August 5, 2020

To,

Dr. Harsh Vardhan
Minister for Health & Family Welfare,
Government of India,
348-A, Nirman Bhawan,
Maulana Azad Road,
New Delhi – 110 011.

Sir,

Petition seeking greater transparency regarding drug regulation under the Drugs and Cosmetics Act, 1940

1. We are a group of citizens, concerned about the lack of transparency with which the pharmaceutical industry is regulated in India. For far too long, we have known about the corruption in drug approval process; the unholy nexus between drug manufacturers and medical experts; and the inaction against manufacturers of substandard and ineffective medicines. This troubling state of affairs, we believe, is a direct fallout of systemic opacity prevalent within the institutions responsible for regulating the pharmaceutical industry. This is an issue that you had expressed concern about several years ago, in an interview to the *Indian Express* wherein you had stated the following:

> "There is corruption in the approval of drugs. The Central Drugs Standard Controls Organisation, which is supposed to oversee clinical trials, is another snake pit of vested interests……The corruption that goes behind approving drug approvals was exposed through Wikileaks and later confirmed by the Standing Committee of the Health Ministry in 2012."[1]

2. We could not agree more with your assessment of the situation back in 2014. We believe that the best way to reform drug regulation is by making the entire regulatory apparatus under the Drugs and Cosmetics Act, 1940 (D&C Act) more transparent. Our demand for greater transparency flows from Section 4 of the Right to Information Act, 2005 (RTI Act) which requires the government to make *proactive* disclosures of its records through the internet and other means of communications to the general public. This provision must be taken seriously by the government because the 'Right to Information' is a fundamental right of citizens flowing from the right to free speech and expression under Article 19(1)(a) of the Constitution.[2] The underlying rationale of reading the right to information into the right to free speech is the fact that citizens cannot

[1] Pritha Chatterjee, *MCI corrupt, clinical trials body a snake pit: Harsh Vardhan*, *Indian Express* (July 18, 2014), available at: indianexpress.com/article/india/politics/mci-corrupt-clinical-trials-body-a-snake-pit-harsh-vardhan/ (last accessed on July 10, 2020).
[2] *See* S.P. Gupta v. Union of India, (1981) Supp SCC 87; State of Uttar Pradesh v. Raj Narain, (1975) 4 SCC 428; Dinesh Trivedi v. Union of India, (1997) 4 SCC 306; People's Union for Civil Liberties v. Union of India, (2004) 2 SCC 476.

effectively assert their fundamental right to free speech against the state without access to information about the internal workings of the state. By making available more information to the public regarding the workings of the Indian drug regulatory system, the government will make it possible for important stakeholders like doctors, pharmacists, journalists and patients to hold both the regulators and the pharmaceutical industry accountable for their actions. The availability of such information will also provide doctors with the information required to make better medical decisions with regard to treatment of patients.

3. In the specific context of drug regulation in India, the need for greater transparency has been stressed on by the Parliamentary Standing Committee on Health & Family Welfare, in its 59th Report (2012) and 66th Report (2013), which called for "increased transparency in decision-making" of the Central Drugs Standard Controls Organization (CDSCO) and other regulatory authorities. Even the Central Information Commission (CIC) has repeatedly called upon the CDSCO and other regulatory bodies to take *proactive* steps to keep the public informed about various regulatory activities. And more recently, the CIC made the following scathing observations in a case involving files that went missing from the Office of the Drug Controller General of India (DCGI):[3]

> "The Commission however expressed its serious concern over the record keeping methodology in the office of DCGI / CDSCO due to the fact that an important report relating to the review of procedures and practices followed by CDSCO for granting approval and clinical trials on certain drugs went missing from their office that had to be procured from the author after receipt of notice of hearing from the Commission. This is despite the fact that the Parliamentary Standing Committee had also taken cognizance of the lapses by the Public Authority. The intent and the conduct of the Public Authority should always be above board in matters relating to grant of approvals through a transparent and objective mechanism. The Commission advises Secretary, M/o Health and Family Welfare, Govt. of India to examine this matter appropriately for further necessary action at its end."

4. In this petition, we identify specific aspects of drug regulation that are required to be made far more transparent than is the case currently and we explain how exactly such transparency may be achieved in this regard:

   (i) Clinical trial data, along with final outcomes, must be disclosed through Clinical Trial Registry of India or such other database regardless of the success or failure of the trial;
   (ii) Decisions and file notings relating to applications for approval of new drugs decided by DCGI, including the ones that are rejected or withdrawn, must be made public;

[3] Prashant Reddy T. v. Central Public Information Officer, Drug Controller General of India & Ministry of Health, CIC/MH&FW/A/2018/159460-BJ (May 26, 2020), available at: indiankanoon.org/doc/115080764/ (last accessed on July 10, 2020).

(iii) Applications for state manufacturing licenses and accompanying safety data for generic drugs must be made public;

(iv) Inspection reports by Drug Inspectors and lab test results by the Government Analysts, at Central and State levels must be available in the public domain;

(v) Enforcement actions under the D&C Act, such as criminal complaints initiated against drug manufacturers and judgments must be made available to the public; and

(vi) The latest and previous editions of Indian Pharmacopeia should be made available to the public at free of cost.

A. Ensuring greater transparency of Clinical Trials by mandating disclosure of both positive and negative results

5. The regulation of clinical trials in India has for long been a controversial issue. After much litigation before the Supreme Court, the Ministry of Health began the process of increasing transparency around clinical trials in India by creating the Clinical Trials Registry of India (CTRI), as an online database administered by the Indian Council of Medical Research (ICMR). As per the New Drugs and Clinical Trials Rules, 2019, it is mandatory for all sponsors to register clinical trials in the CTRI database before enrolling the first subject for the trial.[4]

6. Launched in 2007, the CTRI database is valuable for doctors and researchers to learn from developments in medical research. Furthermore, the CTRI database allows citizens to monitor the recruiting practices employed by pharma companies during trials conducted in India. With nearly 30 data fields, the CTRI database captures various aspects of clinical study; viz., title, subject matter, nature and stage of trial, locations, details of ethics committee review, outcomes, and concludes with a 'brief summary.'[5]

7. Be that as it may, the CTRI database and the legal framework governing it does not address two critical issues related to transparency. These issues are discussed in greater detail below:

(a) **Limited Disclosures**: The CTRI database does not contain three crucial pieces of information. The *first* piece of missing information is the minutes of the meeting of the institutional Ethics Committee where the clinical trial is to be carried out. These minutes are important because they will contain the details of the deliberations (including disclosure of conflict of interest) conducted by the Ethics Committee before allowing

[4] *See* Rules 25(v), 35(vi) & 49.

[5] NATIONAL INSTITUTE OF MEDICAL STATISTICS, 'CTRI Dataset and Description', ctri.nic.in/Clinicaltrials/CTRI_Dataset_and_Description.pdf (last accessed on June 27, 2020).

the institution to conduct the clinical trial. The *second* missing piece of information is the application submitted to the DCGI for permission to conduct the clinical trial. The application will presumably contain a host of pre-clinical data (study protocols, toxicology and pharmacology data, and other technical studies). This data needs to be made available to the public health community in order to ensure that the DCGI makes responsible decisions while granting permissions to conduct clinical trials in India. While the pharmaceutical industry would like to claim a proprietary interest in such data, it can be argued that the public interest in the disclosure of safety data can outweigh any IP concerns. As per Section 8(1)(d) of the RTI Act, information can be disclosed if public interest outweighs IP concerns. The *third* critical piece of missing information is the reasoned decision of the DCGI granting approval or rejecting an application for the conduct of clinical trials. Without access to the DCGI's decision there is no way for the people to hold the DCGI accountable for its decision.

(b) **Disclosure of primary data**: The CTRI database only requires sponsors to indicate the status of the clinical trial. However, there is no legal obligation to disclose the primary datasets containing the results of the clinical trials. As a result, it has been alleged that pharmaceutical companies cherry pick the best data for publication in peer-reviewed journals while suppressing the most damaging data. The reasons are self-evident. Many in the pharmaceutical industry fear that publication of all clinical trial data may invite more public scrutiny of their claims and even adversely impact decisions by doctors to prescribe some of the riskier drugs. However, internationally, there has been a demand by the public health community for the release of all clinical trial data regardless of whether the trial succeeded or failed. Access to such health data will help both the regulatory community and the patient community in making more informed decisions regarding the true potential of a drug and the public interest in disclosure of this information outweighs the proprietary interests of the pharmaceutical companies. It maybe pertinent to mention that 'The Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subject' (2013) adopted by the World Medical Association (WMA) states "[r]esearchers have a duty to make publicly available the results of their research … Negative and inconclusive as well as positive results must be published."[6] ICMR also endorsed a global

[6] WORLD MEDICAL ASSOCIATION, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 310 (20) JOURNAL OF MEDICAL ASSOCIATION 2191 (2013), available at: wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf (last accessed on June 27, 2020).

pledge to disclose results of trials in a timely manner.[7] However, the disclosure is limited to trials that are funded or supported by ICMR. The results of a vast majority of trials in India are unreported. Internationally, there has been a move in both the EU and the US to mandate the public disclosure of more clinical trial data.[8] India should follow suit and make the disclosure of such clinical trial data a precondition to the approval of any new drug.

8. Similar issues, regarding the disclosure of regulatory safety data under the RTI Act, have come before CIC. In *Divya Raghunandan v. Dept. of Biotechnology* (2007)[9] and *Kavita Kuruganti v. MoEF* (2016)[10] the CIC required the public disclosure of raw trial data (viz., biosafety, toxicity and allergencity data) pertaining to genetically modified brinjal studies because the public interest in making such data public, over-rode all other considerations such as commercial confidence, trade secrets or intellectual property. In the *Kavita Kuruganti* case, the CIC went as far as to require the publication of regulatory data even if the trials were a failure. Further in context of pharmaceutical safety data, the CIC in the past mandated the disclosure of clinical study reports of observational studies relating to HPV vaccines after redaction of the names of the patients and any information that may be considered the intellectual property of the pharmaceutical companies.[11] In a subsequent decision, the CIC ordered the DCGI to "suo motu disclose Regulatory Information redacting/obliterating the information exempted u/s 8 (1)/9 of the RTI Act, 2005 for the benefit of public at large."[12] This order, however, has not been complied with by the DCGI.

9. **Therefore, we submit that the CDSCO has a legal obligation to disclose regulatory data especially primary datasets for all clinical trials authorized in India, after redacting private patient information. The information should be available in a searchable online database that can be freely accessed by any citizen.**

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[7] 'Joint statement on public disclosure of results from clinical trials' (May 18, 2017), available at: who.int/ictrp/results/ICTRP_JointStatement_2017.pdf?ua=1 (last accessed on June 27, 2020).

[8] Sergio Bonini et. al., *Transparency and the European Medicines Agency – Sharing of Clinical Trial Data*, 371 (26) NEW ENGLAND JOURNAL OF MEDICINE 2452, available at:nejm.org/doi/pdf/10.1056/NEJMp1409464?articleTools=true (last accessed on July 10, 2020); Lev Facher, *Federal judge rules clinical trial sponsors must publish a decade's worth of clinical data Stat News* (February 25, 2020), available at: statnews.com/2020/02/25/clinical-trial-sponsors-publish-missing-data/ (last accessed on July 20, 2020).

[9] CIC/WB/A/2009/000668 (June 16, 2009), available at: indiankanoon.org/doc/103342038/ (last accessed on July 20, 2020).

[10] CIC/SA/A/2015/901798 (April 01, 2016), available at: indiankanoon.org/doc/145596348/ (last accessed on July 20, 2020).

[11] Deepa Venkatachalam v. Directorate General of Health Services, CIC/AD/A/2011/000115 (March 24, 2011), available at: ciconline.nic.in/cic_decisions/CIC_AD_A_2011_000116_M_54028.pdf (last accessed on June 27, 2020).

[12] Amresh Chandra Mathur v. Directorate General of Health Services, CIC/DTGHS/A/2018/609161-BJ+ (April 09, 2019), available at: indiankanoon.org/doc/4580255/ (last accessed on July 20, 2020).

II. Make public all records pertaining to new drug approvals

10. As per the New Drugs and Clinical Trial Rules, 2019 the DCGI is the designated licensing authority responsible for granting approvals to import or market 'new drugs' in India. This approval is distinct from the manufacturing license which is granted by the State Licensing Authorities for individual manufacturing plants. Over the last decade the DCGI has been heavily criticized for the manner in which it has given approval to dubious new drugs. The 59th report of the Parliamentary Standing Committee on Health & Family Welfare harshly criticized the DCGI for approving drugs that have not been approved in other countries. The fact that the Ministry of Health had to ban several hundred irrational Fixed Dose Combinations (FDCs) from the Indian market also pointed to the fact that unapproved drugs were being sold in India without permission from the DCGI. Since that report of the Parliamentary Standing Committee, the drug approval process was revamped by creating Subject Expert Committees (SEC) consisting of external experts with expertise in different areas. These SECs make a recommendation to the DCGI on approval of drugs and the DCGI is the final authority who can make a decision on whether a new drug can be sold in India.

11. As of today, the DCGI publishes very little information, compared to foreign regulators, regarding the approval of new drugs. The only information of some worth that is published, are the recommendations of the SECs but even this information is inadequate because these recommendations are very brief and do not contain the reasoning of the SEC or the deliberations of the Committee prior to making recommendations.[13] Usually the recommendations do not even contain the names of the experts who attended the meeting, whether they have any potential conflict of interests and whether they agreed or dissented with the recommendations of their peers. On the other hand, foreign drug regulators in the Western world release extensive information about the review process conducted by their regulators prior to approving or rejecting and application for a new drug. For example, the United States Food and Drugs Administration (USFDA) publishes at least 6 reviews of an application for a new drug, on different aspects of the new drug.[14] This includes a medical review, chemistry review, pharmacology review, statistical review, microbiology review and a clinical pharmacology biopharmaceutics review. Similarly, the European Medicines Agency (EMA) publishes a detailed EPAR (European Public

[13] The Minutes of the different SEC meetings can be accessed here: cdsco.gov.in/opencms/opencms/en/Committees/SEC/ (last accessed on July 20, 2020)
[14] For example, see the following approval granted by the USFDA: www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022257_021304s007_valcyte_valganciclovir%20hydrochloride_toc.cfm (last accessed on July 20, 2020).

Assessment Report) for all its decision (including rejections) that outlines the scientific justification for granting approvals.[15]

12. The following is a list of information that we think should be made public with regard to new drugs approvals in order to fulfill the requirements of Section 4 of the RTI Act:

    a. The entire application dossier submitted by pharmaceutical companies for approval of a new drug, inclusive of data pertaining to efficacy, toxicity and other clinical data must be proactively published by the DCGI on its website and the Gazette of India at least 90 days prior to any final approval so as to enable public comment.

    b. As mentioned earlier, it is not enough to make available the recommendation of the SEC. It is also necessary to make available the deliberations of the SEC along with any internal memos or file notings of the DCGI regarding the decision to grant approval. Unless such information is made publicly available, there is no scope for citizens to verify whether the DCGI is discharging its duty as per the law. Most other countries provide detailed information about the review process followed for each application requesting approval of a new drug.

    c. Along with publishing the above details regarding approved drugs, the CDSCO must also publish the details of applicants and drugs that fail to receive final approval. Other regulators like the EMA and Australia's TGA publishes 'negative opinions' in respect of applications that fail to meet approval standards. Such assessment reports are intended to benefit the scientific community in future endeavors.[16]

13. **To conclude, we believe that the DCGI must be directed to disclose details of the entire lifecycle of a drug's approval process so that the public health community can be informed of the basis of decisions taken by the DCGI. Additionally, disclosure of such information will provide both doctors and patients with more information about the efficacy and toxicity of new drugs. The information should be available in a searchable online database that can be freely accessed by any citizen.**

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[15] For more information on the European approval process please see the following: ema.europa.eu/en/medicines/what-we-publish-when/european-public-assessment-reports-background-context (last accessed on July 20, 2020).

[16] Tafuri G, Trotta F, Leufkens HG, Pani L., 'Disclosure of grounds of European withdrawn and refused applications: a step forward on regulatory transparency' BR J CLIN PHARMACOL. 2013;75(4):1149-1151. doi:10.1111/j.1365-2125.2012.04424.x

III. Disclosure of applications for state manufacturing licenses and accompanying regulatory data

14. While the marketing approval for new drugs is granted by the DCGI, the manufacturing licenses for all drugs are granted by individual State Drug Controllers, also referred to as State Licensing Authorities (SLA). An individual manufacturing licence is given for each individual drug manufactured by a pharmaceutical company. If the same drug is being manufactured at more than one plant of the same company, separate licenses will have to be issued for each plant.

15. As per the mandate under Rule 79 of the D & C Rules, 1945 each manufacturing plant is required to be physically inspected by a Drug Inspector at the time of granting or renewing a license. The inspection is to cover the premises, plant, appliances and the process of manufacture and testing of drugs. After the inspection, an 'inspection report' as per Rule 80 of the D & C Rules, 1945 containing descriptive findings as well as recommendations is required to be sent by the Drug Inspector to the licensing authorities.

16. Apart from the inspection of the premises, the approval process for generic drugs (i.e. not 'new drugs') also requires an assessment of bioequivalence and stability data for each drug, in order to assess the capacity of the manufacturer to synthesis the drug in a manner that ensures its therapeutic efficacy over a long duration of time. The bioequivalence data is a measure of the ability of the drug to become bioavailable within a patient's body. If a drug is not properly synthesized it will not dissolve in the blood in a proper manner and that will affect its bioavailability and therapeutic efficacy.[17] Stability data measures whether the drug can withstand different atmospheric conditions such as temperature and humidity, that it is expected to encounter through the supply chain, without breaking down. This data is required to be recorded through the lifecycle of a drug by testing retained samples from each manufactured batch. From the many exposes by the USFDA, it is very clear that many pharmaceutical companies in India regularly fabricate both bioequivalence and stability data for drugs that were intended for foreign markets.[18]

17. From a public health point of view, it is important for each and every central and state licensing authority under the D&C Act to disclose all of the above mentioned information so that citizens can better inform themselves about the workings of the state regulators. A centralized and open database of

[17] *See generally* Jerome P. Skelly, "Bioavailability and Bioequivalence", 16(10) THE JOURNAL OF CLINICAL PHARMACOLOGY 539-545 (1976) available at: accp1.onlinelibrary.wiley.com/doi/10.1177/009127007601601013 (last accessed on July 20, 2020).
[18] *See* Katherine Eban, "Bottle of Lies: The Inside Story of the Generic Drug Boom", Harper Collins, (2019).

manufacturing licences along with the accompanying inspections reports, licensing decisions, bioequivalence and stability data will go a long way in providing the healthcare industry with better information about every manufacturer and drug being sold within the country. Such transparency of information will also help procurement officers at hospitals, pharmacies and individual patients to make better procurement decisions while purchasing drugs.

18. **Therefore we submit that the Ministry of Health must take steps to create a publically accessible searchable national online database that contains all necessary information manufacturing/loan licences (including decisions regarding approval or rejections), all inspections reports and all bioequivalence and stability data.**

IV. Disclosure of test reports prepared by Government Analysts of drugs drawn from the market

19. Under the D&C Act, the Drug Inspectors appointed at the central and state levels collect hundreds of samples every month for quality testing. These samples are then tested by Government Analysts working at the Central Drug Laboratories (CDL) and State Drug Laboratories (SDLs) as per the requirements mentioned in the Indian Pharmacopeia. The findings of the Government Analyst guide the decision of the Drug Inspectors on whether the manufacturer is required to be prosecuted under the law for violation of quality requirements.

20. Given the importance of the test reports prepared by the Government Analyst, it is crucial that all these reports be made publicly available. In an excellent move towards transparency, the Central Government and 14 states have come together to deploy a platform called 'XLN – Xtended Licensing, Laboratory & Legal Node' that operates as a consolidated database of all the drugs/manufacturers that failed quality testing.[19] When originally created, the XLN database used to provide an option to download the test report prepared by Government Analysts after testing in government laboratories. For reasons not clear, the test reports prepared by Government Analysts are no longer being made available on the website, instead only some of the results of the report are provided in an inconvenient hover-over mode. However, as per the RTI Act even the primary documents i.e. test reports are required to be made publicly available.

21. The more significant problem is the fact that not all government laboratories are contributing their test reports to the XLN database. As of now only 14 states are

[19] The database can be accessed over here: https://xlnindia.gov.in/GP_FailedSample.aspx

contributing their test reports to the XLN database. It is not clear as to why the remaining states are not participating in this noteworthy exercise to boost administrative transparency. If required, the Central Government must consider a statutory mandate for all states to participate in the XLN database.

22. **Therefore, we submit that the test reports conducted by CDL and SDLs must be published *suo motu* in a searchable national database. By creating a consolidated, searchable, digital database that is open to the public, the government will make it considerably easier for citizens to be informed about the quality of drugs available in the market. This same information will allow procurement officers of public and private hospitals to make a determination about the track record of pharmaceutical companies before purchasing drugs from any of them.**

V. Enforcement actions against the pharmaceutical industry must be disclosed in public domain

23. If a drug sample fails a quality test conducted by a Governmental Analyst, it is standard procedure for the Drug Inspector to conduct a root-cause investigation. Such investigation is summarized usually in the form of an inspection report of the manufacturing facility where the drug was manufactured. This report is sent to the State Drug Controller who may or may not grant sanction to prosecute the pharmaceutical company for violations of the D&C Act. If permission for criminal prosecution is granted, the Drug Inspector files a criminal complaint before a criminal court to initiate a prosecution. None of these documents are proactively published by any of the State Governments or the Central Government. As a result it is impossible for citizens to inform themselves of the state of enforcement of drug regulatory laws.

24. It should be noted at this stage that the 59th Report of the Parliamentary Standing Committee on Health & Family Welfare recommended to the Ministry that it maintain a centralized database of prosecutions launched all over the country.[20] The 66th Report recorded the Ministry's acceptance and commitment to create such an infrastructure on a 'priority basis.'[21] Despite the passage of over 7 years, the CDSCO has failed to create such a database.

25. Transparency over enforcement actions is vital for the following reasons. *First*, secrecy over inspections creates a doubt about the impartiality and independence of drugs inspectors. *Second*, secrecy allows unscrupulous pharmaceutical companies to escape accountability and encourage further violations without adequate notice to the public.

[20] See Para 4.8.
[21] See Para 3.19 & 3.21.

26. **Therefore, we submit that the CDSCO must create a digital database to disseminate all enforcement actions (civil or criminal) at all levels of drugs regulation. In particular we request that the following documents be made proactively available online in a publically accessible searchable database in order to ensure that citizens are well informed of the working of the enforcement mechanism under the D & C Act:**

(a) Inspection Reports by Drug Inspectors
(b) Decisions on whether or not to grant sanction for prosecutions by the State Drug Controllers;
(c) The criminal complaints filed by Drug Inspectors before criminal courts;
(d) The judgments delivered by criminal courts in such cases.

VI. Enable Free and Open Access to the Indian Pharmacopoeia (IP)

27. One of the critical regulatory functions under the D&C Act is the setting of standards of drug quality which are required to be followed by all pharmaceutical manufacturers in India. Section 16 of the D&C Act read along with the Second Schedule to the legislation entrust this standard setting function to primarily the Indian Pharmacopeia Commission (IPC) (an autonomous body under the Ministry of Health) which publishes the Indian Pharmacopeia (IP). The IP contains monographs prescribing testing mechanisms for almost all drugs being sold in the Indian market. A drug manufacturer who fails to comply with standards of "identity, purity and strength" of the drug specified in IP, is criminally liable for manufacturing "not of standard quality" drugs and can be sentenced to prison.[22] In other words, the IP assures patients that the drugs sold in the market are safe and meet the requisite quality parameters. Thus, for all practical purposes the IP is "law" within India.

28. Despite the IP being law in the country, it is not freely available to the members of the public. The latest edition (8th) of IP standards, for instance, costs a whopping Rs. 52,500.[23] The IPC which publishes the IP has so far refused to make the IPC freely available and has instead been treating it as a cash-cow which is to be milked for profits despite the fact that the IPC receives significant subsidies from the Central Government to support its functioning. Simply put, the IPC is charging citizens to access the law.

[22] See Section 27.
[23] Product listing on the website of the IPC:
http://www.ipc.gov.in/shop/index.php?route=product/category&path=59

29. The Supreme Court has made it clear that while 'ignorance of the law' is no defense, the state is required to ensure that the law must be accessible to all citizens.[24] More recently, the CIC has reiterated that the government has a duty to make available the law to people.[25] In pertinent part, the CIC stated the following:

> "6. Needless to say that a duty upon the state to inform citizens about the Law as and when it was made and the citizens also have right to know of the Law. It is impossible for any Government to expect obedience to their Law without informing the people in legible form. It is more difficult especially when the text of Law is not available in easy accessible format. It will result in two major problems, (1) People will be kept in dark about their Laws, (2) Private Publishers will exploit this in-access to Law to make money by publishing updating Acts as their copyrighted work. It is surprising that the Ministry has not used the Information technology to provide access to text of law.
>
> 7. The law and enactments are in public domain and none can claim copyright in the law. Apart from this general right to know, RTI Act has offered a specific and enforceable right to information. Section 4 mandates the Ministry of Law to place the texts of enactments. It is the duty of Legislative Department to provide information about access of every updated enactment. It is not just an recommended obligation under Section 4(1)(a) of RTI Act, but a constitutional mandate, a legal necessity, and an essential requirement for peace. It is not possible to imagine 'enactment' becoming secret because of this ambiguity and non-legibility."

30. When this decision was appealed to the Delhi High Court, not only did the court uphold the ruling of the CIC but it also oversaw the entire process wherein the Law Ministry entirely refurbished the website (https://www.indiacode.nic.in/) to ensure the availability of the latest version of the law for free to all citizens. In the course of its ruling, the Delhi High Court held the following:[26]

> "The directions given by the CIC in the impugned order are not only fair and reasonable but also promote the concept of rule of law. It is unfortunate that the petitioner did not take the initiative on its own to upload the latest amended bare Acts.
>
> 5. Public can be expected to follow the law only if law is easily accessible 'at the click of a button'. In fact, as rightly pointed out by the CIC, the RTI Act itself mandates the Government to place the texts of enactments in public domain."

31. **We submit that since the IP is for all practical purposes the law of the land, it is incumbent on the IPC to make it publicly available on its website without charge because of the manner in which Section 4 of the RTI Act has been interpreted by the CIC and the Delhi High Court. The IPC must not forget that it was setup to improve public health and it receives funding**

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[24] Harla v. State of Rajasthan, [1952] SCR 110.
[25] Vansh Sharad Gupta v. PIO, Legislative Department, CIC/SS/C/2013/900008SA, Central Information Commission decided on November 4, 2015.
[26] W.P.(C) No. 4761/2016 (May 24, 2016), available at: indiankanoon.org/doc/123116384/(last accessed on July 20, 2020).

from Parliament to perform its function. It cannot be allowed to profiteer from the sale of the IP.

32. Please do let us know if you have any queries or doubts regarding the contents of this petition and we would be glad to clarify the same. We can be contacted at dinesh.thakur@gmail.com.

Best Regards,

Dinesh Thakur

Co-Signatories

1. Dr. Sanjay Nagral, MS, FACS, Senior Consultant & Director , Dept of Surgical Gastroenterology, Jaslok Hospital & Research Centre, Mumbai
2. Dr. K V Babu MD, Ophthalmologist, Payyanur Kerala
3. Dr. Anant Bhan, MBBS, MHSc, Past President, International Association of Bioethics, Bhopal
4. Dr. Aju Matthew, MD, MPhil, FACP, Ernakulam Medical Centre & MOSC Medical College, Kolenchery, Kerala
5. Dr. Soumitra Pathare, MD DPM MRCPsych PhD, Centre for Mental Health Law and Policy, Pune
6. Dr. Gopal Dabade MD, President, Drug Action Forum – Karnataka, Bangalore
7. Dr. Amar Jesani, MBBS, Independent Researcher and Teacher (Bioethics, Public Health), Founding Editor Indian Journal of Medical Ethics
8. Ms. Sandhya Srinivasan, Consulting Editor, Indian Journal of Medical Ethics
9. Dr. Yogesh Jain MD, Paediatrician, Jan Swasthya Sahyog, Bilaspur, Chhattisgarh
10. Ms. Anjali Bharadwaj, co-convenor of the National Campaign for People's Right to Information
11. Ms. Amrita Johri, RTI Activist, Sathark Nagrik Sangathan
12. Mr. Shailesh Gandhi, Former Chief Information Commissioner of India
13. Ms. Vinita Deshmukh, RTI Activist, Consulting Editor, Corporate Citizen