



PHASE 2

End of Project Report

Project Name: "Policy guidelines" for Reuse of Single Use Medical Devices"

Report Period: 1st May to 30th September 2025

Report Date: 13th October 2025

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END OF PROJECT REPORT

1. Phase 1

In Phase 1 of the project, Dakshama Health conducted a comprehensive assessment on the reuse of high-end single-use medical devices (SUDs) in India, aligning the analysis with global best practices. The activities included filing 10-RTIs to explore the current national regulatory environment, organizing 2-expert webinars to gather ethical and legal perspectives, collecting 5-patient testimonials to highlight gaps in transparency and consent, and engaging a wide range of stakeholders from government, healthcare, and advocacy sectors. Insights drawn from international case

The white paper developed through this effort highlighted significant regulatory gaps, low patient awareness, and the absence of standardized protocols for reprocessing. As part of our outreach, we received a formal response from the CDSCO Medical Device Division clarifying that licensed single-use devices cannot be reused and must be discarded after a single use. The rationale provided was that the safety, quality, and

studies—particularly from the USA, Japan, UK, and Australia—helped shape key recommendations, including the need for a phased regulatory framework, mandatory informed consent, and targeted patient education campaigns. Although the response from some stakeholders was limited, the work laid a solid foundation for evidence-based advocacy. It paved the way for Phase 2, which aims to build regulatory momentum and enhance stakeholder engagement.

performance standards—originally certified by the manufacturer—cannot be guaranteed upon reuse. We also engaged with the Quality and Patient Safety Secretariat at the Ministry of Health and Family Welfare (MoHFW), who appreciated the white paper and offered guidance for Phase 2 of the project.

2. Phase 2 (April-September 2025)

Deliverables

Month 1: April 2025

- Conducted stakeholder mapping and prepared the final version of the white paper, which was [published on the website](#) and officially announced.
- Disseminated the white paper and requested the appointment with 15 key stakeholders (**Appendix 1**)

Month 2: May 2025

- Dissemination expanded to 35 stakeholders, including members of the Standing Committee on Health (**Appendix 1**)
- Appointments were conducted with Mr Hitendra Sahu, Director of Medtech Policy, Mr Samuel V Panchuav, the Joint Director of NHA, and the Dr Avinash Sunthalia, Patient Safety Secretariat, MoHFW, Dr L Swasticharan, Addl.DDG & Director(EMR), DGHS, MoHFW.
- As part of the advocacy efforts, communication has been initiated with both the Standing Committee on Health and the Indian Medical Parliamentarians Forum (IMPF). The focus areas for engagement are distinct: A formal request is being made to the Standing Committee on Health to raise a Legislative Assembly Question (LAQ) during the upcoming Monsoon Session of Parliament. The drafted LAQ is provided below. In parallel, outreach to the IMPF is aimed at raising awareness and encouraging members to support dialogue and raise pertinent questions related to the safe reuse of single-use medical devices in both public and private healthcare settings.

Month 3&4: June and July 2025

- The white paper has been disseminated to 55 Stakeholders.
- White paper has also been shared on LinkedIn and other platforms
- White paper has been shared with Center for Legislative Research & Advocacy (CLRA) for appointments and with Indian medical parliamentarian's form (IMPF) and other elected representatives.
- Disseminated to Parliamentary Standing Committee (PSC)
- Draft of the framework for the guideline shared for the review.

Month 5&6: August & September 2025

- Disseminated to 77 stakeholders (Appendix 1)
- Appointment held with Shri Kirti Azad, Chairperson of the Committee on Chemicals and Fertilizers on 28th August 2025. During which a detailed discussion took place on policy gaps and the reuse of single-use devices. Shri Azad requested comprehensive information to support the drafting of a Private Member Bill, and all relevant documents along with the action-taken report have been shared with his PA. He further requested Dr. Ratna to present the findings as an expert witness before the Standing Committee in September. In this regard, a draft bill proposing amendments to the Clinical Establishment Act and the Drugs and Cosmetics Act is being prepared for submission by Shri Kirti Azad, in the forthcoming winter session of Parliament. The draft is being reviewed by experts for submission.
- Dr. Ratna has been invited to serve as an expert witness in the next committee meeting. The meeting initially planned for 26th September 2025 was postponed to 10th October 2025 due to the reconstitution of the committee. Following this, the first meeting will be held on 15th October 2025, during which the subjects for discussion will be selected through a lottery system by the Parliamentary Standing Committee.
- The White Paper and other documents related to the Reuse of Single-Use Medical Devices were shared with Dr. Ravi Kumar, Deputy Director General and Nodal Officer, National Council for Clinical Establishments. Following this, Dr. Ravi Kumar responded, requesting a short document outlining the proposed amendments for possible inclusion in the Clinical Establishments Act (CEA). He informed that a 20-member committee has already been constituted to review the CEA (not limited to reuse guidelines).
- Subsequently, a request was made for an in-person meeting on 10th October to discuss the draft framework in detail, present our work on the reuse of single-use medical devices, and seek guidance on the amendments to be incorporated into the Act, as well as to request the inclusion of the topic in the agenda of the upcoming committee meeting.

Appendix 1

Stakeholder Approach: For details, pls refer to the shared sheet: [List of Stakeholders](#)

S. No.	Name
1	Amit Agrawal
	Anil Kumar Singhal
3	Aurang Goel
4	Azad Kirti Jha
5	B. Padmaja
6	Bhaskar Katamneni
7	C.R. Khampa
8	Dr. (Smt.) Jyoti Mirdha
9	Dr. (Smt.) Kruparani Killi
10	Dr. Aditya Kapoor
11	Dr. Akshay Jain
12	Dr. Amar Singh
13	Dr. Anbumani Ramadoss
14	Dr. Anil Suchak
15	Dr. Aparna Singh
16	Dr. Arvind Kumar Sharma
17	Dr. Atul Goel
18	Dr. Atul Kotwal
19	Dr. Atul Mohan Kochhar
20	Dr. Dipes Kumar Mandal
21	Dr. Deepika Sharma
22	Dr. Dhiman Kahali
23	Dr. Honnamma
24	Dr. Hilde De Graeve
25	Dr. J.N. Srivastava
26	Dr. Karthikeyan
27	Dr. L. Swasticharan
28	Dr. L.S. Changsan
29	Dr. Mahesh Devnani
30	Dr. Manoj Jain
31	Dr. Manaswi Kumar
32	Dr. M. Srinivas
33	Dr. Nikhil Prakash
34	Dr. Nikhil Tandon
35	Dr. Pankaj Arora
36	Dr. Priyadarshani Galappatthy
37	Dr. Rajiv Bahl
38	Dr. Rajiv Singh Raghuvanshi

39	Dr. Radhakant Nayak
40	Dr. Rakesh Yadav
41	Dr. Sanjay Jaiswal
42	Dr. Sanjay Tyagi
43	Dr. Saritha Nair
45	Dr. Sevith Rao
46	Dr. Sishir Rao
47	Dr. Smrit Rana
48	Dr. Smt. Jayshreeben Patel
49	Dr. Sunita Sharma
50	Dr. Tarun Mandal
51	Dr. Vinod Jain
52	Dr. Yangchen Dolma
53	Hitendra Sahu
54	Lakshmanan S.
55	Mr. Samuel Pachuaau
56	Ms. Sai Rekha
57	Ms. Vimmy Arora
58	P.K. Arora
59	P. Parthiban
60	Prof. Dr. Anup Kumar
61	Prof. Aditya Kapoor
62	Punya Salila Srivastava
63	Rajiv Wadhawan
64	Ram Gopal Yadav
65	Ravindra Pratap Singh
66	Roli Singh
67	Sh. Assem Sahu
68	Sh. Rajendra Singh
69	Shri Amar Singh
70	Shri Balbir Punj
71	Shri Datta Raghobaji
72	Shri Janardan Dwivedi
73	Shri J.M. Aaroon Rasheed
74	Shri Kirstappa Nimmala
75	Shri Kristappa Nimmala
76	Shri M.K. Raghavan
77	Shri Nilotpol Bal