Citizens for Affordable,
Safe & Effective Medicine
CASEM

To:

October 24, 2021

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

Dear Dr. Mandaviya,

Sub: Regarding the Committee to draft a new Drugs, Cosmetics and Medical Devices Act

By way of introduction, I am a public health activist and the Founder of Citizens for Affordable, Safe & Effective Medicine (CASEM) which aims to be a collective of like-minded individuals working towards ensuring that the medicines supplied to India and other countries are affordable, safe and effective. I have formerly worked in the Indian pharmaceutical industry and was responsible for exposing the regulatory violations at Ranbaxy Laboratories after which the company was prosecuted and fined $500 million dollars by the United States Food and Drug Administration (USFDA).

Since the end of my whistle-blower lawsuit against Ranbaxy in 2013, I have been engaged in advocacy aimed at strengthening the drug regulatory framework in India. This includes multiple petitions and reports that I have submitted to your Ministry with various recommendations to improve drug regulation in India.

I am writing to you with specific reference to the committee recently constituted by the Ministry of Health to draft a new comprehensive law to regulate drugs, cosmetics and medical devices. This was a much-needed initiative and I am glad that the Ministry finally took this important step to replace the now antiquated Drugs & Cosmetics Act, 1940. I have also read in the newspapers that the Committee has been conducting pre-legislative consultations with stakeholders including consumer organisations although it is not clear how the committee is choosing the stakeholders with whom it is engaging. The committee has not published any public notice inviting interested members of the public to contribute to the process.

In any event, I would like to share with you a roadmap that I have prepared in this regard with the help of experts in the area of drug regulation. This roadmap is attached to this letter and I hope it can be shared with the committee for its perusal and action. Thank you!

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Sincerely,

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A roadmap for India's new drug regulatory law

A. Making transparency the bedrock of any new regulatory model

1. One of the biggest problems with the currently drug regulatory system in India is the complete opacity with which it is run by the concerned bureaucracy. There is hardly any publicly available information about the basis of new drug approvals, the results of inspections of manufacturing facilities, recalls or prosecutions of manufacturers for failing to meet quality standards. These are just a few examples. This needs to change. Transparency must become the bedrock of any new drug regulation law for the following three reasons:

   (a) The Right to Information is a fundamental right: The Supreme Court has interpreted the right to free speech and expression in Article 19(1)(a) to mean the fundamental right to information. This right has since been codified into the Right to Information Act, 2005 by Parliament. Despite the RTI Act requiring all public authorities to proactively disclose information to the public, the authorities responsible for administering the Drugs & Cosmetics Act rarely fulfill this requirement. Even basic information, such as the basis of approval of a new drug is not made available. Requests for information made under the RTI Act, asking about specific regulatory actions are regularly rejected by public authorities such as the Central Drugs Standard Control Organisation (CDSCO) on the grounds that disclosure of such information would hurt the competitive position of one or another pharmaceutical company and also that any such disclosure would be in violation of the fiduciary duty owed to the company by the regulator. Neither of these grounds are legally sustainable and any new law should make it clear that all information pertaining to the approval of a new drug or inspection or investigation of a pharmaceutical company is vital to public health and in the larger public interest must be proactively disclosed on the regulator's website.

   (b) Doctors and patients need to understand the scientific basis of new drug approvals: Currently, the only source of information about new drugs in India, for both doctors and patients are either expensive peer-reviewed journals or information sheets provided by salespersons from pharmaceutical companies. The lack of any information from the drug regulator, which is freely accessible for all doctors and patients is deeply problematic from a public health perspective. For doctors to make informed decisions on prescribing new drugs, they should be able to access all the information on the basis of which a drug regulator has made its decision to

approve a new drug. Similarly, patients should be able to access such records to make an informed decision on whether they should consume any particular medicine and what its adverse effects could be on patients.

(c) Procurement agencies need to verify quality record of suppliers: As of today, there is no single publicly accessible database in India that can be used by procurement agencies in both the public and private sector to verify the quality record of pharmaceutical companies before procuring medicines from such companies. This, despite the fact that regulatory agencies under the Drugs & Cosmetics Act have an extensive record of inspections reports, test reports and convictions of pharmaceutical companies. None of these records are made publicly available. As a result, many public procurement agencies, like the Indian Railways for example, conduct their own inspections of manufacturing facilities before ordering supplies from these companies. This duplication of efforts is a complete waste of public money. More efficient information sharing will make the entire public procurement process more efficient and safer.

B. The federalism issue – India needs a single regulator

2. One of the most debated issues about drug regulation in India is the distribution of regulatory powers between the central and state governments. Under the original Drugs Act, 1940 the central government was in charge of regulating imports while the provinces were responsible for regulating manufacturing and selling of drugs within their territories. Each province was allowed to make its own rules under the Drugs Act, 1940.

3. Post-independence, the rule making authority under the Drugs Act was centralized with the government of India, while manufacturing licensing powers were delegated to the states and enforcement powers were shared between the central and state governments. Over the years this arrangement has become even more complex with the central government's regulator exercising control over the manufacture of new drugs for the first 4 years of the drug's existence on the market, after which states can issue their own manufacturing licences for drugs that can then be sold across the country.

4. The above-described setup has led to complicated administrative problems. For example, if a drug inspector in Maharashtra detects a Not of Standard Quality (NSQ) drug manufactured by a facility licensed by the drug controller in Himachal Pradesh, the Maharashtrian drug inspector can at most file a criminal complaint against the manufacturer and wait for the criminal court to hear the case. In the meanwhile, the drug inspector from Maharashtra cannot conduct a

'raid' on the manufacturer's facility in Himachal Pradesh because of a lack of territorial jurisdiction or cancel its manufacturing license or stop the drugs manufactured by this facility from entering Maharashtra. Only the drug controller in Himachal Pradesh can 'raid' the manufacturer to seize evidence or cancel/suspend the manufacturing license.

5. The recent case from January, 2020 when 12 children from Jammu died after allegedly drinking adulterated cough syrup is an unfortunate example of how poor-coordination between different state drug controllers can lead to manufacturers with poor safety records to continue transacting business in India, despite being cited for manufacturing and selling adulterated drugs. The manufacturer of the allegedly adulterated cough syrup – Digital Vision – was reportedly found to have manufactured NSQ drugs on 19 different occasions by different state drug controllers prior to the tragedy in Jammu. Yet the drug controller in Himachal Pradesh reportedly did take any strong action against the company.[1]

6. Apart from this issue of one state being unable to stop the sale of drugs by a compromised manufacturing facility located in another state, is the fact that several state drug controllers have found to be engaged in blatantly illegal licensing of thousands of fixed-dose-combinations (FDCs) despite lacking the legal power to do so. In most of these cases the Ministry of Health has to invoke its extraordinary powers under Section 26A to prohibit these FDCs from the market. The state drug controllers have an incentive to engage in such blatantly illegally licensing because it is seen as a means to earn revenue through licensing fees as well as engage in corruption.

7. The backdrop to many of these problems is a competition between different state governments to attract investment from the pharmaceutical industry. While state governments are known to provide various kinds of incentives to the industry, while competing for their investment, it is unhealthy for state governments to go lax on the issue of regulation as a means to attract investment. Such a policy is disastrous from a public health perspective.

8. In 2003, a committee constituted by the Health Ministry and headed by Dr. Mashelkar recommended the centralization of all licensing powers with the central government.[2] No action was taken in this regard until 2013 when the

[1] Priyanka Pulla, 'How Weak Drug Laws Are Costing Lives' *mint* (28 September 2021) <https://www.livemint.com/politics/policy/how-weak-drug-laws-are-costing-lives-11632761831130.html> accessed 17 October 2021.
[2] Government of India, Ministry of Health and Family Welfare, *Report of The Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, including the problem of Spurious Drugs (Mashelkar Committee Report)* (No Z.28015/112/2002-D/DMS&PFA, 2003).

Government introduced the Drugs & Cosmetics (Amendment) Bill, 2013 centralising the licensing function. The bill was never debated or passed in Parliament. Thereafter in 2017, through a rule-change, the Government created a joint licensing rule for future manufacturing units wherein drug inspectors from the Central and State Governments will have to jointly inspect a facility before the issuance of a manufacturing licence.[3] It is not clear how these inspectors are supposed to reconcile any differences in opinion amongst themselves and who exactly will be responsible from an accountability perspective. A constitutionality challenge to this rule by the All India Drug Control Officers Confederation and the Pharmaceutical Manufacturer's Association of Tamil Nadu was dismissed by the Madras High Court on 28 February, 2020.[4]

9. In our opinion, the responsibility for licensing all manufacturing facilities should be concentrated in one central regulator rather than divided between central and state regulators. We believe there are four distinct advantages to this approach. *First*, a licensing authority controlled by the Government of India will end the 'race to the bottom' that we experience in the current setup where different state drug controllers compromise on quality control because of competing political pressures to attract investment from the pharmaceutical industry. *Second*, we believe that such a setup is in keeping with the federal scheme of the Indian Constitution wherein the regulation of inter-state commerce, as well as regulation of quality standards for inter-state commerce lies squarely on List 1 of Schedule VII (Entry 42 & 51). This means that Parliament can enact laws on these issues and vest licensing powers with a central drug licensing authority. *Third,* we believe such centralization of regulatory power will greatly increase co-ordination and information sharing with different drug inspectors thereby leading to far more efficient regulatory actions. *Fourth,* we strongly believe that such centralization of regulatory powers will make it far easier for citizens to demand accountability. The present situation wherein power is divided between the centre and states leads to an evasion of accountability where the states are busy blaming each other or the central regulator for different scandals.

10. If a proposal for creating a central regulator is accepted by the government, it is important that the manpower of existing state drug controllers be absorbed into the new central regulator because some states like Maharashtra, Karnataka and Tamil Nadu have very competent and experienced drug inspectors who can contribute towards building capacity of a new regulator. A concrete plan to

[3] Government of India, Ministry of Health and Family Welfare, *GSR 1337(E)* (Gazette of India Extraordinary, Part II – s 3(i), 27 October 2017).
[4] *All India Drugs Control Officers Confederation vs The Government of India* W.P. Nos. 33924 of 2017 (28 February 2020) <https://indiankanoon.org/doc/191958036/> accessed 17 October 2021.

absorb the existing manpower into a new centralised regulator will also hopefully weaken any opposition from existing state drug controllers to the issue of centralization.

C. Giving the Central Drug Standards Control Organisation (CDSCO) statutory status with a sustained source of financing

11. Over the last three decades, India has created several new regulators for different sectors of the economy. These statutory regulators include the Securities and Exchange Board of India (SEBI) to regulate the securities market, the Telecom Regulatory Authority of India (TRAI) to regulate the telecom market, the Food Safety and Standards Authority of India (FSSAI) to regulate food and the Competition Commission of India (CCI) to regulate competition. A common feature of these statutory regulators is their independent corporate character which gives them the power to manage their own finances, recruitment and exercise rule making power. Such autonomy is crucial for a regulator to operate efficiently.

12. In 2013, the Government of India had introduced in Parliament the Drugs & Cosmetics (Amendment) Bill, 2013 proposing to convert the CDSCO into a statutory body but the bill never translated into law.

13. As of now the CDSCO is dependent entirely on the Ministry of Health for its finances and recruitment. Similarly, the rule making power under the Drugs & Cosmetics Act, 1940 is exercised by the poorly equipped Drug Regulation Section of the Ministry of Health & Family Welfare although enforcement of such rules is left to the CDSCO. By giving the CDSCO a statutory character with an independent corporate identity and rule-making powers, it will be possible to create a nimble and efficient drug regulator that can respond rapidly to new challenges thrown up by the pharmaceutical industry and respond to issues of public health in the country.

14. Any new regulatory model should also factor in the financial aspect of running a complex regulatory framework. A model used in the United States is to charge the industry user fees which is then used to run the regulator. There are certain drawbacks to this model namely, the fear of 'regulatory capture' wherein the regulator ends up serving the industry's interest instead of consumer interests. An alternate model that could work in India would involve imposing a cess on the pharmaceutical industry specifically for the purpose of financing the regulator. Both financing models have their advantages and disadvantages and must be carefully evaluated before a decision is taken. In any case it is important

that this aspect be considered in advance so as to save any future regulator from the whims of arbitrary budgetary allocations.

D. Building the capacity of the CDSCO

15. As a regulator dealing with a highly specialized area of science that affects virtually every Indian, the CDSCO face an uphill task in ensuring that only the best of drugs are approved, manufactured and sold across India. The most urgent challenge in this regard, is in terms of human resources that are well qualified and well paid.

16. The issue of recruiting more drug inspectors and analysts has been raised by multiple Parliamentary Standing Committees and is a goal that can be met if adequate financial resources are provided for the purpose.[5] The more complicated issue is whether the law is prescribing the right kind of qualifications for personnel meant to staff India's drug regulators. In most developed countries, drug regulators are headed by doctors of medicine with specialized training in 'Public Health'. This is because drug regulation is seen as a component of a larger public health policy. The CDSCO however has been headed, mostly, by persons with degrees in pharmacology which is limited to understanding how chemical/biological formulation work. Some of the state regulators like in Telangana are headed by an officer from the Indian Police Service (IPS) cadre.[6] The Parliamentary Standing Committee on Health & Family Welfare flagged this issue in 2012 and asked the government to consider amending the rules to facilitate the appointment of doctors in medicine with MBBS degrees to the post of DCGI.[7] It is our recommendation that the position of the Drugs Controller of India needs to be filled with someone who has formal education in medicine and in public health i.e., a MD & MPH.

17. It also necessary to build capacity of the rank and file of a drug regulator. Recent advances in medical technology require regulators to have multi-disciplinary scientific teams. Future regulators will be approving not just new medicines but medical devices and software programs embedded within these devices. Many of these technologies will be of such complexity, that it will be difficult to hire talent for the public sector within the current recruitment framework. Recruitment regulations need to be flexible enough to hire expert consultants from the private sector or foreign countries, with adequate safeguards to avoid any

[5] Department Related Parliamentary Standing Committee on Health and Family Welfare, *The Functioning of The Central Drugs Standard Control Organisation (CDCSO)* (Fifty-Ninth Report) (RS 2012).
[6] DC Correspondent, 'No IAS or IPS Officer Head of Drug Control Administration' *Deccan Chronicle* (Hyderabad, 7 July 2014) <https://www.deccanchronicle.com/140707/nation-current-affairs/article/no-ias-or-ips-officer-head-drug-control-administration> accessed 17 October 2021.
[7] *The Functioning of The Central Drugs Standard Control Organisation (CDCSO)* (n 5) para 2.23, 3.6.

conflict of interest. The qualifications of the personnel staffing the regulator is of utmost importance to any new regulatory framework and must be given adequate attention.

E. Creating a scientifically rigorous and consultative procedure for approving "new drugs":

18. In its 59th report (2012), the Parliamentary Standing Committee on Health & Family Welfare raised very serious concerns about the manner in which the CDSCO was approving for sale in India, new drugs that had not been approved in any of the developed countries like the U.S. and E.U.[8] A subsequent internal inquiry by a committee appointed by the DCGI, revealed the true extent of the rot in the drug approval process.[9] While part of the problem may have been related to corruption, the core of the problem was the vesting of absolute discretion in the DCGI of the day, to approve or reject new drug applications in an environment of complete opacity.

19. Despite these findings by successive committees the government has not really reformed its internal processes. At most, the CDSCO created subject expert committees (SECs) consisting of external experts to provide recommendations to the DCGI on whether to approve a drug. This did reduce the discretion vested solely in the DCGI but failed to create a scientifically rigorous process. It is difficult to assess the functioning of the SECs since only a brief summary (usually less than 200 words) of their internal deliberations are released in the public domain.[10] From these brief summaries it appears that these SECs, surprisingly, almost never appear to have internal disagreements. This is true even when the SEC is deliberating highly controversial drug applications, including for therapies with poorly designed and controlled Phase III clinical studies. Further, the composition of the SECs at each hearing is also not always disclosed and there are no disclosures pertaining to any conflict of interest on part of the members of the SEC.[11]

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[8] *The Functioning of The Central Drugs Standard Control Organisation (CDCSO)* (n 1) para 7.
[9] Prabha Raghavan, 'CDSCO Faces CIC Ire over "Misplaced" 2013 Report on "Irregular" Approval to Drugs' *The Indian Express* (New Delhi, 2 June 2020) <https://indianexpress.com/article/business/cdsco-faces-cic-ire-after-2013-report-on-irregular-approval-to-drugs-goes-missing-6437906/> accessed 17 October 2021; Government of India, Ministry of Health and Family Welfare, *Report of Committee constituted to review the procedures & practices followed by CDSCO for granting approval and clinical trials on certain drugs* (Drugs Controller General of India, Ref: Order no DCG(I) Misc/2013-18, 26 March 2013).
[10] Central Drugs Standard Control Organization (CDSCO), 'Subject Expert Committees (SECs)' <https://cdsco.gov.in/opencms/opencms/en/Committees/SEC/> accessed 17 October 2021.
[11] R Prasad, 'Coronavirus | Government Releases Names of Vaccine Expert Panel' *The Hindu* (Chennai, 5 April 2021) <https://www.thehindu.com/news/national/coronavirus-government-releases-names-of-vaccine-expert-panel/article34246372.ece> accessed 17 October 2021.

20. In contrast to the Indian position, the American and European regulators release their internal 'scientific reviews' and 'impact assessments' for every new drug. In addition, when external experts are recruited for the purpose of giving their opinion on drug approvals, the discussions of these experts are available to the general public. Further raw and anonymized clinical trial data is also made publicly available.[12] The high levels of transparency in these jurisdictions ensures a certain degree of peer review by experts in the field thereby creating an incentive for the regulator to adopt the most rigorous of scientific standards. Domestically, public health activists and doctors have been asking for similar levels of transparency and any new regulatory model should keep these demands in mind.[13]

F. Revamping the regulatory framework for clinical trials

21. An important component of any drug regulatory framework is the regulation of clinical trials. Over the last decade, the functioning of clinical research organisations (CRO) and conduct of clinical trials by medical establishments have come under close scrutiny after a series of scandals. Both the Supreme Court and the Parliamentary Standing Committee for Health & Family Welfare have hauled up the Ministry of Health after various reports regarding the failure of CROs and hospitals to comply with basic medical ethics during the conduct of clinical trials. The most scandalous of these episodes took place in Madhya Pradesh where vaccines were apparently tested on underaged girls without the consent of their parents. A different kind of problem identified by only foreign regulators pertains to the lack of data integrity at Indian CROs. The most prominent example in this category is the scandal at GVK Bio which caused the cancellation of over 700 drug approvals. All too often, the results of trials and studies are fudged. A third problem that has made itself all too obvious in the recent past is the utter lack of scientific rigour in designing clinical trials. This became most obvious during the pandemic when a series of questionable clinical trials were approved by the DCGI.

22. All of these issues point to a problem with the regulatory framework for clinical trials in India. As per the current framework under the New Drugs and Clinical Trial Rules, 2019 the oversight of clinical trials is left mainly to the Ethics Committees of the hospitals or CROs conducting clinical trials. The key problem

[12] Meagan Weiland, 'Missing Clinical Trial Data Must Be Made Public, Federal Judge Says' (*Science*, 26 February 2020) <https://www.science.org/content/article/missing-clinical-trial-data-must-be-made-public-federal-judge-says> accessed 17 October 2021.
[13] Prabha Raghavan, 'Health Minister Petitioned: Medical Professionals Seek Transparency in Pharma Regulations' *The Indian Express* (New Delhi, 7 August 2020) <https://indianexpress.com/article/india/health-minister-petitioned-medical-professionals-seek-transparency-in-pharma-regulations-6543378//*> accessed 17 October 2021.

appears to be that the institution setting up the Ethics Committee has too much power over the members, thereby reducing their incentive to perform their role as an institutional watchdog.[14] The government exercises very limited oversight over clinical trials, almost limited to a rubber stamp role. For example, all clinical trials and ethics committees have to be registered and approved by the DCGI. In addition, details of the clinical trials have to be entered into the Clinical Trials Registry of India (CTRI) which is maintained by the Indian Council of Medical Research (ICMR). While there are no detailed studies on the workings of these institutions, anecdotal evidence suggests that the DCGI and ICMR do a relatively poor job in exercising oversight over the conduct of clinical trials and the CTRI.[15] For all practical purposes, hospitals and CROs appear to be 'self-regulating'. In such a scenario, it is of utmost importance that the highest levels of transparency are maintained in the conduct of clinical trials.[16] This means ensuring that the CTRI maintains accurate registration data while also forcing hospitals and CROs conducting clinical trials to proactively publish all such clinical trial data. Such transparency measures coupled with rigorous audits of clinical trial sites, can bolster confidence and trust in the quality of data generated at these clinical trial sites.[17] Before any such reforms are pushed through legislation, it is incumbent on government to commission an empirical study of the functioning of the existing institutions meant to regulate clinical trials.

G. Turning the regulatory focus to manufacturing processes, rather than drugs

23. As per the current scheme of Indian law, the focus of drug regulation is only on drugs sold in the market rather than the processes by which such drugs are manufactured. Drug inspectors usually purchase these drug samples and get them tested by government analysts. The sampling process is quite arbitrary and states do not appear to have any scientific protocols to conduct sampling. Further, the budgets allocated for purchase of such samples are paltry.[18] If a sampled drug fails a quality test, a notice may be sent to the manufacturer asking

[14] Shreya Dasgupta, 'Why Ethics Committees Are Key to Good Clinical Trials' *The Suno India Show* <https://www.sunoindia.in/the-suno-india-show/why-ethics-committees-are-key-to-good-clinical-trials/> accessed 18 October 2021.
[15] Shreya Dasgupta, 'A Good Registry Means Accountable Clinical Trials. But Does India Have One?' (*The Wire Science*, 7 September 2020) <https://science.thewire.in/the-sciences/covid-19-clinical-trial-registry-india-medical-research-accountability/> accessed 18 October 2021.
[16] Shreya Dasgupta, 'The Mystery of India's Missing Clinical Trial Results' (2020) 371 BMJ m4835.
[17] Shreya Dasgupta, 'India Needs More Transparency in Its COVID-19 Vaccine Trials, Critics Say' (*Science*, 25 November 2020) <https://www.science.org/content/article/india-needs-more-transparency-its-covid-19-vaccine-trials-critics-say> accessed 17 October 2021; Shreya Dasgupta, 'A Good Registry Means Accountable Clinical Trials. But Does India Have One?' (*The Wire Science*, 7 September 2020) <https://science.thewire.in/the-sciences/covid-19-clinical-trial-registry-india-medical-research-accountability/> accessed 17 October 2021.
[18] Swagata Yadavar, "Few Inspectors, No Records, Poor Communication Mar India's Drug Regulation" (*IndiaSpend*, 15 November 2019) <https://www.indiaspend.com/few-inspectors-no-records-poor-communication-mar-indias-drug-regulation/> accessed 18 October 2021.

for an explanation and in some cases an inspection of the manufacturing plant may ensue. In some cases, a criminal prosecution will be mounted on the basis of the failed sample.

24. The problem with such an arbitrary sampling approach is that it is likely to cover only a small number of manufacturers in the market and even then, this strategy covers only certain drugs produced by that manufacturer. A large number of manufacturers will simply escape any kind of scrutiny if their drugs are not caught in the sampling drag net. This is simply unacceptable for a country like ours. A new regulatory model must revolve around mandatory surprise inspections of all pharmaceutical manufacturing facilities on a bi-annual basis to monitor for Good Manufacturing Practices (GMPs) compliance. The focus of such inspections should be on cleanliness of facilities, proper batch-testing before and after release of drugs into the market, the maintenance of accurate manufacturing and testing records and efficient recall procedures. Furthermore, the skills and capabilities of people involved in the manufacturing process must be commensurate with the requirements of complex manufacturing practices for pharmaceutical products that are used today in clinical practice.

25. In order to affect this regulatory shift from products to processes, it is necessary to amend certain legal definitions. For example, the definition of sub-standard drugs in India is currently limited to drugs that do not comply with the prescribed standards laid down in the Indian Pharmacopeia. The definition of adulterated drugs is limited to those drugs in which foreign material is present. These definitions can be amended to include all drugs produced without complying with GMPs recognised under Indian laws. This is the position of law in countries like the United States, where drugs produced in a plant found to be in breach of GMPs are presumed to be adulterated, thereby incentivizing the manufacturer to ensure adherence to quality standards.

H. Rethinking criminal penalties as the standard tool of regulation:

26. When it comes to regulating quality of medicines being sold in India, the Drugs & Cosmetics Act, 1940 prescribes only criminal penalties for the sale of spurious, misbranded or not of standard quality drugs. While criminal penalties are definitely warranted in the case of spurious drugs, since it involves an element of criminality, it is not always warranted in cases of sub-standard drugs – where the drug fails to test against the reference standards set by the relevant Pharmacopeia) which are caused due to manufacturing errors or improper storage procedures.

27. In fact, there is anecdotal evidence to suggest that both, regulators and courts, are reluctant to enforce the criminal penalties in the Drugs & Cosmetics Act, 1940.[19] Indian regulators have adopted prosecution guidelines which significantly reduce the possibility of criminal prosecution in most cases involving sub-standard drugs, possibly because of a reluctance to send the directors/promoters of pharmaceutical companies to prison, the complexity of prosecuting such cases before Indian courts and the time that it takes to secure a verdict.[20] As a result, most cases involving sub-standard drugs are resolved through minor administrative penalties such as suspension of a manufacturing licenses for a day or a week by the regulator. The manner in which these suspension orders are enforced is unknown and we doubt the efficacy of such punishments. Even when cases cross the threshold set by the prosecution guidelines and are prosecuted, courts very often impose only a minor monetary fine (usually less than Rs. 1 lakh) along with a sentence of imprisonment till the rising of the court, which basically means that the management of the company is free to leave the courtroom once the judge rises for the day. In either case, the manufacturer is rarely adequately punished for profiting from the sale of sub-standard medicines. A criminal penalty is likely seen as a nuclear option by both the regulator and the courts and may be the reason that they are unwilling to use it unless the facts of the case are very grave. For example, in cases where adulterated drugs cause deaths, regulators have demonstrated the willingness to use criminal prosecutions as a tool.

28. In our opinion, the interests of public health would be better served if a new law provided regulators with the option to choose between existing criminal remedies or a new system of punishing monetary fines. The law should also have well-defined thresholds for criminal prosecutions. For example, if a drug sample is detected to be sub-standard during random sampling and on further inspection of the manufacturing facility, it turns out that the manufacturer has failed to comply with GMP standards, a criminal prosecution will be warranted. However, if the sample has failed testing, despite compliance with GMP standards then a monetary fine aimed at disgorging profits may be the more appropriate remedy.

29. Furthermore, detailed root-cause analysis, which are often lacking in the current prosecutions will lead to development of evidence which can be used effectively

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[19] Dinesh S Thakur and Prashant Reddy T, *A report on fixing India's broken drug regulatory framework* (4 June 2016) <https://spicyip.com/wp-content/uploads/2016/06/Report_India-Drug-Regulatory-Framework_June-2016.pdf> accessed 17 October 2021.

[20] Central Drugs Standard Control Organization, *GUIDELINES FOR TAKING ACTION ON SAMPLES OF DRUGS DECLARED SPURIOUS OR NOT OF STANDARD QUALITY IN THE LIGHT OF ENHANCED PENALTIES UNDER THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008* (2008) <https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Consumer_Section_PDFs/DCC_Guidelines_Spurious_Drugs.pdf> accessed 17 October 2021.

during prosecutions. A model that is used effectively in countries like the US progresses from inspection findings (Form 483) to Warning Letters and in rare cases, invoking their Application Integrity Policy and finally, Debarment.[21] These actions are graded and successively more serious and applied in a reasoned manner by the regulator. In comparison, the system we employ is like a blunt instrument that treats all violations the same. It is imperative that prosecutions need to be viewed from a point of view of protecting public health rather than punitive legal action against erring manufacturers.

I. Making it an offence to advertise or claim therapeutic uses of a drug without prior permission from the regulator

30. One of the most important aims of drug regulation anywhere in the world is to control the type of therapeutic claims that can be made by a pharmaceutical company on its labelling or in its advertisement. As of today, the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 regulates only certain type of advertisements which are obscene or targeted at specified list of diseases for which there is no known cure. If a disease does not fall within the latter list under this law, there is no prohibition against making unsubstantiated claims. This needs to change. No company should be allowed to make unsubstantiated therapeutic claims about drugs without first receiving approval from a drug regulator who has had an opportunity to verify such a claim based on the results of evidence generated through clinical trials. The Ministry of Health has already enacted such rules on December 21, 2018 specifically prohibiting advertisements of Ayurvedic, Siddha and Unani medicine without the prior permission of the Ministry.[22] Unfortunately, these rules have not been enforced because of pending litigation before the Delhi High Court. In any event, the Ministry must consider enacting similar measures for all drugs, not just Ayush drugs and it should ensure parliamentary backing for such a prohibition.

J. Overhauling the Indian Pharmacopeia Commission (IPC)

31. One of the key aspects of drug regulation is the formulation of legally binding standards. This includes preparation and publication of monographs for each new formulation, as well as the sale of reference standards. While the monographs contain detailed information on the methods of testing for each formulation, the reference standards are test quantities of various formulations

[21] Application Integrity Policy, USFDA *available at* https://www.fda.gov/media/71236/download; USFDA Disbarment Policy: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications
[22] Government of India, Ministry of AYUSH, *GSR 1230(E)* (Gazette of India Extraordinary, Part II – s 3(i), 21 December 2018).

which are used to measure the quality and purity of every batch before they are shipped to the market by a pharmaceutical manufacturer. The task for publishing monographs and manufacturing reference products is usually vested with an independent body in most countries. In some countries like the United States, the task of setting standards vests in private bodies like the United States Pharmacopeia (USP), while in countries like India this task is vested with the government controlled Indian Pharmacopeia Commission (IPC) which is headquartered in Ghaziabad.

32. The IPC is responsible for publishing the Indian Pharmacopeia, which contains monographs of various formulations and also selling reference standards to both the industry and the government laboratories that are responsible for testing samples picked up from the market by drug inspectors. While there have not been any detailed studies documenting the shortcomings of the IPC, we do know from anecdotal evidence that the IPC is not very efficient in ensuring the timely delivery of reference standards. These delays in supplying reference standards can cause delays in both manufacturing as well as testing by government laboratories, thereby causing inefficiencies for both the private sector and the regulators who need access to these standards for the purpose of testing market samples. More worryingly, there are concerns that the IPC does not update its monographs in a timely manner even for drugs that are central to treating India's disease burden. From our research we are aware that the IPC does not have monographs for the following drugs: antifungals such as Amphotericin B liposomal and voriconazole, the anti-helminthic drug ivermectin, and tuberculosis drugs such as pyrazinamide oral liquid, linezolid injection, moxifloxacin tablets and rifabutin liquid. You are no doubt aware of the importance of these drugs in our response to dealing with the Covid-19 pandemic. Such delays could mean that the latest testing methods are not used promptly in India and this could have adverse implications for public health in the long run.

33. If the government is in fact serious about improving drug quality in India, it must seriously focus its efforts on revamping the IPC. The government would be well advised to setup an external committee to review the functioning of the IPC with a view to improve its functioning.