the experimental use of all non-human primates, whether wild-caught, captive-bred or sourced from self-sustaining colonies.
- A clear explanation of how the Government considers the occupational and zoonotic disease risks associated with non-human primate breeding and experimental facilities within its One Health responsibilities.

- A regulatory direction that prioritises investment in, development and adoption of scientifically appropriate human-relevant non-animal methods.

India should not continue to authorise the breeding and experimental use of non-human primates under a regulatory framework that fails to adequately address their scientific limitations, conservation implications and potential risks to human health.

Rule 22: Facilitating the international outsourcing of animal experiments

MWC strongly objects to Rule 22, which permits research institutions or agencies not defined under the rules to outsource research activities involving animals to establishments registered with CCSEA. Read alongside Rule 2(g), which explicitly includes foreign individuals, companies, firms, corporations and institutions within the definition of contract research, this provision creates a route for foreign organisations to commission animal experiments to be conducted in India.

This has serious international implications. While jurisdictions such as the United Kingdom, United States and European Union are taking steps towards reducing and phasing out animal testing in particular areas of research, these draft rules would allow foreign organisations to continue commissioning animal experiments through Indian facilities, subject to the Indian regulatory framework. In effect, work that is being moved away from animal experimentation in one jurisdiction could continue through facilities in another.

This creates a significant risk of regulatory displacement: rather than accelerating the transition to modern, human-relevant non-animal methods internationally, India could become a destination for animal experiments commissioned by organisations operating in countries seeking to move away from such testing. The fact that the Indian establishment must be registered and comply with IAEC and CCSEA requirements does not address this fundamental concern. It still permits foreign organisations to procure animal experimentation through Indian facilities.

The absence of explicit disclosure requirements makes this particularly concerning. The draft does not clearly require the identification of foreign commissioning organisations, their country of operation, the full contractual and subcontracting arrangements, the purpose of the commissioned research, or whether the proposed experiments would be prohibited, restricted or subject to different regulatory requirements in the commissioning jurisdiction. Without these requirements, the scale and nature of foreign-commissioned animal research may be difficult to identify and scrutinise.

This is not simply an issue of administrative oversight. It raises a fundamental question of international responsibility. A country should not facilitate the continuation or relocation of animal experimentation that other jurisdictions are seeking to move away from. Nor should animals in India be subjected to experiments commissioned by organisations elsewhere simply because those organisations can access a regulatory route to conduct the work in another country.

MWC calls for Rule 22 to be withdrawn and for the rules to prohibit the outsourcing of animal experiments by foreign organisations to Indian establishments. India should not become a destination for the international transfer of animal experimentation. It should be contributing to the global transition towards modern, human-relevant non-animal methods and the end of animal testing.

Rules 1(6) and 15: Aftercare, rehabilitation, reuse and euthanasia

Medicine Without Cruelty objects to the lack of clear and enforceable provisions addressing the fate of animals currently subjected to experimentation.

Rule 1(6) states that the Rules apply until animals have been euthanised or rehabilitated to a suitable habitat or husbandry system. This presents euthanasia and rehabilitation as alternative outcomes without establishing a clear requirement to secure the future of animals or provide for their continued lives.

Rule 15 defers detailed requirements concerning rehabilitation and reuse to future CCSEA guidelines. It also permits death as an experimental endpoint where considered unavoidable, while stating that this should be avoided “as far as possible”. However, it does not clearly define what constitutes an early and humane endpoint or establish sufficiently clear criteria for determining when death is unavoidable.

The provisions concerning reuse are also unacceptable. Animals must not be subjected to further experiments simply because they remain available for research. The priority must be to end their use in experimentation, not extend it.

Medicine Without Cruelty's Roadmap calls for mandatory aftercare and rehoming, including veterinary treatment and behavioural rehabilitation, supported by a national rehoming strategy. Animals should be adopted where appropriate or provided with lifelong sanctuary care where adoption is not possible. These are necessary measures to address the consequences of existing animal experimentation; they must not be used to justify its continuation.

Medicine Without Cruelty therefore requests that:

1. Rules 1(6) and 15 establish mandatory aftercare, rehabilitation and long-term care arrangements for animals currently held and used in experimentation.
2. Reuse provisions are removed so that animals are not subjected to further experimentation.
3. The provisions permitting death as an experimental endpoint are strengthened, with clear criteria and no reliance on institutional convenience or the absence of aftercare arrangements to justify euthanasia.
4. CCSEA establishes a national rehoming strategy, including specialist carers, adoption where appropriate and lifelong sanctuary care where necessary.

Aftercare and rehabilitation are not alternatives to ending animal experimentation. They are essential responsibilities in addressing the harm already caused and ensuring that animals currently held in laboratories are not simply discarded. The objective must be to end animal experimentation, not to make its continuation more acceptable.

National knowledge sharing, scientific collaboration and access to non-animal methods

The effective implementation of Rule 3 also requires a coordinated approach to scientific collaboration, data sharing and knowledge exchange. India has already begun developing important foundations in this area. The Centre for Predictive Human Model Systems (CPHMS), a joint initiative involving the Atal Incubation Centre at the Centre for Cellular and Molecular Biology and Humane World for Animals India, has developed publicly accessible databases mapping Indian researchers working on human-relevant model systems and publications on New Approach Methodologies. Furthermore, the Government of India reported in August 2026 that the Indian Council of Medical Research had supported 109 research projects involving non-animal testing methods across 71 institutions and laboratories.

These initiatives demonstrate that expertise and research activity in non-animal methods are developing across India. However, mapping researchers and supporting individual research projects are not sufficient to ensure that existing scientific knowledge is routinely identified and applied when decisions about research methods are made. There remains a need for a coordinated, accessible national resource through which researchers and Institutional Animal Ethics Committees can identify relevant non-animal methods, published evidence, protocols, datasets, validation studies, technical expertise and examples of successful applications.

IAECs should not be expected to assess the availability and scientific suitability of non-animal methods in isolation. They must have access to appropriate independent expertise and to the accumulated knowledge and experience of the wider scientific community, both nationally and internationally. Greater collaboration and systematic sharing of research data, methodologies and scientific findings would also help avoid duplication of research effort and accelerate the development and adoption of human-relevant approaches.

We therefore urge the Government to build upon existing initiatives, particularly the work of CPHMS, and support the development of a coordinated national knowledge-sharing infrastructure for non-animal science. This should include an accessible repository of methods, protocols, datasets, validation evidence and relevant scientific expertise, alongside mechanisms for collaboration between universities, research institutions, industry and developers of non-animal technologies. Access to this resource should be incorporated into the assessment process of IAECs, so that scientifically appropriate non-animal approaches are actively identified and considered before any proposal involving animals is authorised.

MWC does not consider improved institutional oversight, additional animal welfare representation or more rigorous ethical review to be an adequate response to the fundamental problem with these Rules. Our position is that animal experimentation should be brought to an end, not made more administratively acceptable or permitted to continue under improved regulatory supervision. Independent animal protection organisations should not be expected to legitimise or facilitate the approval of animal experiments. Their role should be to provide independent scrutiny, challenge the continued authorisation of animal use and advocate for the adoption of scientifically appropriate non-animal methods. The purpose of scientific expertise, knowledge-sharing and independent scrutiny must be to accelerate the transition away from animal experimentation, not to make its continuation more efficient.

The breadth of non-animal methodologies is considerable and continues to expand. These are not limited to individual alternative tests but encompass diverse scientific approaches, including human cell and tissue-based models, organoids, organ-on-chip and microphysiological systems, computational modelling, artificial intelligence, genomics, transcriptomics, proteomics, metabolomics and integrated approaches combining multiple methods. Their applications extend across basic and applied research, disease investigation, drug development, toxicology, environmental research and other scientific disciplines. It is therefore unrealistic to expect individual IAEC members to possess comprehensive knowledge of all relevant methodologies. Without access to specialist expertise and an up-to-date national knowledge resource, committees cannot reliably identify the full range of scientifically appropriate non-animal approaches available for a proposed research objective.

Investment in non-animal methods: a scientific, economic and strategic opportunity for India

The proposed Rules should be considered in the context of India's opportunity to become a leader in the development and application of human-relevant non-animal methods. The transition away from animal experimentation should not be approached merely as a regulatory challenge or a requirement to identify alternatives to existing animal-based procedures. It represents an opportunity to develop a modern scientific and biotechnology sector, strengthen research capability, generate skilled employment and establish India as an international centre for non-animal science.

The economic potential of this transition is increasingly recognised internationally. The 2026 report by the Common Sense Policy Group at Northumbria University, *Non-Animal New Approach Methodologies (NAMs): More effective, more ethical and more economically productive*, commissioned by Lush, examined the growth and economic potential of the UK NAMs sector. Its analysis identified substantial growth in company turnover, gross value added and employment between 2021 and 2024, demonstrating the potential for non-animal science to support a growing commercial and research sector. The report also identifies the importance of sustained public investment, research infrastructure, skills development, knowledge transfer, collaboration between universities and industry, and regulatory modernisation.

India has already established important foundations upon which to build. Government-supported research projects, the work of CSIR and ICMR institutions, emerging human-relevant model systems and the initiatives of the Centre for Predictive Human Model Systems demonstrate existing scientific capability and growing interest in this field. These investments should be expanded and connected through a coherent national strategy.

We urge the Government to establish a properly funded national programme to accelerate the development, validation and adoption of non-animal methods. This should support academic research, specialist

infrastructure, technology development, skills and workforce training, commercialisation, and collaboration between universities, research institutions, industry and regulators. It should also build on existing initiatives such as CPHMS to strengthen national and international knowledge sharing, ensuring that scientific expertise, methodologies, protocols, datasets and research findings are accessible and actively used.

Investment should support the development of regional research and innovation hubs, enabling universities, start-ups, established biotechnology companies and research organisations to contribute to the growth of this sector. India should also assess the potential for international collaboration, technology transfer and the development of Indian expertise and technologies for global application.

The Government should commission an assessment of the economic and scientific opportunities associated with accelerating the transition to non-animal methods in India, including the potential for new enterprises, skilled employment, research investment and international competitiveness. Funding should be accompanied by clear objectives, implementation milestones and a commitment to redirect resources towards non-animal science rather than perpetuating investment in animal experimentation.

India has the scientific expertise, research institutions, biotechnology capabilities and human resources to make a significant contribution to this transformation. Rather than establishing a regulatory framework that continues to facilitate animal experimentation, India should invest in the science and infrastructure needed to bring it to an end and position itself at the forefront of modern, human-relevant research.

India should not invest in expanding the infrastructure for animal experimentation. It should invest in the scientific infrastructure, expertise, technologies and businesses that will bring animal experimentation to an end.

Conclusion

The Draft Rules represent a significant step in the wrong direction. Rather than establishing a pathway towards ending animal experimentation, they would perpetuate and facilitate an entire system of animal exploitation: breeding animals into lives of confinement, capturing and trading animals from wild and other unregistered sources, subjecting animals to experimentation, and sustaining the supply chains and infrastructure required to continue this practice. They also raise serious concerns for biodiversity, zoonotic disease transmission and human health.

At a time when the United Kingdom, United States and European Union are developing strategies and roadmaps to move away from animal testing, India should not introduce legislation that risks enabling animal experimentation to continue within its own borders, or allowing foreign organisations to commission experiments that they may increasingly seek to move away from elsewhere. India must not become an international destination for outsourced animal experimentation.

The scientific case for ending animal testing is overwhelming, recognising the limitations of translating animal-based research into application for another species. India has the scientific expertise, research institutions, biotechnology capabilities and potential to become a global leader in human-relevant, non-animal science. It has an opportunity to lead a fundamental transformation in research and testing, rather than invest in expanding a system that depends on the continued breeding, confinement and use of animals.

Medicine Without Cruelty calls for the complete withdrawal of the Draft Rules. They should not be amended simply to make animal experimentation more administratively acceptable or to facilitate its continuation under improved regulatory oversight. India needs a fundamentally different direction: a clear, funded and time-bound commitment to ending animal experimentation, ending the breeding and sourcing of animals for experimental purposes, and directing scientific investment, research infrastructure and regulatory development towards modern, human-relevant non-animal methods.

Animals currently held in laboratories must also be provided with mandatory aftercare, rehabilitation and lifelong care where necessary. Their futures must not be sacrificed to the continuation of this system.

India has an opportunity to demonstrate global leadership by adopting non-animal methods and bringing animal experimentation to an end. The Government should seize that opportunity, not legislate for its continuation.

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