To

Shri Narendra Modi, MP
Hon'ble Prime Minister of India
7 Lok Kalyan Marg, New Delhi 110011.

Subject: FRAMING OF A NEW LEGISLATIVE FRAMEWORK FOR REGULATION OF MEDICAL PRODUCTS AND COSMETICS TO REPLACE "THE DRUGS AND COSMETICS ACT, 1940"

Hon'ble Pradhan Mantri ji,

Greetings from Patient Safety & Access Initiative of India!

We take this opportunity to compliment the Government and you personally on completion of EIGHT years of exemplary stewardship of this great country. Envisioning all-round development of the cross-sections of society during ***Amrit Kal*** and bringing out a blueprint for realizing it have ignited the imagination of our countrymen who now believe that, amongst the comity of nations, we could soon occupy a place at the top. As a result, the country now aspires for a complete transformation through disruptive solutions rather than relying endlessly on incrementalism.

2. **Hon'ble Pradhan Mantri ji**, you might recollect that one of the pillars identified by the Government for scaling global heights as early as in 2014 was the pharmaceutical and medical devices sector. Admittedly, the initiatives such as the Production Linked Incentive Schemes and dedicated parks for pharmaceuticals and medical devices are important public policy innovations and these could, with further honing in consultation with stakeholders, go a long way in furthering the dream of "Make in India." The Indian Pharmaceutical industry which is labeled as "the Pharmacy to the World" and the allied healthcare sectors including AYUSH, could revolutionize the entire global healthcare delivery by imbibing confidence amongst the global healthcare providers, governments and regulators.

3. Notwithstanding the above, there are serious concerns from the perspective of patient safety and consumer welfare especially with regard to laws for regulation of the quality of medical products. Numerous communications from the Patient Safety & Access Initiative of India Foundation (PSAIF) including representations before several expert committees have, unfortunately, not delivered the desired results. Considering that the entire edifice dealing with the Indian pharmaceutical and medical devices industry needs urgent reforms to realize the goal set out in 2014, the Foundation decided to constitute a Committee comprising professionals of high integrity to address the pertinent issues and underscore the urgency for enacting a completely new legislative framework to enable India's eventual transition to the

Global leadership position in healthcare sector. The key areas that need to be addressed are encapsulated in the succeeding paragraphs.

4. It has been noted with concern that the major stumbling block in the journey of transitioning to global heights in the pharmaceuticals and medical devices sector, in the short run and, in the entire healthcare sector, in the long run, is the antiquated pre-independence legislative framework comprising the Drugs & Cosmetic Act and Rules thereunder which are of 1940 and 1945 vintage, respectively. The framework, which is, at best, a patchwork of innumerable amendments in the law and rules over decades, needs to be replaced by a forward-looking new legal arrangement. It has also been noted that the patient and consumer interests can only be guarded by a regulatory structure comprising qualified, capable and motivated manpower with specialization in relevant verticals which the present structures largely lack.

5. The existing law does not have provisions for regulating advertisements, Clinical Trials, Medical Devices, Public Testing Laboratories, Blood Centers, Exports, and emerging areas such as Stem Cell therapy, robot assisted treatments, on-line consultations, recall, online sale of over the counter (OTC) medicines, sale of prescription drugs, auditing of prescriptions, etc. Also, it does not provide for speedy and seamless periodic updates in the practices such as Good Manufacturing Practices (GMP), Good Pharmacy Practices (GPP) guidelines, Good Distribution Practices (GDP), Good Storage Practices (GSP), Good Laboratory Practices (GLP), Good Documentation and Record Practices (GDRP), Good Clinical Practices (GCP) and Good Regulatory Practices **(GRP),** etc. Technology needs to be leveraged to regulate online pharmacy and tracking and tracing of poor quality medical products in the supply chain to empower the citizens to differentiate between safe and unsafe products and services.

6. The areas that need unstinted focus include rectifying the provisions that are *inter se* contradictory and not in conformity with the global best practices; enhancing the expertise and skills of regulators in all relevant disciplines; acting on the recommendations of various committees set up from time to time; covering all medical products such as medical devices, diagnostics, vaccines, biologics, stem cells, regenerative medicine, AYUSH products, etc. and establishing a robust system for recall of medical products in the event of any suspicion of quality compromise.

7. In keeping with the philosophy of good governance, specific measures need to be taken to encourage compliance, introduce graded penalties in proportion to the gravity of the offence along with compounding of offences to reduce protracted legal proceedings. The **one nation, one law and one autonomous regulatory authority** working in close coordination with State authorities is an imperative that should wait no further.

8. The regulatory framework needs to take care of the supply and value chains; lay down manufacturing, distribution, dispensing, delivery, storage and disposal norms and mandate capacity/competency building for traditional as well as allopathic medicines, cosmetics, medical devices, diagnostics and vaccines. The required changes need to include manufacturing and trading; promoting and nurturing innovation without compromising the safety and quality of medical products. The national regulatory practices also need to align with the global best practices including the ICH guidelines.

9. It is the time that the new legislation establishes an accountable, transparent and robust citizen-friendly surveillance system to assure the quality and safety of medical products including those used in various programs of the Government. A well calibrated, structured and comprehensive pharmacovigilance programme and audit regime for prescriptions needs to be put in place without any further delay.

10. Encompassing the rich heritage of the country, AYUSH has, *inter alia*, the potential to galvanize medical tourism in the country, generate new employment opportunities and earn foreign exchange in addition to providing leadership in domiciliary treatment at affordable cost. For this, it was necessary that AYUSH products comply with the norms of standards for medical products, and clinical trials, etc. to imbibe the confidence amongst the global community about patient safety.

11. **Hon'ble Pradhan Mantri ji**, it needs to be recognized that laws cannot be framed without transparent and comprehensive consultations with all stakeholders. It is pertinent to note that on earlier occasions, the attempts made did not fructify in the light of differing views of stakeholders. We, therefore recommend that comprehensive consultations be undertaken by involving all stakeholders.

12. Time is of essence and we believe that any further delay in putting in place an appropriate legislative framework could be disastrous and therefore, we sincerely hope that the Government will take immediate steps for replacing the existing law viz. '**The Drugs and Cosmetics Act, 1940'**. The Foundation will, in the larger interest of patient safety and consumer welfare, be willing provide further specific inputs for reforming the existing archaic law and facilitate the change that has waited for 82 long years to happen. It will be a yeoman service to the humanity at large if the accessibility and affordability of made in India medical products of unquestionable quality with "**Zero Defect- Zero Deficiency**" could become the norm.

With great regards and best wishes,

Yours sincerely,

Copy to: (1) Shri ……., Minister of HFW,
(2) Principal to PM,
(3) Cabinet Secretary,
(4) CEO, NITI Ayog,
(5) Secretary, HFW,
(6) Secretary, Department of Pharmaceuticals,
(7) Secretary, Health Research and DG, ICMR
(8) Secretary, AYUSH