

Toward Mercury-Free Medical Devices

TRANSFORMING INDIA'S PRODUCTION AND CONSUMPTION OF THERMOMETERS AND SPHYGMOMANOMETERS

Final Report



Supported By



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Dome Hall, Ambassador Hotel, New Delhi

A Business Roundtable Discussion Organized by Toxics Link, Health Care Without Harm and the World Health Organization

I. Why Business Roundtable Meeting?

Toxics Link and Health Care without harm has organized Business Roundtable on developing a mercury-free medical device industry in India on 4th December 2008 at Ambassador Hotel. The event is co-hosted by Toxics Link and HCWH with support from World Health Organisation (WHO). The Roundtable in its discussion explored the options that how India could become a production center of environmentally sound, accurate, affordable digital thermometers, as well as digital and aneroid blood pressure devices.

The business roundtable meeting also a to catalyze the creation of forum for medical device manufacturers that produce mercury-based devices and their alternatives, as well as manufacturers associations for participation in dialogue regarding the transition to mercury-free health care.

One of the important components of the business round table meeting is to discuss how mercury-free medical device production and supply could synergies with growing demand in India for these alternatives. This shift in demand is occurring in light of steady increase in public level of awareness on hazards of mercury. It also comes from the initial steps taken by Indian health care sector at the hospital and policy levels to switch to alternatives.

The meeting also looked in to the question of how production in India could tap into the changing world market where international demand is quickly shifting away from mercury, this includes a ban on mercury thermometers in the EU, the rapid movement away from mercury-based devices in the US, and significant shifts in Latin America and South East Asian countries.

The business round table initiated with the opening remarks of Director of Toxics Link Ravi Agarwal. He mentioned that all societies are faced with the challenge of providing quality affordable health care to its mass population. But over a period of time we have become increasingly concerned about the relationship between human health and environmental contamination or degradation by usage of metals like mercury in very basic clinical devices like thermometer and sphygmomanometer that jeopardizes the health care professionals and patients alike.

Studies indicate that the health care sector is the main source of global mercury demand and emissions. It is also a source of low-level, chronic and acute mercury poisoning. Mercury contamination and exposure can happen regularly through breakage of thermometers, spill, incineration and lack of mercury waste management protocols.

Mercury causes a number of adverse health impacts. These include life threatening lung damage, serious ailments of kidney, nervous, digestive, and respiratory and immune systems. What is frightening is that most hospitals, especially in developing countries, have no safety or clean-up protocols. Mercury waste is dumped, flushed or burnt thus adding to the global load of mercury.

Gary Cohen, Executive Director and founder member of HCWH, emphasized on the change in thinking and the way health care Industry should shape to become more and more

environmental friendly. He presented on how greening of health care is an emerging area of business opportunity globally. And replacing mercury based measuring devices and production of non-mercury alternative is one of the key emerging business possibilities amongst many.

I. a. WHO-Mercury Policy

WHO mercury policy is a significant step towards making health care mercury free put a strong case for the shift towards non mercury alternatives in the health care sector. Dr A.K Sengupta of WHO-India elucidates the significance of this policy. His presentation described the importance of policy in context of severe health hazards caused by use and subsequent release of mercury and the population groups who are at risk. Mercury from health care industry is released through various sources. Which includes Medical waste incineration, open burning, burning in barrels, gasification, pyrolysis etc, and it is present in various devices and products such as Thermometers, Sphygmomanometers, Dental amalgam, Gastrointestinal tubes, Laboratory chemicals, Pharmaceutical products, Electrical appliances. Because of these uses it is also a serious occupational hazard. Around the world a significant number of health care workers has poor risk perception on mercury hazard. This low risk perception coupled with high spill rates and in-house calibration is a significant risk to health care givers. Large numbers of health care facilities are using mercury-containing devices with no accident/incident reporting mechanisms and proper protection measures.

Realizing this WHO has developed a Policy on mercury in Health Care. The policy described strategies in short, medium and long term. These strategies clearly lay path for addressing the issue of mercury on immediate basis to ultimate phase out (Annexure WHO Mercury Policy). WHO has taken significant steps towards adopting these strategies through various platforms that includes World Health Assembly; it's regional and country offices and also providing support and by participating in various conferences organized nationally and globally.

At present range of alternatives are available for almost all the mercury containing health care products ranging from dental amalgams, thermometer, Sphygmomanometers, Esophageal devices, Gastrointestinal tubes etc. It is important to have increased awareness especially amongst population at risk as well as to create various platforms, development of road map and labeling of mercury free products are some measures to achieve these objectives.

I. b. Partnership for Phase Out of Mercury Containing Devices from Health Care Industry

A significant global development to address the issue of mercury in health care is the HCWH and WHO partnership to substitute mercury based medical devices around the world. Presenting the partnership between WHO and HCWH Dr. Alex Hildebrand, Regional Advisor, WHO-SEARO mentioned that the Business Plan of the Mercury Containing Products Partnership Area, calls for "By 2017, to phase out the demand for mercury-containing fever thermometers and sphygmomanometers by at least 70% and to shift the production of all mercury-containing fever thermometers and sphygmomanometers to accurate, affordable, and safer non-mercury alternatives."

The background to this partnership emerged from following key global actions -

1. Initiative based on the 2005 WHO Policy Paper which calls for short, medium and long-term steps to achieve the gradual substitution of mercury-based medical devices.
2. Health Care Without Harm's over ten years of experience working with national governments in North America, Europe, Asia, Africa and Latin America to achieve mercury substitution in health care sector.
3. UNEP Mercury Products Partnership, to eliminate mercury in products such as batteries, lighting and lamps, electrical and electronic devices, dental products, and measuring and control devices.

He further mentioned five strategies of partnership to achieve above-mentioned objective.

1. Establish an international mechanism to certify the accuracy and efficacy of mercury-free alternative medical devices.
2. Continue to expand awareness raising and mobilization of the health care sector in all countries, including actors involved in health care emergency responses, in order to shift demand towards alternative devices and educate societies as to the broader impacts of mercury.
3. Support the development of model policies and catalytic activities that leverage resources to shift demand at global, regional, national, state and municipal levels.
4. Define safe elimination strategies for existing mercury equipment. Develop and implement interim and long-term mercury waste management plans at the health care sector, national and regional levels.
5. Support the establishment and/or adequate expansion of production facilities for mercury-free fever thermometers and other medical devices in developing countries with an emphasis on encouraging substantial production in China and/or India.

The partnership also defines short-term objectives for implementation of these strategies. These objectives are:

1. Identify and/or establish international standards for mercury-free alternative medical devices.
2. Establish and implement national policies to phase-out mercury-based medical devices minimally in one country each in Asia, Africa, and Latin America.
3. Achieve the phase-out of mercury sphygmomanometers in the European Union.
4. Replicate the municipal policies of Buenos Aires and New Delhi in 3 other developing country mega cities.
5. Establish the commitment to, or activities designed to, phase out mercury-based medical devices in 1,000 hospitals in Asia, Africa, the Americas
6. Establish demonstration pilots in 10 new countries.
7. Develop and globally distribute a training module focused on substituting mercury-based medical devices; conduct additional outreach and educational activities.
8. Establish with the Basel Convention Secretariat, model national health care mercury waste management project and promote their replication.

9. Develop a plan of action to establish and fund the development of production facilities for high quality, affordable mercury-free medical devices in developing countries.
10. Assess progress after two years, refine medium term objectives and develop activities for years 4-6.

The partnership will be co-led by Health Care Without Harm and the World Health Organization. Responsible parties will be for HCWH. This partnership is open to any institution working towards or providing resources for mercury elimination in the health care sector.

II. THE GLOBAL SHIFT TOWARD MERCURY FREE HEALTH CARE

The Business Roundtable is organized to provide a way forward to measuring device manufacturers in India and internationally on how to develop a sound business strategy for developing an affordable, high quality product supply for the transition to mercury-free health care with in the India and outside. The key for this shift is creation of financial and political support the development of such an industry.

Shifting Demand: The Global Transition Toward Mercury Free Health Care

Presenting on the global movement towards making health care mercury free, Joshua Karliner of HCWH emphasized that HCWH is working globally along with its partners on three basic objectives:

1. Phase mercury out of the health care industry, globally.
2. Replace mercury in health care with viable, cost-effective alternatives and safely dispose of mercury as it is phased out of the health care system.

Contribute to broader coalition, governmental and inter-governmental efforts to eliminate environmental contamination from mercury.

With these objectives this global coalition has achieved a significant results all across the world Such as US Market has seen significant change due to its efforts in convinced all the top pharmacy chains in the nation to stop selling mercury thermometers. Passed mercury thermometer bans or severe restrictions in 28 states. Presently, One-third of the US population is covered by sphygmomanometer bans or restrictions.

Similar initiatives were taken up in Europe where many countries have banned mercury based equipments especially Thermometre. And countries like Sweden denmark and Netherlands had almost eliminated mercury from health care sector.

He also stressed on the significant steps taken in the global south and made special mention of Philipines, Latin America and India. He stressed that the reasons for these shift is because of efforts in education, market development and demonstration on the ground and also significant policy initiatives, which brought in regulatory framework.

He ended his talk by mentioning that the writing is on the wall mercury-based medical devices are the dinosaurs of temperature and blood pressure measurement. Whole world is moving towards mercury free practices. Sooner or later these instruments are going to be history. It is important for manufacturers and business houses to know who will capture the markets? At present China is leading in producing digital equipments, but there is room for competition. There are significant concerns which is vital for the discussion here are:

1. **Accuracy:** Establish standards.
2. **Affordability:** Reach economies of scale and create regulatory environment to make alternatives affordable.
3. **Availability:** Create investment climate so that alternatives will become readily available domestically in India and globally exported

Accuracy and Precision of Alternative Devices in the Health Care Sector

Presenting on the issue of accuracy Dr. Peter Orris, talked about availability of various alternatives of products used in medical sector and issue of cost and accuracy.

He mentioned that “the gold standard for clinical blood pressure measurement has always been readings taken by a trained health care provider using a mercury sphygmomanometer and the Korotkoff sound technique, but there is increasing evidence that this procedure may lead to the misclassification of large numbers of individuals as hypertensive and also to a failure to diagnose blood pressure that may be normal in the clinic setting but elevated at other times in some individuals.”

Presenting the findings of Swedish study he mentioned “since 1992 thermometers and other measuring instruments containing mercury may not be commercially manufactured or sold in Sweden. All heads of department of clinical physiology in Swedish hospitals were contacted and asked to report their experiences from the phase out of mercury in blood pressure equipment. IT is found that there is no problem in diagnosing any condition. Quoting another study on aneroid BP apparatus he said that Aneroid Sphygmomanometer provide accurate pressure measurement when a proper maintenance protocol is maintained.

A study in Brazil on digital, mercury and aneroid blood pressure measurements carried out in 400 South American adults. It was found that there was slight under-reading of the aneroid instrument (hypertension prevalence 30%, compared with 32% for digital and mercury). The study concludes that Aneroid’s robustness and simplicity makes it a suitable alternative to mercury machines in tropical field conditions.

The recommendations of American Heart Association mentioned that:

1. Aneroid devices are suitable, but they require frequent calibration.
2. Hybrid devices that use electronic transducers instead of mercury have promise.
3. The oscillometric method can be used for office measurement,
4. Only devices independently validated according to standard protocols should be used, and individual calibration is recommended.

Dr Orris reemphasized the statement of World Medical Association

Explore eliminating mercury containing products in their offices and clinical practices,

And

Encourage local hospitals and medical facilities to phase out mercury containing products and switch to non mercury equivalents.

Market Situation

Market research studies have come up with eye-openers.

Under individual user categorization survey it is found that:

- **95 %** end-users do not know about the ill effects of mercury.
- Out of **5%** who know the ill effects , **70 %** are fence-sitters.

In a survey of doctors who are considered to be the influencers it is found that:

- A shocking **10 %** do not know the ill effects of mercury.
- Out of **90 %** who know , the percentage of fence-sitter is **50 %**.

The business round table in addressing questions about fostering investment opportunities and developing a road map towards mercury-free medical device manufacturing the main points decided were:

- Creation of awareness about the negative impacts of mercury in health care
- Creation of demand for non mercury devices to take benefits of economies of scale to bring down cost and thus make them affordable to individual end-users
- Information dissemination, best practice sharing, knowledge, experience and expertise sharing
- Capacity building
- Integration of efforts of all major stake-holders including governments culminating in a pull and push mechanism
- Strong regulation and penalty like import tariff as a deterrent mechanism
- Peer to peer education

Mercury-free world is certainly possible though the strategies need to be framed and implemented in a phase out manner.

List of participants
'Business Round Table On Promoting Alternatives of Mercury in Health Sectors'
On 4, Dec. 2008 at Hotel Taj Ambassador, Delhi

1. Dr. Kathleen Mc Keehan
Himalayan Institute Hospital Trust
Jolly Grant, Dehradun,
Uttaranchal 248140
Ph. No. 0135-2471321, 2471133
E-mail: k_mckeehan@yahoo.com

2. Dr. Neeraj Gupta
COEH
Centre for Occ. & Env-Health
MAMC, New Delhi
Ph. No. 09871052930
E-mail: guptadrneeraj@yahoo.com

3. Mr. Sasanka Dev
Gen. Secretary
DISHA
20/4, Sil Lane Kolkata 700015
Ph. No. 09433941940
E-mail: sasankadev@gmail.com

4. Dr. J. N. Srivastava
ISHWM & HOS MAC India Pvt. Ltd.
C-503, K. M. Apartment,
Plt-12, Sector-12, Dwarka, Delhi
Ph. No. 09871212528
E-mail: jnsrivastava@hotmail.com

5. Mr. Ashutosh Mittal
Importer
Shri Jai Durge Import Pvt. Ltd.
204/20, 2nd Floor, Ansari Nagar
Darya Ganj, New Delhi
Ph. No. 09811199551
E-mail: sjdil@vsnl.com

6. Dr. Peter Orris
GPIO Senior Advisor
University of Illinois at Chicago
8355, Walcott ST Chicago
IL 60612, U. S. A.
Ph. No. 312-413-0105
E-mail: porris@uic.edu

7. Mr. Gary Cohen
HCWH US
41, Oakview Terrace,
Jamaica Plan, MA 02130
Ph. No. 617-524-6018
E-mail: gcohen@igc.org

8. Mr. Jamie Harvie
HCWH US
Sustainable Health
Ph. No. 218-525-7806
E-mail: harvie@isfuso.org

9. Mr. Josh Karliner
HCWH
Ph. No. 415-752-1658
E-mail: josh@hcwh.org

10. Ms. Faye Ferrer
HCWH, SE Asia
Philippines
E-mail: faye@hcwh.org

11. Mr. Pradeep Mittal
Importer
Shri Jai Durge Import Pvt. Ltd.
204/20, 2nd Floor, Ansari Nagar
Darya Ganj, New Delhi
Ph. No. 09810165091
E-mail: sjdil@vsnl.com

12. Mrs. Priya Ghosh
U. S. Embassy
1, Shantipath New Delhi
Ph. No. 011-24198715
E-mail: ghoshp@state.gov

13. Mr. Mathew Sandelands
First Secretary
U. S. Embassy
1, Shantipath New Delhi
Ph. No. 011-24198000
E-mail: sandelandsm@state.gov

14. Dr. Megha Rathi
GEF
E-38, 1st Floor, Panchsheel Park
New Delhi 110017
Ph. No. 09818102661
E-mail: rathi.megha@gmail.com

15. Dr. Ann Mathews
Paediatrics Department
St. Stephens Hospital
Near Tis Hazari, New Delhi
Ph. No. 23966021 / 6, 09871706224

16. Dr. A. K. Sengupta
WHO-India Country Office
537 A Wing, Nirman Bhawan,
Maulana Azad Road,
New Delhi-110011
Ph. No. 09818716586
E: mail: senguptaak@searo.who.int

17. Mr. Himanshu Pradhan
WHO-India Country Office
537 A Wing, Nirman Bhawan,
Maulana Azad Road,
New Delhi-110011
Ph. No. 09818286922
E: mail: pradhanhs@searo.who.int

18. Mr. Alex Von Hilderbrand
WHO-SEARO
WHO Regional Office
Ring Road, New Delhi
E-mail: hilderbranda@searo.who.int

19. Mr. Anuj Munjal
Market Insight Consultant
A-72, Sector-34, Noida
Ph. No. 09899200507
E-mail: monuj@marketins.com

20. Ms. Shobha Mishra
Joint Director
FICCI
Ph. No. 011-23722921, 23557253
23738760-70 ext.468/513
E-mail: shobha.mishra@ficci.com,
healthservices@ficci.com

21. Dr. Swetha Krishnamurthi
Max Hospital
A-8, Gulmohar Park, New Delhi-110049
Ph. No. 09999759584
E-mail: k_swethand@yahoo.com

22. Mr. Rahul Jain
Market Insight Consultant
A-72, Sector-34, Noida

23. Dr. A. K. Aggarwal
Professor
School of Health & Science
Indira Gandhi National Open University
(IGNOU), Maidan Garhi,
New Delhi-110068
Ph. No. 9810423788

24. Mr. Sanjay Nagi
Market Insight Consultant
A-72, Sector-34, Noida
Ph. No. 9810081693
E-mail: sanjayi@marketins.com

25. Ms. Ruma Tavorath
World Bank
70, Lodhi Estate, New Delhi
E-mail: rtavorath@worldbank.org

26. Mr. Rob Donkers
World Bank
70, Lodhi Estate, New Delhi
E-mail: rtavorath@worldbank.org

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WORLD HEALTH ORGANISATION

**Workshop for promoting Alternatives to Mercury in
Healthcare Catalyzing Policy, Markets & Reducing
Risk, New Delhi (Partial Support)**

Budget		Approved	Actual
Item No.	Expenditure Head	Budget	Expenditure
1	Personnel	5,000	
2	Per Diem		
a	Local Participants-60 persons	48,000	329,062
b	Non - Local Participants- 45 persons	135,000	
3	Meeting & Training		
a	Venue Hiring	60,000	24,000
b	Materials & Stationery	37,500	11,800
c	Refreshments-120 persons	60,000	196,906
4	Transportation	269,000	87,578
5	Office Running Costs (small supplies & stationery)	5,000	154
6	Production, Printing of Final Conference Report	20,000	-
7	Miscellaneous	10,000	-
8	Others (specify)		
TOTAL		649,500	649,500

This is to Certify that expenditure have been incurred in accordance with the purpose for which funding was provided for and approved budget

Signature