THE REGULATION OF ARTIFICIAL INTELLIGENCE BILL, 2022

authored by

Zain Khan

1st Year BA. LL. B. (Hons.),

National Law Institute University, Bhopal

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A Bill to regulate Artificial Intelligence in India to ensure transparency, accountability and trustworthiness in the creation, supply and use of Artificial Intelligence within the Republic of India.

WHEREAS, clause (1) of Article 248 empowers the Parliament to make any law with respect to any matter not enumerated in the Concurrent List or State List.

AND WHEREAS, Artificial Intelligence is a fast-evolving family of technology that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities but may also cause a lot of harm if left unchecked and unregulated;

AND WHEREAS, by improving prediction, regulation, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes;

AND WHEREAS, understanding and preparing for the ongoing development of Artificial Intelligence and the development of a well-educated workforce in such technology is critical to the economic and social prosperity of India;

AND WHEREAS, it is imperative that artificial intelligence be developed in a way that does not compromise our Indian values, fundamental rights, consumer rights, freedoms and privacy protection;

BE it enacted by the Parliament in the Seventy-third Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

1. Short title, extent, commencement and application.—(*1*) This Act may be called the Regulation of Artificial Intelligence Act, 2022.

(*2*) It shall extend to the whole of India and, save as otherwise provided in this Act, it applies also to any offence or contravention thereunder committed outside India by any person.

(*3*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint and different dates may be appointed for different provisions of this Act.

(*4*) Notwithstanding anything contained in any other law for the time being in force, the provisions of this Act shall apply to—

(*a*) providers placing on the market or putting into service AI systems in India, irrespective of whether those providers are established within India or outside India; and

(*b*) users of AI systems located within India; and

(*c*) providers and users of AI systems that are located outside India, where the output produced by the system is used in India.

2. Definitions.—In this Act, unless the context otherwise requires,—

(*1*) "Artificial Intelligence system" or "AI system" means software that is developed with one or more of the following techniques,—

(*a*) machine-learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; or

(*b*) logic and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; or

(*c*) statistical approaches, Bayesian estimation, search and optimization methods.

AI systems can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

(*2*) "authorised representative" means any natural or legal person established in India who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Act;

(*3*) "biometric categorisation system" means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, caste, religion, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data;

(*4*) "biometric data" means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person, such as facial images or dactyloscopy data;

(*5*) "CE marking of conformity" or "CE marking" means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in the provisions of this Act and of any other law for the time being in force;

(*6*) *"*Commission" means the Indian Artificial Intelligence Commission constituted under section 43;

(*7*) "common specifications" means a document, other than a standard, containing technical solutions providing a means to, comply with certain requirements and obligations established under this Act;

(*8*) "Conformity Assessment Body" means a body that performs third-party conformity assessment activities, including testing, certification and inspection. Such a body shall be constituted by the Commission through notification in the Official Gazette;

(*9*) "conformity assessment" means the process of verifying whether the requirements set out in the provisions of this Act relating to an AI system have been fulfilled;

(*10*) "distributor" means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Indian market without affecting its properties;

(*11*) "emotion recognition system" means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data;

(*12*) "heinous offences" includes the offences for which the minimum punishment under the Indian Penal Code or any other law for the time being in force is imprisonment for seven years or more;

(*13*) "importer" means any natural or legal person established in India that places on the market or puts into service an AI system that bears the name or trademark of a natural or legal person established outside India;

(*14*) "input data" means data provided to or directly acquired by an AI system on the basis of which the system produces an output;

(*15*) "instructions for use" means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used;

(*16*) "intended purpose" means the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;

(*17*) "law enforcement authority" means,—

(*a*) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; or

(*b*) any other body or entity entrusted by the Central Government or the State Government to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(*18*) "law enforcement" means activities carried out by law enforcement authorities for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(*19*) "making available on the market" means any supply of an AI system for distribution or use on the Indian market in the course of commercial activity, whether in return for payment or free of charge;

(*20*) "Market Surveillance Authority" means the national authority carrying out the activities and taking the measures deemed fit. Such a body shall be constituted by the Commission through notification in the Official Gazette;

(*21*) "National Competent Authority" means the Notifying Authority and the Market Surveillance Authority;

(*22*) "Notifying Authority" means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of

conformity assessment bodies and for their monitoring. Such a body shall be constituted by the Commission through notification in the Official Gazette;

(*23*) "operator" means the provider, the user, the authorised representative, the importer and the distributor;

(*24*) "performance of an AI system" means the ability of an AI system to achieve its intended purpose;

(*25*) "placing on the market" means the first making available of an AI system on the Indian market;

(*26*) "post-market monitoring" means all activities carried out by providers of AI systems to proactively collect and review experience gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

(*27*) "provider" means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to place it on the market or put it into service under its own name or trademark, whether for payment or free of charge;

(*28*) "publicly accessible space" means any physical place accessible to the public, regardless of whether certain conditions for access may apply;

(*29*) "putting into service" means the supply of an AI system for first use directly to the user or for own use on the Indian market for its intended purpose;

(*30*) "real-time remote biometric identification system" means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also limited short delays in order to avoid circumvention;

(*31*) "reasonably foreseeable misuse" means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;

(*32*) "recall of an AI system" means any measure aimed at achieving the return to the provider of an AI system made available to users;

(*33*) "remote biometric identification system" means an AI system for the purpose of identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified;

(*34*) "safety component of a product or system" means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property;

(*35*) "serious incident" means any incident that directly or indirectly leads, might have led or might lead to any of the following

(*a*) the death of a person or serious damage to a person's health, to property or the environment; or

(*b*) a serious and irreversible disruption of the management and operation of critical infrastructure;

(*36*) "small-scale provider" means a provider that is a micro or small enterprise within the scope of Micro, Small and Medium Enterprises Development Act, 2006;

(*37*) "special categories of personal data" means data that reveals the racial or ethnic origin, caste, political opinions, religious or philosophical beliefs, or trade union membership, and it includes the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation;

(*38*) "substantial modification" means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in the provisions of this Act or results in a modification to the intended purpose for which the AI system has been assessed;

(*39*) "testing data" means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service;

(*40*) "training data" means data used for training an AI system through fitting its learnable parameters, including the weights of a neural network;

(*41*) "user" means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity;

(*42*) "validation data" means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split;

(*43*) "withdrawal of an AI system" means any measure aimed at preventing the distribution, display and offer of an AI system.

CHAPTER II

PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES

3. Deploys subliminal techniques.—The placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm, is prohibited.

4. Exploits any vulnerabilities of a specific group of persons.—The placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that person or another person physical or psychological harm, is prohibited.

5. Evaluates or classifies the trustworthiness of natural persons.—The placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons over a certain period of time, based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to—

(*a*) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected; or

(*b*) detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity.

6. 'Real-Time' remote biometric identification system.—The use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement, is prohibited unless and in as far as such use is strictly necessary for one of the following objectives—

(*a*) the targeted search for specific potential victims of crime, including missing children; or

(*b*) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack; or

(*c*) the detection, localisation, identification or prosecution of a perpetrator or suspect of a heinous offence.

CHAPTER III

HIGH-RISK AI SYSTEMS

7. Classification as a high-risk AI system.—(*1*) An AI system shall be automatically considered to be a high-risk AI system, irrespective of whether it is placed on the market or put into service independently from the product when the AI system is intended to be used as a safety component of a product or is itself a product.

(*2*) The Commission shall make a list of AI systems, that are to be automatically treated as high-risk, publicly available by notification in the Official Gazette.

8. Requirements for high-risk AI systems.—(*1*) A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems.

(*2*) The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps—

(*a*) identification and analysis of the known and foreseeable risks associated with each high-risk AI system; and

(*b*) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse; and

(*c*) evaluation of other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in section 47; and

(*d*) adoption of suitable risk management measures.

(*3*) High-risk AI systems shall be tested for the purpose of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the necessary requirements.

(*4*) The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

9. Implementation of the risk management system.—(*1*) The intended purpose of the high-risk AI system and the risk management system shall be taken into account when ensuring compliance with requirements.

(*2*) In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

(*3*) When implementing the risk management system, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.

10. Data and data governance.—(*1*) High-Risk AI systems that involve the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the appropriate quality criteria. Training, validation and testing data sets shall be subject to appropriate data governance and management practices.

(*2*) Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or group of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

(*3*) Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the

specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

(*4*) To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

11. Data governance standards for High-risk AI systems that do not involve training of models with data.—Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that they too meet the required standard of quality.

12. Technical documentation.—The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to-date. The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the appropriate requirements and provide national competent authorities with all the necessary information to assess the compliance of the AI system with those requirements.

13. Record-keeping.—(*1*) High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while a high-risk AI system is operating. Those logging capabilities shall conform to recognised standards or common specifications.

(*2*) The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system.

14. Transparency and provision of information to users.—(*1*) High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving

compliance with the relevant obligations of the user and of the provider according to the provisions of this Act.

(*2*). High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.

15. Human oversight.—(*1*) High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

(*2*) Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in the provisions of this Act.

16. Accuracy, robustness and cybersecurity.—(*1*) High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

(*2*) The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

(*3*) High-risk AI systems shall be resilient as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular, due to their interaction with natural persons or other systems.

(*4)* The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.

(*5)* High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs due to outputs used as an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

(*6)* High-risk AI systems shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities. The

technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

(*7)* The technical solutions to address the vulnerabilities specific to the AI system shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

CHAPTER IV

OBLIGATIONS OF PARTIES

17. Obligations of providers of high-risk AI systems.—Providers of high-risk AI systems shall ensure that—

(a) ensure that their high-risk AI systems are compliant with the requirements set out in the provisions of this Act; and

(*b*) have a quality management system in place which complies with section 18; and

(c) draw-up the technical documentation of the high-risk AI system; and

(*d*) when under their control, keep the logs automatically generated by their high-risk AI systems; and

*(*e*)* ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service; and

(*f*) comply with the registration obligations referred to in section 39; and

(*g*) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in the provisions of this Act; and

(*h*) inform the national competent authorities of the non-compliance and of any corrective actions taken; and

(*i*) upon request of a National Competent Authority, demonstrate the conformity of the high-risk AI system with the requirements set out in the provisions of this Act.

18. Quality management system.—Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with the provisions of this Act. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

19. Obligation to draw up technical documentation.—Providers of high-risk AI systems shall draw up the technical documentation referred to in section 12 in accordance with the specifications that Commission shall make public by notification in the Official Gazette.

20. Obligation to undergo relevant conformity assessment.—Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with section 33, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in the provisions of this Act has been demonstrated following that conformity assessment, the providers shall draw up a declaration of conformity in accordance with section 33 and affix the CE marking of conformity in accordance with section 37.

21. Automatically generated logs.—Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in light of the intended purpose of the high-risk AI system and applicable legal obligations.

22. Corrective actions.—Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with the provisions of this Act shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

23. Duty of information.—Where the high-risk AI system presents a risk and that risk is known to the provider of the system, that provider shall immediately inform the National Competent Authority that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

24. Cooperation with competent authorities.—Providers of high-risk AI systems shall, upon request by a National Competent Authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in the provisions of this Act. Upon a reasoned request from a National Competent Authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

25. Authorised representatives.—(*1*) Prior to making their systems available on the market, where an importer cannot be identified, providers established outside India shall, by written mandate, appoint an authorised representative which is established in India;

(*2*) The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks—

(*a*) keep a copy of the declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities and; and

(*b*) provide a National Competent Authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in the provisions of this Act, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law; and

(*c*) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.

26. Obligations of importers.—(*1*) Before placing a high-risk AI system on the market, importers of such system shall ensure that—

(*a*) the appropriate conformity assessment procedure has been carried out by the provider of that AI system; and

(*b*) the provider has drawn up the technical documentation in accordance with the specifications that Commission shall make public by notification in the Official Gazette; and

(*c*) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use.

(*2*) Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with the provisions of this Act, it shall not place that system on the market until that AI system has been brought into conformity.

(*3*) Importers shall indicate their name, registered trade name or registered trademark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable.

(*4*) Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise its compliance with the requirements set out in the provisions of this Act.

(*5*) Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in the provisions of this Act, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action National Competent Authority takes in relation to that system.

27. Obligations of distributors.—(*1*) Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the obligations set out in the provisions of this Act.

(*2*) Where a distributor considers or has reason to consider that a high-risk AI system is not in conformity with the requirements set out in the provisions of this Act, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements.

(*3*) Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in the provisions of this Act.

(*4*) A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in the provisions of this Act shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions.

(*5*) Upon a reasoned request from a National Competent Authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation

necessary to demonstrate the conformity of a high-risk system with the requirements set out in the provisions of this Act. Distributors shall also cooperate with that National Competent Authority on any action taken by that authority.

28. Obligations of distributors, importers, users or any other third-party.—*(1)* Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Act and shall be subject to the obligations of the provider under section 17, when—

(*a*) they place on the market or put into service a high-risk AI system under their name or trademark; or

(*b*) they modify the intended purpose of a high-risk AI system already placed on the market or put into service; or

(*c*) they make a substantial modification to the high-risk AI system.

(*2*) Where the circumstances referred to in aforementioned clause (*b*) or (*c*), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Act.

29. Obligations of users of high-risk AI systems.—(*1*) Subject to the provisions of this Act and of any other law for the time being in force, users of high-risk AI systems shall use AI systems in accordance with the instructions of use accompanying the systems. This shall be without prejudice to the user's discretion in organising their own resources and activities for the purpose of implementing the human oversight measures indicated by the provider.

To the extent the user exercises control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system.

(*2*) Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. Users shall inform the provider or distributor when they have identified any serious incident or any malfunctioning within the meaning of section 48 and interrupt the use of the AI system. In case the user is not able to reach the provider, section 48 shall apply according to the circumstances of the case.

(*3*) Users of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent such logs are under their control. The logs shall be kept for a period that is appropriate in light of the intended purpose of the high-risk AI system and applicable legal obligations.

CHAPTER V

NOTIFYING AUTHORITIES

30. Notifying authority.—(*1*) A Notifying Authority shall be established which shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring.

(*2)* Notifying authorities shall be established, organised and operated in such a way that no conflict of interest arises with conformity assessment bodies and the objectivity and impartiality of their activities are safeguarded.

(*3*) Notifying authorities shall be organised in such a way that decisions relating to the notification of conformity assessment bodies are taken by competent persons different from those who carried out the assessment of those bodies.

(*4*) Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform or any consultancy services on a commercial or competitive basis.

(*5*) Notifying authorities shall safeguard the confidentiality of the information they obtain.

31. Notification procedure.—(*1*) Notifying authorities may notify only conformity assessment bodies that have satisfied the requirements laid down by the Commission.

(*2*) Notifying authorities shall notify the Commission using the electronic notification tool developed and managed by the Commission.

(*3*) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the artificial intelligence technologies concerned.

(*4*) Notifying authorities shall notify the Commission of any subsequent relevant changes to the notification.

CHAPTER VI

STANDARDS, CONFORMITY ASSESSMENT, CERTIFICATES AND REGISTRATION

32. Presumption of conformity with certain requirements.—(*1*)Taking into account their intended purpose, high-risk AI systems that have been trained and tested on data concerning the specific geographical, behavioural and functional setting within which they are

intended to be used shall be presumed to be in compliance with the requirement set out in section 10.

(*2*) High-risk AI systems that have been certified shall be presumed to be in compliance with the cybersecurity requirements set out in section 16 of this Act in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements.

33. Conformity assessment.—(*1*) The conformity assessment of the AI system is based on the assessment of the quality management system and the assessment of the technical documentation is the conformity assessment procedure.

(*2*) The quality management system shall be assessed by the conformity assessment, which shall determine whether it satisfies the requirements referred to in section 18. The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.

(*3*) The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the conformity assessment by the provider.

(*4*) High-risk AI systems shall undergo a new conformity assessment procedure whenever they are substantially modified, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.

(*5*) The technical documentation shall be examined by the conformity assessment. To this purpose, the Conformity Assessment Body shall be granted full access to the training and testing datasets used by the provider, including through application programming interfaces or other appropriate means and tools enabling remote access.

The decision shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.

34. Technical Documentation Assessment Certificates.—(*1*) Where the AI system is in conformity with the requirements set out in the provisions of this Act, a technical documentation assessment certificate shall be issued by the Conformity Assessment Body. The certificate shall indicate the name and address of the provider, the conclusions of the

examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.

(*2*) The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated and to allow for control of the AI system while in use, where applicable.

(*3*) Where the AI system is not in conformity with the requirements set out in the provisions of this Act, the Conformity Assessment Body shall refuse to issue a technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the Conformity Assessment Body refusing to issue the technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance.

(*4*) Certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the provider, the validity of a certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.

(*5*) Where a Conformity Assessment Body finds that an AI system no longer meets the requirements set out in the provisions of this Act, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it, unless compliance with those requirements is ensured by appropriate corrective action taken by the provider of the system within an appropriate deadline set by the Conformity Assessment Body. The Conformity Assessment Body shall give reasons for its decision.

35. Appeal against decisions of Conformity Assessment Bodies.—The commission shall ensure that an appeal procedure against decisions of the Conformity Assessment Bodies is available to parties having a legitimate interest in that decision.

36. Derogation from conformity assessment procedure.—(*1*) By way of derogation from section 33, any Market Surveillance Authority may authorise the placing on the market

or putting into service of specific high-risk AI systems within the territory of India, for exceptional reasons of public security or the protection of life and health of persons, environmental protection and the protection of key industrial and infrastructural assets. That authorisation shall be for a limited period of time, while the necessary conformity assessment procedures are being carried out, and shall terminate once those procedures have been completed. The completion of those procedures shall be undertaken without undue delay.

Provided the Market Surveillance Authority concludes that the high-risk AI system complies with the requirements set out in the provisions of this Act, the Market Surveillance Authority shall inform the Commission of any such authorisation.

(*2*) Where, within 15 calendar days of receipt of the information referred to in the proviso of sub-section (1), no objection has been raised by the Commission in respect of an authorisation issued by a Market Surveillance Authority in accordance with sub-section (1), that authorisation shall be deemed justified.

(*3*) If the authorisation is considered unjustified by the Commission, the specific high-risk AI system shall be withdrawn by the Market Surveillance Authority.

37. CE marking of conformity.—The CE marking shall be affixed visibly, legibly and indelibly for high-risk AI systems. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.

38. Document retention.—The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities—

(a) the technical documentation referred to in section 12; and

(b) the documentation concerning the quality management system referred to in section 18; and

(c) the documentation concerning the changes approved by Conformity Assessment Body where applicable; and

(d) the decisions and other documents issued by the Conformity Assessment Body where applicable.

39. Registration.—Before placing on the market or putting into service a high-risk AI system referred to in section 7(2), the provider or, where applicable, the authorised representative shall register that system in the database for stand-alone high-risk AI systems referred to in section 46.

40. Transparency obligations for certain AI systems.—(*1*) Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way that natural persons are informed that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.

(*2*) Users of an emotion recognition system or a biometric categorisation system shall inform of the operation of the system the natural persons exposed thereto. This obligation shall not apply to AI systems used for biometric categorisation, which are permitted by law to detect, prevent and investigate criminal offences.

(*3*) Users of an AI system that generates or manipulates image, audio or video content that appreciably resembles existing persons, objects, places or other entities or events and would falsely appear to a person to be authentic or truthful (‘deep fake’), shall disclose that the content has been artificially generated or manipulated.

CHAPTER VII

MEASURES IN SUPPORT OF INNOVATION

41. AI regulatory sandboxes.—(*1*) AI regulatory sandboxes established by competent authorities shall provide a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan. This shall take place under the direct supervision and guidance of the competent authorities with a view to ensuring compliance with the requirements of this Act.

(*2*) The AI regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of the development and testing process until such mitigation takes place.

(*3*) Participants in the AI regulatory sandbox shall remain liable under any law for the time being in force, for any harm inflicted on third parties as a result of the experimentation taking place in the sandbox.

(*4*) Competent authorities that have established AI regulatory sandboxes shall coordinate their activities and cooperate within the framework of the Commission. They shall submit annual reports to the Commission on the results from the implementation of those schemes, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Act supervised within the sandbox.

42. Measures for small-scale providers and users.—(*1*) The State shall undertake the following actions—

(*a*) provide small-scale providers and start-ups with priority access to the AI regulatory sandboxes to the extent that they fulfil the eligibility conditions; and

(*b*) organise specific awareness-raising activities about the application of this Act tailored to the needs of the small-scale providers and users; and

(*c*) where appropriate, establish a dedicated channel for communication with small-scale providers and users and other innovators to provide guidance and respond to queries about the implementation of this Act.

(*2*) The specific interests and needs of the small-scale providers shall be taken into account when setting the fees for conformity assessment under section 33, reducing those fees proportionately to their size and market size.

CHAPTER VIII

GOVERNANCE

43. Indian Artificial Intelligence Commission.—(*1*) The Central Government shall, by notification in the Official Gazette, constitute a body to be known as the Indian Artificial Intelligence Commission to exercise the powers conferred on, and to perform the functions assigned to it under this Act.

The Central government, by subsequent notification, shall appoint a Chairperson for the Commission and it shall also appoint such a number of Deputy Chairpersons, members, other officers and employees as it deems fit.

(*2*) The qualifications, experience and terms and conditions of service of the Chairperson, Deputy Chairpersons, other officers and employees shall be such as may be prescribed by the Central Government.

(*3*) The Commission may appoint such committees as may be necessary for dealing with such special issues as may be taken up by the commission from time to time.

(*4*) The Central Government shall, after due appropriation made by Parliament by law in this behalf, pay to the Commission by way of grants such sums of money as the Central Government may think fit for being utilised for the purposes of this Act.

44. Functions of the commission.—The Commission shall perform all or any of the following functions, namely—

(*a*) investigate and examine all matters relating to the use and regulation of AI;

(*b*) present to the Central Government, annually and at such other times as the commission may deem fit, reports upon the working and advancement of AI and related technology;

(*c*) make in such reports recommendations for the effective implementation of rules and regulations for the use, development and regulation of AI;

(*d*) review, from time to time, the provisions for the regulation and control of AI and recommend amendments thereto so as to suggest remedial legislative measures to meet any lacunae, inadequacies or shortcomings in such legislations;

(*e*) take up the cases of violation of the provisions of this Act and other related laws with the appropriate authorities;

(*f*) call for special studies and research into specific problems arising out of the use of AI and identify the constraints so as to recommend strategies for their removal;

(*g*) call for special studies and research into ways to make use and development of AI trustworthy and safe;

(*h*) undertake promotional and educational work to make AI more accessible to micro and small businesses, provide digital literacy, train people to be able to use AI systems properly and responsibly;

(*i*) evaluate the development in the field of AI and related technology under the Union and any state;

(*j*) to discharge duties conferred or imposed on it under this act;

(*k*) any other matter which may be referred to it by the Central Government.

45. Exercise of the delegation.—(*1*) The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this section.

(*2*) As soon as it adopts a delegated act, the Commission shall notify it to the Central Government. The Commission shall discharge its delegated legislation functions subject to the general control and direction of the Central Government.

(*3*) The Commission may make regulations consistent with this Act and rules made thereunder to carry out the purposes of this Act by notification in the Official Gazette.

(*4*) Every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the regulation or both Houses agree that the regulation should not be made, the regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that regulation.

46. Database for stand-alone high-risk AI systems.—(*1*) The Commission shall set up and maintain a database containing the information referred to in sub-section (*2*) concerning high-risk AI systems referred to in section 7(2) which are registered in accordance with section 39.

(*2*) The Commission shall make public the data which is to be submitted upon the registration of high-risk AI systems by notification in the Official Gazette. This data shall be entered into the database by the providers. The Commission shall provide them with technical and administrative support.

(*3*) Information contained in the database shall be accessible to the public.

(*4*) The database shall contain personal data only insofar as necessary for collecting and processing information in accordance with this Act. That information shall include the names and contact details of natural persons who are responsible for registering the system and have the legal authority to represent the provider.

(*5*) The Commission shall be the controller of the database. It shall also ensure to providers adequate technical and administrative support.

CHAPTER IX

POST-MARKET MONITORING, INFORMATION SHARING AND MARKET SURVEILLANCE

47. Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems.—(*1*) Providers shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the high-risk AI system.

(*2*) The post-market monitoring system shall actively and systematically collect, document and analyse relevant data provided by users or collected through other sources on the performance of high-risk AI systems throughout their lifetime, and allow the provider to evaluate the continuous compliance of AI systems with the requirements set out in the provisions of this Act.

48. Reporting of serious incidents and malfunctioning.—(*1*) Providers of high-risk AI systems placed on the market shall report any serious incident or any malfunctioning of those systems which constitutes a breach of obligations under a law intended to protect fundamental rights to the market surveillance authorities.

Such notification shall be made immediately after the provider has established a causal link between the AI system and the incident or malfunctioning or the reasonable likelihood of such a link, and, in any event, no later than 15 days after the providers becomes aware of the serious incident or of the malfunctioning.

(*2*) Upon receiving a notification related to a breach of obligations subject to the provisions of any law for the time being in force, intended to protect fundamental rights, the Market Surveillance Authority shall inform the national public authorities or bodies referred to in section 49(3). The Commission shall develop dedicated guidance to facilitate compliance with the obligations set out in sub-section (1). That guidance shall be issued 12 months after the entry into force of this Act, at the latest.

CHAPTER X

ENFORCEMENT

49. Access to data and documentation.—(*1*) Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application

programming interfaces ('API') or other appropriate technical means and tools enabling remote access.

(*2*) Where necessary to assess the conformity of the high-risk AI system with the requirements set out in the provisions of this Act and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.

(*3*) National public authorities or bodies which supervise or enforce obligations under the law protecting fundamental rights shall have the power to request and access any documentation created or maintained under this Act when access to that documentation is necessary for the fulfilment of the duty under their mandate within the limits of their jurisdiction. The relevant public authority or body shall inform the Market Surveillance Authority of any such request.

(*4*) By 3 months after the entering into force of this Act the Commission shall identify the public authorities or bodies referred to in sub-section (*3*) and make a list publicly available by notification in the Official Gazette.

(*5*) Where the documentation referred to in sub-section (3) is insufficient to ascertain whether a breach of obligations subject to the provisions of any law, for the time being in force, intended to protect fundamental rights has occurred, the public authority or body referred to in sub-section (3) may make a reasoned request to the Market Surveillance Authority to organise testing of the high-risk AI system through technical means. The Market Surveillance Authority shall organise the testing with the close involvement of the requesting public authority or body within a reasonable time following the request.

(*6*) Any information and documentation obtained by the national public authorities or bodies referred to in sub-section (3) pursuant to the provisions of this section shall be treated in compliance with the confidentiality obligations set out in section 54.

50. Procedure for dealing with AI systems presenting a risk at the national level.— (*1*) Where the Market Surveillance Authority has sufficient reasons to consider that an AI system presents a risk as insofar as risks to the health or safety or to the protection of fundamental rights of persons are concerned, they shall carry out an evaluation of the AI system concerned in respect of its compliance with all the requirements and obligations laid down in this Act. When risks to the protection of fundamental rights are present, the Market Surveillance Authority shall also inform the relevant national public authorities or bodies referred to in section 49(3). The relevant operators shall cooperate as necessary with the

market surveillance authorities and the other national public authorities or bodies referred to in section 49(3).

(*2*) Where, in the course of that evaluation, the Market Surveillance Authority finds that the AI system does not comply with the requirements and obligations laid down in this Act, it shall without delay require the relevant operator to take all appropriate corrective actions to bring the AI system into compliance, to withdraw the AI system from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(*3*) Where the operator of an AI system does not take adequate corrective action within the period referred to in sub-section (2), the Market Surveillance Authority shall take all appropriate provisional measures to prohibit or restrict the AI system's being made available in the market, to withdraw the product from that market or to recall it. That authority shall inform the Commission without delay of those measures.

(*4*) Where, within three months of receipt of the information referred to in sub-section (3), no objection has been raised by the Commission in respect of a provisional measure taken, the provisional measures shall be deemed justified. The Market Surveillance Authority shall then ensure that appropriate restrictive measures are taken in respect of the non-compliance of the AI systems concerned, such as withdrawal of the product from the market, without delay.-

51. Compliant AI systems that present a risk.—(*1*) Where, having performed an evaluation under section 50, the Market Surveillance Authority finds that although an AI system is in compliance with this Act, it presents a risk to the health or safety of persons, to the compliance with obligations under a law intended to protect fundamental rights or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the AI system from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(*2*) The provider or other relevant operators shall ensure that corrective action is taken in respect of all the AI systems concerned that they have made available on the market within the timeline prescribed by the Market Surveillance Authority.

52. Formal non-compliance.—(*1*) Where the Market Surveillance Authority makes one of the following findings, it shall require the relevant provider to put an end to the non-compliance concerned—

(*a*) the conformity marking has been affixed in violation of section 37; or

(*b*) the conformity marking has not been affixed; or

(*c*) the declaration of conformity has not been drawn up; or

(*d*) the declaration of conformity has not been drawn up correctly; or

(*e*) the identification number of the Conformity Assessment Body, which is involved in the conformity assessment procedure, where applicable, has not been affixed.

(*2*) Where the non-compliance referred to in sub-section (1) persists, the Commission shall take all appropriate measures to restrict or prohibit the high-risk AI system being made available on the market or ensure that it is recalled or withdrawn from the market.

53. Codes of conduct.—(*1*) The Commission shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems other than high-risk AI systems of the requirements set out in the provisions of this Act on the basis of technical specifications and solutions that are appropriate means of ensuring compliance with such requirements in light of the intended purpose of the systems.

(*2*) The Commission shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to AI systems of requirements related for example to environmental sustainability, accessibility for persons with disability, stakeholders' participation in the design and development of the AI systems and diversity of development teams on the basis of clear objectives and key performance indicators to measure the achievement of those objectives.

(*3*) Codes of conduct may be drawn up by individual providers of AI systems or by organisations representing them or both. Codes of conduct may cover one or more AI systems taking into account the similarity of the intended purpose of the relevant systems.

(*4*) The Commission shall take into account the specific interests and needs of the small-scale providers and start-ups when encouraging and facilitating the drawing up of codes of conduct.

54. Confidentiality.—Competent authorities involved in the application of this Act shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular—

(*a*) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code; and

(*b*) the effective implementation of this Act, in particular for the purpose of inspections, investigations or audits;(c) public and national security interests; and

(*c*) the integrity of criminal or administrative proceedings.

CHAPTER XI

PENALTIES

55. Penalties.—(*1*) In compliance with the terms and conditions laid down in this Act the Commission shall lay down the rules on penalties, including administrative fines, applicable to infringements of this Act and shall take all measures necessary to ensure that they are properly and effectively implemented. The penalties provided for shall be effective, proportionate, and dissuasive. They shall take into particular account the interests of small-scale providers and start-ups and their economic viability.

(*2*) The following infringements shall be subject to administrative fines which may extend up to one thousand crores rupees or, if the offender is a company, up to 6 % of its total worldwide annual turnover for the preceding financial year, whichever is higher—

(*a*) non-compliance with the prohibition of the artificial intelligence practices referred to in Chapter II of this Act; and

(*b*) non-compliance of the AI system with the requirements set in section 10.

(*3*) The non-compliance of the AI system with any requirements or obligations under this Act, other than those laid down in Chapter II and section 10, shall be subject to administrative fines which may extend up to five hundred crore rupees or, if the offender is a company, up to 4 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

(*4*) The supply of incorrect, incomplete or misleading information to national competent authorities in reply to a request shall be subject to administrative fines of up to one crore rupees or, if the offender is a company, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.

(*5*) When deciding on the amount of the administrative fine in each case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following—

(*a*) the nature, gravity and duration of the infringement and its consequences; and

(*b*) whether administrative fines have been already applied by other market surveillance authorities to the same operator for the same infringement; and

(*c*) the size and market share of the operator committing the infringement.

56. Administrative fines on government institutions, agencies and bodies.—(*1*) Administrative fines may be imposed on Government institutions, agencies and bodies falling within the scope of this Act. When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following—

(*a*) the nature, gravity and duration of the infringement and its consequences; and

(*b*) the actions that have been taken by the Government institution, agency or body to remedy the infringement and mitigate the possible adverse effects of the infringement; and

(*c*) any similar previous infringements by the Government institution, agency or body; and

(*2*) The following infringements shall be subject to administrative fines of up to four crore rupees—

(*a*) non-compliance with the prohibition of the artificial intelligence practices referred to in Chapter II of this Act; and

(*b*) non-compliance of the AI system with the requirements laid down in section 10.

(*3*) The non-compliance of the AI system with any requirements or obligations under this Act other than those laid down in Chapter II and section 10, shall be subject to administrative fines of up to two crore rupees.

(*4*) Funds collected by the imposition of fines in this section shall be the income of the general budget of India.

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Ms. Zain Khan,
1st Year BA. LL. B. (Hons.), NLIU Bhopal