Citizens for Affordable,
Safe & Effective Medicine
CASEM

March 17, 2020

To,

Mr. R. G. Singh,
Under Secretary (Drug Regulation),
Ministry of Health and Family Welfare,
Room No. 414A, D Wing, Nirman Bhawan,
New Delhi - 110011.

Ref: Public Notice dated February 3, 2020 regarding the proposed Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020 (F.No.A.11035/133/2014-DFQC/DRS)

Dear Mr. R. G. Singh,

1. I am writing to you in furtherance of the above-captioned subject matter. By way of introduction, I am a public health activist and the Founder of Citizens for Affordable, Safe & Effective Medicine (CASEM) which is a group of like-minded individuals working towards ensuring that medicines supplied to India and the world 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).[1] Since the end of my whistleblower lawsuit against Ranbaxy in 2013, I have been engaged in advocacy aimed at strengthening the drug regulatory framework in India. This includes a report that I submitted to the Ministry on measures to improve drug regulation in India[2], a petition to the Prime Minister's

[1] 'Ranbaxy pleads guilty, to pay $500 mln in settlement', *Reuters*, May 13, 2013.
[2] Dinesh Thakur & Prashant Reddy, 'A report on fixing India's broken drug regulatory framework' (June, 2016) *available here*: https://dineshthakur.com/wp-content/uploads/2016/06/CDSCO-Reform.pdf. Dinesh Thakur, 'India needs strict prosecution laws to fix drug regulatory system: Ranbaxy whistleblower Dinesh Thakur', *Economic Times,* June 24, 2016.

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Office[3] requesting a prohibition on certain harmful drugs, as well as an ongoing writ petition before the Delhi High Court[4] requesting directions to the Central Government to prohibit certain drugs that were red flagged by a Parliamentary Standing Committee on Health.

2. At the very outset, we would like to commend the Health Ministry for conducting this pre-legislative consultation on the proposed amendments to the draft Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020. While we are deeply appreciative of the Ministry's attempt to conduct pre-legislative consultations, we also implore upon the Ministry to make available the reports of the multiple sub-committees of the Drugs Consultative Committee (DCC) which were setup, as per the minutes of its 57th meeting, to study various issues related to advertisements of drugs and over-the-counter (OTC) drugs. The two sub-committees in question were headed by Dr. H. Mahapatra and another by Dr. N. K. Ahooja.[5] The Central Drug Standards Control Organisation (CDSCO) is not making available these reports despite requests under the RTI Act.[6] It is difficult for all stakeholders to contribute constructively to the Ministry's efforts to amend the law in the interest of public health unless the expert reports on the subject are made publicly available.

3. The issue of false and misleading advertisements has been of increasing concern over the last few years and there is no doubt that we need better regulation of

[3] Prabha Raghavan, 'Ranbaxy whistleblower petitions PMO to investigate 'illegal' drug approvals', *Economic Times*, May 21, 2018. The text of the petition can be accessed over here: https://dineshthakur.com/wp-content/uploads/2018/05/Petition-to-the-Prime-Minister.pdf
[4] Dinesh Thakur v. Union of India, W.P. No. 11107 of 2018.
[5] Minutes of the 57th Meeting of the Drugs Consultative Committee (DCC) held on August 20th, 2019. The sub-committee headed by Dr. Mahapatra was to examine the issue of advertisements from the perspective of the Drugs & Cosmetics Rules, 1945 and the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 while the sub-committee headed by Dr. N.K. Ahooja was looking at the definition of Over-The-Counter drugs. The minutes of the meeting can be accessed over here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=OTYz
[6] In response to RTI No. CDSCO/R/T/20/00029 filed with the CDSCO, the Public Information Officer declined to share copies of either reports.

advertisements for drugs and other products that advertise therapeutic benefit in India. One way of ensuring better regulation of such advertisements is to increase penalties under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (DMRA) as proposed by the Ministry. An alternative and more effective solution, in our opinion, is to replace this outdated legislation from 1954 with a new modern legislation that provides an **integrated policy** towards regulating different aspects of advertisements of drugs.

4. In this memorandum, we will explain the following four issues in order to make the case for replacing the DMRA, 1954 with a new law:
   A. The origins, evolution and failings of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
   B. The overlap between DMRA and Rule 106/Schedule J to the Drugs & Cosmetics Rules, 1945
   C. The overlap between DMRA and the Drugs & Cosmetics (Eleventh Amendment) Rules, 2018 regarding the prohibition of advertisements of Ayurvedic, Yoga, Siddha, Unnani or Homeopathy (AYUSH) drugs
   D. The inadequate legal framework for trade names, drug labeling and package inserts

A. The origins, evolution and failings of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

5. As originally enacted in 1954, the DMRA prohibited three specific types of advertisements. The first category of advertisements related to drugs that claimed to treat or prevent sexual disorders, menstrual disorders, conception in women, venereal diseases such as syphilis, gonorrhea etc. or any other disease

notified by the government under the Act.[7] The second category dealt with misleading advertisements relating to drugs which gave a false impression regarding the true character of a drug, made a false claim for the drug and otherwise made false or misleading assertion in any material particular.[8] The third category covered advertisements of "magic remedies" claiming to be directly or indirectly efficacious with regard to the conditions mentioned in the first type i.e., primarily venereal diseases or sexual disorders.[9]

6. From a reading of the Statement of Objects and Reasons[10] of the original DMRA, as well as the legislative debates in the Rajya Sabha, it is clear that the version of the law enacted in 1954 was inspired by three policy goals. The first goal was to discourage the publication, especially in newspapers, of advertisements that were "objectionable" in light of prevalent sexual mores in India.[11] This was more of a censorship measure than a means to protect public health. The second goal was to prevent misleading advertisements that made false or misleading claims in relation to any drug, irrespective of the category of disease that it was advertised to provide therapeutic benefit for. This prohibition was meant to protect public health. The third goal was to prohibit the advertisement of magic remedies for venereal diseases, sexual disorders. This was partly inspired by the same prudish policy goal of discouraging advertisements that were considered

[7] Section 3 of DMRA, 1954.
[8] Section 4 of DMRA, 1954.
[9] Section 5 of DMRA, 1954.
[10] "In recent years, there has been a great increase in the number of objectionable advertisements published in newspapers or magazines or otherwise relating to alleged cures for venereal diseases, sexual stimulants and alleged cures for diseases and conditions peculiar to women. These advertisements tend to cause the ignorant and the unwary to resort to self-medication with harmful drugs and appliances, or to resort to quacks who indulge in such advertisements for treatment which causes great harm. It is necessary in the public interest to put a stop to such undesirable advertisements. This Bill is intended for this purpose". Statement of Objects and Reasons, 12 August, 1953 – The Drugs and Magic Remedies (Objectionable Advertisements) Bill, 1953.
[11] The following are the opening remarks of the Minister of Health Rajkumari Amrit Kaur in the Rajya Sabha on February 16, 1954 while debating the DMRA before the vote: "I would just like to say a few words by way of introductory remarks. In recent years there has been a **great increase in the number of objectionable advertisements** relating to certain diseases and these advertisements border on the obscene—in fact they are obscene— and in addition they cause the ignorant and the unwary to resort to self-medication with very harmful drugs and appliances and even to resort to quacks who indulge in such advertisements and offer treatment which causes very great harm." (Emphasis supplied)

"objectionable". The more laudatory aspect though is the attempt to prevent superstitious and magical remedies in order to protect public health.

7. After Parliament enacted this bill into law, its constitutionality was challenged before the Supreme Court in the case of *Hamdard Dhawakhana (Wakf) Lal* v. *Union of India*[12] on several grounds. These included arguments that the Bill was an unconstitutional abridgement of the fundamental right to free speech under Article 19(1)(a) of the Constitution and also on the grounds that Parliament had excessively delegated powers to the government to prohibit drugs for certain diseases without laying down any particular discerning criteria. While the Supreme Court rejected the argument that the legislation was an unconstitutional abridgment of the fundamental right to free speech, since this right did not extend to commercial advertisements, it did strike down parts of Section 3 and Section 8 on the grounds that Parliament had excessively delegated powers to the government without outlining any parameters.

8. As a result of the Supreme Court's judgment in *Hamdard Dhawakhana* the government moved an amendment to the DMRA in 1963. The Drugs and Magic Remedies (Objectionable Advertisements) Amendment Act, 1963 adopted a slightly different approach towards regulating drug advertisements. It amended Section 3(d) to allow for the prohibition of advertisement of drugs for diseases for which it was accepted that there was no remedy or for diseases which required timely treatment in consultation with a registered medical practitioner. The amendment also required consultation with the Drugs Technical Advisory Board (DTAB) before prohibiting any drugs under this provision. The remaining prohibitions in Sections 3, 4 and 5 remained untouched.

[12] 1960 AIR 554

9. The original list of diseases notified, in 1963, under Section 3(d) in the Schedule accompanying the law included 54 named diseases covering everything from cancer to cataract to diabetes to heart disease to treating tumours to sterility in women and to venereal diseases. The list was expanded gradually over time and now includes 78 named diseases.

10. There is little published material available on the manner in which the DMRA has been enforced in India. From reported judgments of the High Courts and the Supreme Court, it appears that this legislation has been used to initiate actions against advertisements ranging from homeopathic drugs to even modern lens developed as treatment for cataract.[13] More recently, this legislation has been used to crack down on advertisements by private companies for a series of drugs, developed by government research labs and subsequently licensed to private manufacturers, who then advertised the sale of such drugs as a cure for diabetes and other diseases/disorders.[14]

11. In the recent past, the Government has given exemptions, under Section 15 of the law, for certain drugs, allowing for them to be advertised as remedies for diseases that are otherwise prohibited under the Act. This includes, an exemption for I-pill ® which was advertised as a birth control pill – a category that is prohibited under Section 3(a) ("prevention of conception in women") as well as for paracetamol as a remedy for fever – a category that is prohibited in the Schedule under Section 3(d). Such exemptions were given after consultation with the DTAB.[15]

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[13] Dr. Yash Pal Sahi v. Delhi Administration AIR 1964 SC 784; Amit Singh v. State MANU/DE/2191/2011.
[14] Sumaiya Shaikh, "Under the microscope: Questionable claims about Ayurvedic drugs for diabetes, malaria", *Scroll,* August 15, 2019 *available at* https://scroll.in/article/919424/how-manufacturers-of-ayurvedic-drugs-make-claims-backed-by-ayush-ministry; *Also see* Shyama Rajagopal, "Drug labeled as Ayurvedic 'diabetic cure' seized", *The Hindu*, October 7, 2016 *available at* http://www.thehindu.com/news/cities/Kochi/Drug-labelled-as-Ayurvedic-%E2%80%98diabetic-cure%E2%80%99-seized/article15474306.ece.
[15] Agenda No. 13, Minutes of the 60th meeting of the Drugs Technical Advisory Board held on October 10th, 2011 at New Delhi ("The drug is safe for use in young as well as elder women. It has no serious side effects even after multiple uses. However, it should be promoted as emergency contraceptive only and not as regular means of contraception.")

12. The problem with the aforementioned legislative design of the DMRA is that it is outdated, discriminatory, vague and perhaps even irrational. A few such examples illustrating this statement are provided below:
    (a) The legislation blatantly discriminates against women. For example Section 3 specifically prohibits advertisements targeting women , such as birth control methods, Entry 59 of the Schedule to DMRA is targeted against all female related diseases (in general). There appears to be no scientific or constitutional policy rationale for such exclusions targeting advertisements for only women's diseases.
    (b) Secondly, since the Schedule mentions specific diseases for which drugs cannot be advertised, it is most certainly an under-inclusive list that does not capture the entire range of diseases which are either not treatable or of the kind that should not be subject to self-medication by the patient.
    (c) Section 4 of the legislation is vague because it prohibits the publication of misleading advertisements that make false claims or are misleading or give a false impression regarding the true character of the drug. The provision however does not mention any specific standard against which the falsity can be adjudicated and established. In the absence of an objective standard, it is left to the discretion of the enforcement authority to apply the law thereby creating an unequal treatment of applications for exemptions under law. While such discretion maybe acceptable in the cases of other products, it is unacceptable in the realm of medicine.

13. Rather than continuing with the existing model wherein advertisements are based on the nature of the disease sought to be treated, the government would

available here: https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee; Agenda No. 11, Minutes of the 90th meeting of the Drugs Technical Advisory Board held on July 25, 2018 at New Delhi ("DTAB deliberated and agreed to the proposal for exemption under Section 15 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 to communicate "Fever" for creating public awareness on management of fever associated with common self-limiting conditions such as fever associated with Common Cold and Flu, Dengue, Chikungunya, fever associated with vaccination etc.") *available here:* https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee/.

be well-advised to consider a new regulatory model for advertisement of drugs based on the following parameters:

(a) Prohibit advertisements for **all** prescription drugs (Schedule H drugs), in all publications except for in medical journals, irrespective of the nature of the disease they are intended to treat because the rationale for mandating a doctor's prescription (Schedule H drugs) is that it is scientifically risky for patients to consume a certain category of drugs without adequate medical advice/supervision. There is no point of allowing these drugs to be advertised to the general population.;

(b) Allow the advertisement of over-the-counter (OTC) drugs that have been approved by the central licensing authority, preferably without allowing for the explicit advertisement of brand-names as such a policy would go against the government's decision to encourage doctors to write prescriptions with only the generic name of medicines rather than specific brand names. If the drug is safe enough to be purchased directly from a pharmacist, it should be legally permissible for the industry to directly advertise it to the general population. However given the concerns regarding unnecessary expenditure by these companies on advertisements and promotion, which in turn will lead to an increase in prices for consumers, it would be advisable to prohibit brand names from being advertised. Rather, these advertisements should be focused on the generic name of the drug along with its therapeutic benefits and side-effects. Such marketing (promotion and advertisement) could be sponsored either through a single pharmaceutical company or through a consortium of such companies which manufacture the generic drug in question.;

(c) Require certification of all drug advertisements making claims of therapeutic effect, by an independent panel of medical and scientific experts, that is constituted by the government, with broad representation and who publicly

disclose no affiliation to the manufacturer(s) of such products for whom these claims are made prior to the publication or broadcast of such advertisements;

(d) Penalize all drug advertisements that make claims of therapeutic efficacy that go beyond the indications that were approved by the licensing authorities while giving marketing approvals;

(e) Amend Section 4 on the lines of Section 24(2)(c) of the Food Safety and Standards Act, 2006 to place the burden of proof on drug manufacturers to produce scientific evidence to defend, in a court of law in case of prosecution, the claims they make on the labels of their products;

B. The overlap between DMRA and Rule 106/Schedule J to the Drugs & Cosmetics Rules, 1945

14. Rule 106 states that no drug may purport or claim to prevent or cure or convey any such idea that it may prevent or cure any of the 51 diseases or ailments specified in Schedule J. It appears that Rule 106 was amended in 1954, most likely to bring about some degree of coherence between the Drugs & Cosmetics Rules, 1945 and DMRA which was also enacted in 1954. It is not clear as to why Rule 106 was introduced into the law, when the DMRA serves exactly the same purpose. It is possible that Rule 106 was targeted at the labeling of drug packages since the Rule appears in Part IX of the Drugs & Cosmetics Rules which deals with "labeling and packing of drugs". The wording of the provision does not convey its intention very clearly. As per the minutes of the 57th meeting of the DCC, an expert sub-committee was setup under Dr. H. Mahapatra to study the overlap between Rule 106 and DMRA. Unfortunately, the recommendations of the committee have not yet been made public and the CDSCO had declined to share a copy of the report under the RTI Act.[16]

[16] CDSCO/R/T/20/00029.

C. The overlap between DMRA and the Drugs & Cosmetics (Eleventh Amendment) Rules, 2018 regarding the prohibition of advertisements of Ayurvedic, Yoga, Siddha, Unnani or Homeopathy (AYUSH) drugs

15. This set of amendments to the Drugs & Cosmetics Rules, 1945 by the Ministry of Ayush, in 2018, created a regulatory mechanism to specifically prohibit the advertisement of any AYUSH drugs for the use of diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, syndrome or condition. In other words, none of the AYUSH drugs can be advertised as having a therapeutic effect. This was a much required amendment, since the therapeutic efficacy of AYUSH drugs, unlike allopathic drugs, has not been established through the rigour of scientifically designed clinical trials. If at all these manufacturers want to advertise AYUSH drugs for any purpose, other than the uses for which they are specifically prohibited (diagnosis, cure, mitigation, treatment or prevention), they are required by the amended rules to submit an application to state licensing authorities for approval. These officers are required to check the advertisement and reject those displaying vulgarity or obscenity or those that give a false impression about the true character of the AYUSH drug or those that make misleading or exaggerated claims about the effectiveness of the drugs. A failure to follow this process can lead to a cancellation of the manufacturing license.

16. This framework brought in by the amendments in 2018, is substantially stricter than the DMRA. One of the reasons the government put in place these rules is because of the increasing number of complaints it received from the general public regarding misleading advertisements regarding AYUSH drugs. Even a parliamentary panel slammed the government for not doing more to regulate

these advertisements.[17] In pertinent part, the parliamentary report noted the following[18]:

> "3.23 The Committee is constrained to note the snail's pace of progress made in amending the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. Taking into account the fact that the lack of stringent regulatory provisions has allowed unscrupulous elements to dupe innocent people by making tall claims about providing cure to cancer, liver cirrhosis, kidney failure and other chronic diseases without scientific evidence, the Committee in its 75th Report concerning Ministry of AYUSH (the then Department of AYUSH) presented to Parliament on 9th December, 2013 had recommended that urgent measures be taken to amend the said Act. Almost four years have passed since then, but the amendment could not be finalized. The Committee, therefore, deprecates the Ministry of Health and Family Welfare in whose legislative domain the amendment to the said Act falls, for its inertia and indifference in the matter and would like the Ministry of AYUSH to convey this Committee's displeasure to the former. The Committee would also recommend that the necessary amendments be carried out expeditiously within a specified time-frame and the outcome intimated to the Committee."

17. Given the strict regulatory framework put in place by the amendments in 2018 it is not surprising that private companies are pushing back against these amendments in 2018 by way of lawsuits challenging the constitutionality of the

[17] "Parliamentary panel slams govt. over delay in framing law to regulate Ayush ads", *Hindustan Times*, March 17, 2018 *available here* https://www.hindustantimes.com/india-news/parliamentary-panel-slams-govt-over-delay-in-framing-law-to-regulate-ayush-ads/story-LISaYmGWJinacq3KCGfECM.html.

[18] The 105th Report of the Department Related Parliamentary Standing Committee on Health and Family Welfare, on "Action taken by the government on the recommendations/observations contained in the one hundredth one report on demands for grants 2017-18 (Demand No.5) of the Ministry of Ayush, December 20, 2017 *available here* http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/105.pdf.

amendments. There are at least two such lawsuits pending before the Delhi High Court.[19]

18. While the new regulatory framework for AYUSH drugs is most welcome, since there is a lack of clinical evidence to back the claims of therapeutic efficacy of most AYUSH drugs, these rules also contradict the existing legal framework under DMRA and may therefore cause significant legal confusion. Even the proposed amendments to DMRA, contemplate the need for the Central Government to take advice from the AYUSH Technical Advisory Board before making any amendments to the Schedule to DMRA. **But given the new regulatory framework put in place in 2018 for AYUSH drugs, it is obvious that AYUSH drugs cannot be advertised for any diseases. There is then no question of creating a negative list of diseases for which they cannot be advertised.** The Ministry would be well advised to seek a legal opinion from its law officers on this possible conflict of legislation.

D. The inadequate legal framework for trade names, drug labelling and package inserts

19. As mentioned earlier, the current legal framework to regulate drug advertisements is incoherent and fragmented. This is partly because the Ministry is currently looking at advertisements published in the media in isolation from other measures, such as trade names, labeling of drugs and package inserts. Together, these last three components form the most important information that is being conveyed to both patients and the medical community, ranging from pharmacists to medical doctors. Any policy regulating advertisements of pharmaceutical drugs should start with looking at trade names followed by the

[19] Association of Manufacturers of Ayurvedic Medicine v. Union of India & Anr. W.P. (C) 985 of 2019 before the High Court of Delhi & Reckitt Benckiser India Pvt. Ltd. v. Union of India & Anr. W.P. (C) 321 of 2019 before the High Court of Delhi. "HC protects Reckitt Benckiser against coercive steps on advertising its Ayurvedic drugs", *Economic Times* January 15, 2019 *available here* https://retail.economictimes.indiatimes.com/news/food-entertainment/personal-care-pet-supplies-liquor/hc-protects-reckitt-benckiser-against-coercive-steps-on-advertising-its-ayurvedic-drugs/67543607.

medical claims made on the labeling and packaging inserts. Unfortunately in India, the government is not looking at these issues with the aim of creating an integrated framework. As explained below, each component is being dealt with separately and it is in the best interests of the country to integrate these various components into a single law regulating drug advertisements.

(a) **Drugs & Cosmetics (Thirteenth Amendment) Rules, 2019 regarding trade names:** These rules brought in a new policy to regulate trade names of drugs. Trade names play a key role in any advertisements for drugs. There has however been a tendency in India, amongst pharmaceutical manufacturers to use same or similar names to sell drugs curing completely different and unrelated indications. Not only does this create confusion which is dangerous from a public health perspective, it also leads to a great deal of litigation between pharmaceutical companies on the issue of similar trademarks. In most jurisdictions, regulators have to approve the trade name of a drug since confusing drug names are seen as a threat to patients. The aforementioned amendments that were brought into place in 2019 should have put in place a similar mechanism in India. Instead, these amendments only require pharmaceutical companies to submit a self-certification that the trade names of their drugs are not similar enough to cause confusion or deception. It is dangerous to leave such an important decision to the pharmaceutical companies whose motives are largely pecuniary. Rather, Indian regulators should be vested with making a decision on whether the trade names are confusing from the perspective of the reasonable person, typically a patient in this case.

(b) **On the issue of labeling of drugs:** After the trade name of drugs, the most important information related to a drug can be founding on the label printed on drug packaging. With regard to the label printed on drug packaging, the

relevant law is Rule 96 of the Drugs & Cosmetics Rule. This rule requires the publication of basic information on the label of a drug such as name of the drug, batch number, manufacturing licensing number, expiry data of the potency of the drug etc. There appears to be a lack uniformity on the enforcement of such labeling requirements for drugs that lose their "new drug" status and which are subsequently regulated by state licensing authorities (and not the central licensing authority). At its 79th meeting, the DTAB did discuss the possibility of mandating state licensing authorities to require the publication of the same labeling information mandated by the DCGI.[20] It is not known at this time whether this decision has been implemented by the DCGI.

(c) On the issue of package inserts: Information related to indications that the drug cures, side-effects of the drug and other clinical information is not required to be printed on the labeling, most likely due to lack of space. Usually such information is required to be made available in a "package insert", which is a small printed piece of paper that is inserted into the drug packaging. These "package inserts" are especially important for more complex drugs, which have modes of administration other than oral delivery and also have potentially dangerous side-effects. While it is mandatory, in most countries, to have package inserts supplied along with the drugs, The law on package-inserts is very vague in India. As per Schedule D(II) to the Drugs and Cosmetics Rules, 1945 which covers imports of bulk drugs etc.,

[20] "DTAB deliberated the matter and agreed to the proposal. DCG (I) grants permission/approval for manufacture of new drug formulations in Form-46 subject to certain conditions which involve requirements of its classification as a Scheduled drug or any other specific requirement mentioned as condition of permission. However, after four years of approval of any new drug, the State Licensing Authorities grant licence to manufacture without putting any such conditions in respect of its sale and the drug may be available in the market as non prescription drug. Therefore, the Board recommended to empower DCG (I) for issuing drugs specific labelling requirements after completion of New Drug status at the end of four years from the date of approval and forward the information to the State Drug Controllers along with the specific labelling requirements which they may incorporate as condition of license so as to ensure that the drug is not sold as non schedule drug till such time it is included in the schedule H, H1 or X." Agenda No. 17 as per the Minutes of the 79th meeting of the DTAB held on May 16, 2018 at New Delhi *available over here* https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee.

package inserts containing specific information[21] must be submitted to the licensing authority for approval. For "new drugs" being approved by the central licensing authority under the erstwhile Rule 122-E, it is mandatory for the manufacturer to get approval for the "package insert" as per the requirements of Form 45; but there is no mention of the information that must be made available in the insert. More worryingly, there is no clarity on whether such package inserts are to mandatorily be made available along with the drug in its packaging to the retail customer. At the 79th meeting of DTAB held on May 16th, 2018 the DTAB did discuss a proposal for introduction of mandatory requirement of package insert for new drugs.[22] This suggests that it is currently not mandatory for Indian manufacturers to make package inserts available. Despite the non-existence of a mandatory requirement, there is anecdotal evidence that some companies do make available package inserts available for some of their drugs. However, the medical profession has often expressed a concern that the quality of information available in package inserts in India is incomplete and unsatisfactory.[23] The lack of adequate information for medical practitioners and patients does not bode well for the future of healthcare in India. It would be in the interests of public health for the Ministry to consider making package inserts mandatory for all generic drugs regardless of whether they are licensed by the central or state government.

[21] This includes therapeutic indication, contra-indication, special warnings, special precautions, interaction with other medicaments, if pregnancy and lactation is contra-indicated, effects of the drug on the ability to drive and use machines. The insert should also include pharmaceutical information such list of excipients, incompatibilities, shelf life, special precautions, instructions for use etc.

[22] "DTAB deliberated the matter and agreed to amend Drugs and Cosmetics Rules, 1945 for introduction of mandatory requirement of package insert for new drugs." Agenda No. 16 as per the Minutes of the 79th meeting of the DTAB held on May 16, 2018 at New Delhi *available over here* https://cdsco.gov.in/opencms/opencms/en/dcc-dtab-committee.

[23] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3879884/

FINAL RECOMMENATIONS

20. In light of the above discussion, we recommend that the Ministry takes a consolidated and holistic approach towards the issue of drug advertising by enacting a standalone law separate from the Drugs and Cosmetics Act, 1940 to regulate the issues of drug labeling, package inserts, advertisement of over-the-counter drugs, complete prohibition on advertisements for prescription drugs and AYUSH drugs making therapeutic claims and finally, false advertisements. Since there is little information available on the enforcement of existing laws such as DMRA, it is prudent to study the existing enforcement mechanisms and their effectiveness before finalizing any new enforcement structures. At the very least, it would appear that the central drug inspectors should be given the power to enforce such a law along with the state drug inspectors. Trickier issues such as the regulation of drug advertisements on the internet deserve deeper consideration by experts in the field. A study commissioned by the Ministry should go a long way in bringing some clarity to these issues and perhaps that should be the first step before amending the law. Lastly, any study that is commissioned by the Ministry, its deliberations and recommendations should be made available to the people of India to enable all stakeholders to understand why their government took the decisions it took post the recommendations and impact on their healthcare services.

21. I would like to thank you for this opportunity to contribute to this important discussion and I do hope my feedback is of some use to the Ministry. I can be contacted at dinesh.thakur@gmail.com.

Sincerely,

Dinesh Thakur

Memorandum drafted based on the advice of

Advocate Prashant Reddy T. B.A.LLB (NLSIU), LLM (Stanford)