

DON'T TRADE AWAY OUR LIVES!

Dr. Manmohan Singh
Hon'ble Prime Minister of India
The Prime Minister's Office
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New Delhi, September 28, 2010

**Re: India's central role in medicines supply is under threat
Don't sign on to intellectual property provisions in the India-EU FTA**

Dear Prime Minister,

We are writing on behalf of patient groups, people living with HIV (PLHIV) networks, HIV & public health organisations, medical organisations, public interest groups and individuals, to express our concerns before the next round of negotiations on the EU-India bilateral free trade and investment agreement (FTA), which is to be signed before the end of 2010.

India plays a key role in producing, registering and supplying essential medicines – not only for Indian patients, but to all developing countries.

A study published recently in the International AIDS Society Journal – **“A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries,”** highlights the central role that India's generic production plays in AIDS treatment and concludes that about four million people started treatment between 2003 and 2008, largely due to India's ability to produce low-cost quality medicines. The report documents that Indian generic producers supplied the majority of ARVs in developing countries. Indian-produced generic antiretrovirals (AIDS drugs) comprised 87 per cent of ARV purchase volumes and accounted for 91 per cent of paediatric ARV volumes in 2008. The report raises the concern that trade agreements being currently discussed may further reduce India's vital role as provider of life-saving treatments¹.

We are therefore concerned that the Indian government may accept intellectual property (IP) provisions that will undermine the production, registration and worldwide availability of essential generic medicines.

This is not the first time. India through a series of legal amendments in the last decade has already enforced the requirements for intellectual property protection under international law. The TRIPS agreement - which has bound India to introduce a product patent regime in 2005 - has already begun to curtail the country's ability to produce low-cost generic versions of newer HIV, hepatitis and cancer medicines. Because India signed the TRIPS Agreement, some new essential medicines have already been patented in India and cannot

¹ The study can be downloaded from: <http://www.jiasociety.org/content/13/1/35>

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be domestically produced, leaving patients in India and across the developing world without access to affordable versions of these medicines.

Trade agreements being currently discussed - particularly the one with the European Union (EU) – will further restrict this access. If India signs up to the IP clauses demanded by the EU, which go significantly beyond TRIPS standards (TRIPS Plus), it will further reduce the country's ability to provide affordable essential medicines.

As you know, the EU is trying hard in every forum to increase IP standards that will benefit European pharmaceutical companies but will have a grave impact on generic production and supply of medicines and ultimately access to medicines for patients in the developing world. The EU is also using the FTA negotiations with India to pursue 'TRIPS Plus' IP provisions and enforcement rules that will hinder the production and flow of life-saving generic medicines.

Issues of Concern in EU-India FTA that could affect access to medicines:-

Patent term extension known as "Supplementary Protection Certificates" in the negotiations, is a straightforward way to extend a pharmaceutical company's monopoly by extending the patent life on a medicine beyond 20 years. If India accepts this clause, the years added to the patent in India are extra years in which the company can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.

Exclusive rights over pharmaceutical test data (so called "data exclusivity") figures prominently in the negotiations. The current text of the IP chapter on pharmaceutical test data as proposed by the EU to India essentially requires that India amend its drug regulatory legislation in a manner that will not permit the placing of a generic pharmaceutical product on the market if the originator has submitted any clinical trial data relating to the medicine to the Indian drug regulatory authority (Drug Controller General of India).

If India accepts this clause, India's drug regulator will be legally prohibited from registering a generic medicine as long as the exclusivity lasts over the trial data (usually several years). Generic producers will have to submit their own safety and efficacy data to register the generic. This will oblige generic companies to repeat clinical and pre-clinical trials. The repetition of trials raises grave ethical issues, as it would require withholding safe and effective medicines from some patients (the control group), solely for the purpose of proving something that is already known. This may not pass the scrutiny of ethical committees, making it difficult for generic companies to repeat the clinical trials. In addition, repetition of clinical trials will take time and involve costs that the generic producers usually cannot afford.

A study on the impact of data exclusivity in Jordan found that of 103 medicines registered and launched since 2001 that currently have no patent protection in Jordan, at least 79 per cent have no competition from a generic equivalent as a consequence of data exclusivity.² Data exclusivity in Jordan was introduced as a result of the US-Jordan FTA.

² All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Oxfam Briefing Paper, March 2007

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Intellectual property enforcement provisions include a number of different measures (criminal sanctions for IPR infringement, evidence, injunctions etc.) that attempt to govern the way the disputes around patents and civil trademark infringements will be managed by Indian courts. If India signs up to these clauses, the Indian judiciary will have its hands tied and will no longer be able to balance IP rights with the right to health of patients. In addition, the impact of border enforcement measures is clear from the seizure of generic medicines by the EU that were on their way from India to Africa and Latin America.

The investment chapter extends the definition of investment to include *intellectual property*. If accepted by India, multinational drug companies would then have the standing to sue the Indian government in a bid to block sovereign actions like compulsory licensing, price control and regulation. It is critical to remove IP from the definition of investment so that both the use of compulsory licensing, price regulation, as well as refusal to provide exclusive rights over test data (data exclusivity) cannot be linked to either the definition of investment or factored in the consequences of so called “expropriation”.

Even labeling requirements in the interests of public health can be questioned under such provisions as a recent investment dispute³ filed by Phillip Morris, the tobacco company against Uruguay demonstrates. Philip Morris has alleged that Uruguay’s requirement to increase the size of pictorial warnings of the effects of tobacco on cigarette packets violate their trademark rights. A clear example of how companies can use a bilateral investment treaty to challenge government decisions related to public health on grounds of IP infringement.

Accepting the IP provisions will benefit European pharmaceutical companies - but they will have a grave impact on generic production of medicines and ultimately access to medicines for patients in the developing world. The Indian government will be trading away our lives by agreeing to the EU’s demands on intellectual property and enforcement in FTA negotiations. We request India to NOT TRADE AWAY OUR LIVES and right to health in the name of another trade agreement.

As the Prime Minister of India, we urge you to refuse the IP provisions outlined above. We request you to ensure that generic competition remains possible in India. So many lives depend on it worldwide.

SIGNED BY:

Organizations

1. Aavash Samuha, NEPAL
2. Act Up Paris, FRANCE
3. ACT Project, INDIA
4. Action against AIDS, GERMANY
5. Acción Ciudadana Contra el Sida (ACCSI), VENEZUELA
6. Acciones Voluntarias sobre Educación, MEXICO
7. Alliance for Integrated Development and Empowerment, UGANDA
8. AIDS Access Foundation, THAILAND

² Under the Switzerland-Uruguay Bilateral Investment Treaty

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9. Africa Japan Forum (AJF), JAPAN
10. African Council of AIDS Service Organizations (AfriCASO), Medina, SENEGAL
11. Agape DIC Noklak, INDIA
12. Alianza LAC-Global para el Acceso a los Medicamentos, BRAZIL
13. All India Drug Action Network (AIDAN) , INDIA
14. All India Peoples Science Network, INDIA
15. Alternative Agriculture Network, THAILAND
16. Australian Foundation for Peoples of Asia and the Pacific, AUSTRALIA
17. Artists for a New South Africa, USA
18. Asia Pacific Network of People Living with HIV/AIDS
19. Asian Network of People who Use Drugs (ANPUD) , INDIA
20. Asha Jyoti Sahayog Samuha, NEPAL
21. Avni Health Foundation, INDIA
22. Belize Network of Positive Persons, BELIZE
23. Belorussian community PLWH, BELARUS
24. Bharatiya krishak Samaj, INDIA
25. Bharat Gyan Vigyan Samithi Punjab and Chandigarh, INDIA
26. Biodiversity and Community Right Action, THAILAND
27. Brazilian Interdisciplinary AIDS Association (ABIA), BRAZIL
28. Brazilian Network for the Integration of Peoples (Rebrip), BRAZIL
29. Buds of Christ, INDIA
30. Budem ghit, RUSSIA
31. BUKO Pharmakampagne, GERMANY
32. Cambodian People Living with HIV/AIDS Network (CPN+), CAMBODIA
33. Cancer patients Aid Association, Mumbai, INDIA
34. Cancer Patient Network, THAILAND
35. Center for Health, Human Rights and Development, UGANDA
36. Centre for Trade & Development, New Delhi , INDIA
37. Centro de Tecnologia e Sociedade da Fundação Getúlio Vargas, (CTS/FGV), BRAZIL
38. Change Team, NEPAL
39. Churches Alliance Care and Support(CACS), INDIA
40. Citizens Against Chemicals Pollution, JAPAN
41. Civil Society Health Forum, INDIA
42. Coalition of Asia-Pacific Regional Network on HIV/AIDS (Seven Sisters), INDIA
43. Coalition for Health Promotion and Social Development (HEPS- Uganda), UGANDA
44. Coalition PLUS; FRANCE
45. Colombian Medical Federation, COLOMBIA
46. Conectas-Human Rights, BRAZIL
47. CNS Stop-TB Initiative, INDIA
48. CompWare Medical/GTZ, Germany PPP Project on MMT in Asia, INDIA
49. Community Development Medicinal Unit; Orissa, INDIA
50. Courtyard Attorneys, INDIA
51. Dance4life, UNITED KINGDOM
52. Daycare Centre for children and families affected by HIV “Qaldirgoch”, UZBEKISTAN

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53. Delhi Network of Positive People (DNP+), INDIA
54. Delhi Mahila Samiti (DMS) , INDIA
55. Delhi Science Forum, INDIA
56. Diverse Women for Diversity, INDIA
57. Drug Addict & AIDS Resistance Society, Mizoram, INDIA
58. Drug users and Positive Network, Noklak, INDIA
59. DFID AIDS Technical Assistance Support Team (TAST), Gurgaon, INDIA
60. Dongjen Center for Human Rights Education and Action, CHINA
61. Drug Awareness and Rehabilitation Center, NEPAL
62. Drug Action Forum – Karnataka, INDIA
63. Drug Study Group, THAILAND
64. Drug System Monitoring and Development Program, Chulalongkorn University, THAILAND
65. EHA Duncan Hospital, INDIA
66. Ecological Alert and Recovery, THAILAND
67. East Europe & Central Asia Union of PLWHA, UKRAINE
68. Empower India, INDIA
69. European AIDS Treatment Group, BELGIUM
70. Farmamundi, BRAZIL
71. Federation of Medical And Sales Representatives Association of India , INDIA
72. Federation of NGOs Working in Drugs AIDS Prevention And Care (FONWIDAPAC) , INDIA
73. Focus on the Global South, INDIA
74. Food First Information Action Network, INDIA
75. Forum for Indigenous Perspectives and Action, Manipur , INDIA
76. Foundation for Human Rights and Development, Madurai, INDIA
77. Foundation for Health Action, INDIA
78. Foundation for Consumers, THAILAND
79. Foundation for AIDS Rights, THAILAND
80. Friends of Kidney-failure Patients Club, THAILAND
81. Freedom Foundation, INDIA
82. FTA Watch, THAILAND
83. Fundación Misión Salud, COLOMBIA
84. Fundacion AID FOR AIDS, PERU
85. Fundacion Tucuman Sida, ARGENTINA
86. Group of Support and AIDS Prevention, BRAZIL
87. Gene Campaign, INDIA
88. Geon Health Foundation, BANGLADESH
89. Gestos - Soropositividade, Comunicação e Gênero, BRAZIL
90. Giramatsiko Post Test club, UGANDA
91. Global Coalition of Women Against AIDS, UGANDA
92. Global Concerns, Bangalore , INDIA
93. Global Forum on MSM & HIV (MSMGF)
94. Grace Chapel Noklak, INDIA
95. Grace Chapel Ke-Lomei DIC, INDIA
96. GRAIN (International)

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97. Grupo de Apoio à Prevenção à AIDS São Paulo, BRAZIL
98. Gayatri Rural Educational Society (GRES), INDIA
99. Harm Reduction Network, AZERBAIJAN
100. Harvard Global Health & AIDS Coalition, USA
101. Health Action International (HAI) AFRICA
102. Health Action International COLOMBO
103. Health Action International Asia Pacific
104. Health Action International Latin America and the Caribbean (AISLAC)
105. Health Access Network, GHANA
106. Health Consumer Protection program, Chulalongkorn University, THAILAND
107. Health Mission Foundation, COLOMBO
108. Healthwatch Forum UP, INDIA
109. Health GAP, USA
110. HIV Treatment Bulletin and ARV 4 IDUs, UNITED KINGDOM
111. Hoppers foundation, Chennai, INDIA
112. ICW Eastern Africa/Women & Families in AFRICA
113. ICW (Living for AIDS), URUGUAY
114. IFARMA foundation, COLOMBIA
115. India Competence, INDIA
116. India FDI Watch, INDIA
117. Indian Harm Reduction Network, CANADA
118. Indian Farmers Movement, INDIA
119. Indian Peoples Alliance for Combating HIV and AIDS, INDIA
120. Intan Life Zone Welfare Society, MALAYSIA
121. INSAF, INDIA
122. Instituto de Defesa do Consumidor, BRAZIL
123. Institute de recherche interdisciplinaire sur les enjeux sociaux, FRANCE
124. Instituto de Estudos Sócioeconômicos, BRAZIL
125. International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru), RUSSIA
126. International Community of women living with HIV EASTERN AFRICA
127. Initiative for Medicines, Access & Knowledge (I-MAK), USA
128. Initiative for Health , Equity in Society, INDIA
129. Integrated Community Based Post Test Club (ICOTEST), UGANDA
130. International Peoples Health Council (SOUTH ASIA)
131. International Community of Women Living with HIV and AIDS, ZIMBABWE
132. International Treatment Preparedness Coalition (ITPC), INDIA
133. Italian League For Fighting AIDS, ITALY
134. Jan Swasthya Abhiyan (People's Health Movement), INDIA
135. Jayapura Support Group (JSG) Papua - INDONESIA
136. JOTHI (Indonesia PLHIV Network), INDONESIA
137. Jaunpur Network for positive people living with HIV/AIDS (JNP+), INDIA
138. Kenya Legal & Ethical Issues Network on HIV/AIDS, KENYA
139. Knowledge Commons, INDIA

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140. Knowledge Ecology International, SWITZERLAND
141. Kyagaju Post Test Club, UGANDA
142. Latin American and Caribbean Council of AIDS Service Organizations (LACCASO), BRAZIL
143. Latin American Network of People Living with HIV/AIDS
144. Latin American and Caribbean Movement of Positive Women Network
145. Lao National Network of people living with HIV/AIDS (LNP+), LAO PDR
146. LDKCM Hospital P Ltd, Kanpur, INDIA
147. LOCOST (Low Cost Standard Therapeutics), Baroda, INDIA
148. Luz Marina Umbasia Fundacion Henry Ardila, COLOMBIA
149. Manipur Network of Positive People (MNP+), INDIA
150. Medico Friends Circle (MFC), INDIA
151. Meghalaya State Network of Positive People, INDIA
152. MILANA, Bangalore, INDIA
153. Monthly Index of Medical Specialities (MIMS), INDIA
154. Moldavian League of PLH, MOLDOVA
155. Médecins Sans Frontières' - Campaign for Access to Essential Medicines
156. Nagaland Users Network (NUN), INDIA
157. National association of PLHA in NEPAL
158. National Empowerment Network of PLHAs in Kenya (NEPHAK), KENYA
159. National Federation of Pharmacists – FENAFAR, BRAZIL
160. National Hawker Federation, INDIA
161. National Working Group on Patent Laws, INDIA
162. Network of Maharashtra by People Living with HIV, INDIA
163. Network of People living with HIV/AIDS in Manipur (NMP) , INDIA
164. North East India Drug Users Forum, INDIA
165. New Vector, GEORGIA
166. Ntchisi Integrated Development Organisation, MALAWI
167. Open Society Justice Initiative (OSJI), HUNGARY
168. Oxfam INDIA
169. Pela Vidda, BRAZIL
170. PKNK (South Kalimantan of PUD), INDONESIA
171. Polish National Network of PLWHA “SIEC PLUS”, POLAND
172. Positive Life NSW, AUSTRALIA
173. Positive Lives INDIA
174. Positive Malaysian Treatment Access & Advocacy Group, MALAYSIA
175. Positive Women Network, Tamil Nadu, INDIA
176. Positive Women Network, Kerala, INDIA
177. Positive Women Network, Manipur, INDIA
178. Positive Women Network, Uttar Pradesh, INDIA
179. Positive Women Network, New Delhi, INDIA
180. Positive Women Network, Rajasthan, INDIA
181. Positive Women Network, Karnataka, INDIA
182. PLHIV Network Tuensang, INDIA
183. Prayas Centre for Health Equity, Chittorgarh, INDIA

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184. PRO-VISION, INDIA
185. Promocion para el desarrollo y juventud (Promotion for Youth and Development), MEXICO
186. Public Interest Research Centre, INDIA
187. Public Personalities Against AIDS Trust, ZIMBABWE
188. PRO-VISION, INDIA
189. Red de Coordinación en Biodiversidad, COSTA RICA
190. Rede Nacional de Pessoas Vivendo com HIV/AIDS - São Luis, BRAZIL
191. Red Argentina de Mujeres Viviendo con vih-sida (RAMVIHS), ARGENTINA
192. Red Argentina de Personas Positivas, ARGENTINA
193. Rusli Ismail Institute for Research In Molecular Medicine Universiti Sains, MALAYSIA
194. Sangram, INDIA
195. Samaritan Society of Mizoram, INDIA
196. Sama-Resource Group for Women and Health, INDIA
197. Samavesh, Bhopal, INDIA
198. SECTION27, Incorporating the AIDS Law Project, SOUTH AFRICA
199. Senderos Asociación Mutua, COLOMBIA
200. Sakriya Plus, NEPAL
201. Sambatra Izay Salama (SISAL), MADAGASCAR
202. Social Awareness Service Organisation (SASO), Manipur, INDIA
203. Social Pharmacy Research Unit, Chulalongkorn University, THAILAND
204. Stop AIDS In Liberia (SAIL), LIBERIA
205. Stop AIDS Campaign, United Kingdom
206. Svecha , RUSSIA
207. Sustainable Development Policy Institute, PAKISTAN
208. Thai AIDS Treatment Action Group (TTAG), THAILAND
209. Thai Network of People Living with HIV/AIDS (TNP+), THAILAND
210. Thai NGO Coalition on AIDS, THAILAND
211. Thai Holistic Health Foundation, THAILAND
212. The Good Neighbour, Lagos, NIGERIA
213. The Latinamerican & Caribbean Global Alliance for Access to Medicine
214. The Rural Pharmacist Foundation, THAILAND
215. The Rural doctor foundation, THAILAND
216. Third World Network (TWN)
217. Toxics Watch Alliance, INDIA
218. Transnational Institute (TNI) Amsterdam, NETHERLANDS
219. Treatment Action Campaign, FoTAC, UNITED KINGDOM
220. Treatment Action Campaign (TAC), SOUTH AFRICA
221. Treatment Action Group, USA
222. Universities Allied for Essential Medicines
223. United Belize Advocacy Movement, BELIZE
224. United NGO Mission- Manipur, INDIA
225. Uganda Civil Society Council For Development, UGANDA
226. Ursula Rivera Cuny (Association of Transvestites with HIV and AIDS), PERU
227. Veshya Anyay Mukti Parishad (VAMP), INDIA

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228. Voluntary Health Association Of Meghalaya, INDIA
229. Vrijschrift, NETHERLANDS
230. War on Want, UNITED KINGDOM
231. World AIDS Campaign, THAILAND
232. World Economy Ecology & Development (WEED), GERMANY
233. Women In Development Europe (WIDE) Network, BELGIUM
234. Women Fighting AIDS In Tanzania (WOFATA), TANZANIA
235. Women's Global Network for Reproductive Rights, PHILLIPINES
236. World Care Council (INDIA, FRANCE, DR CONGO)
237. Yayasan Kesehatan Bali (Yakeba), INDONESIA
238. Youth Vision, NEPAL
239. Youth Advocating for Positive Behaviour Change, KENYA
240. Zambia AIDS Law Research & Advocacy Network, ZAMBIA\

Individuals

1. Ajay Kumar Khare, Madhya Pradesh Vigyan Sabha, Bhopal, INDIA
2. Amar Jesani, independent consultant on bioethics and public health, INDIA
3. Amita Shah, Professor, Gujarat Institute of Development Research, INDIA
4. Asif Chishti, President HKS Venture Capital & Private Equity Club, President HKS Biotech Club, Harvard Kennedy School, Harvard Business School, MIT Sloan School of Management, USA
5. Daryo Stamato, THE NETHERLANDS
6. Evgenia Maron, AIDS activist, RUSSIA
7. Jad Al Danaf, LEBANON
8. John Rock, Advisor to APN+, Chair of the Board of AFAP (Australian Foundation for Peoples of Asia and the Pacific), Board Member of ITPC (International Treatment Preparedness Coalition)
9. Kajal Bhardwaj, Lawyer, INDIA
10. Ken Harvey, School of Public Health, La Trobe University, AUSTRALIA
11. Marcela Cabezas Barroso
12. Martha Tholanah, ZIMBABWE
13. Michelle Childs, Lawyer, UK
14. M.Lorena Di Giano
15. Mosadeq Sahebodin, MAURITIUS
16. Nathan Geffen, researcher, SOUTH AFRICA
17. N.Lalitha, Associate Professor, Gujarat Institute of Development Research, INDIA
18. N. Subba Rao (Indian, living in the UNITED ARAB EMIRATES)
19. P.William Christopher, Coordinator IPACHA, Member BHAF
20. Paul Cawthorne, Registered Nurse, THAILAND
21. Ranbir Singh Dahiya (Dr.), INDIA
22. Rebecca Hodes, University of Cape Town, SOUTH AFRICA
23. Rishita Nandagiri (Indian currently living in the PHILIPPINES)
24. Ritwik Nandagiri (Indian, living in the USA)
25. Roz Scourse, Campaigns and Advocacy Intern, Restless Development, UK
26. Romeo F. Quijano, Professor, University of the PHILIPPINES
27. Sara Simon, UNAIDS PCB NGO Delegation, Brussels, BELGIUM

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28. Sarah Rimmington, Lawyer, SWITZERLAND
29. Shila Ka Gennady Roshchupkin, Consultant on programme and management issues
30. Shalini Singh Deo
31. Susan Paxton, Positive Response, HIV Consultant, AUSTRALIA
32. Tom Mangattuthazhe , Bishop'sHouse , Assam, INDIA
33. Thomas Pogge, Leitner Professor of Philosophy and International Affairs, Yale University, USA
34. Usha Ramani Nandagiri (Indian, living in the UAE)
35. Uma Shankari, Andhra Pradesh, INDIA
36. Y. Madhavi, Scientist, INDIA
37. Yousuf A Vawda, University of KwaZulu Natal, SOUTH AFRICA
38. William L. Aldis MD, Asst. Prof. (Global Health), Faculty of Public Health, Thammasat University, THAILAND

CC to:

1. Mr. T.K.A Nair, Principal Secretary, Prime Minister's Secretariat
2. Mr. Ghulam Nabi Azad, Hon'ble Union Minister for Health and Family Welfare
3. Ms. K Sujatha Rao, Secretary, Ministry of Health and Family Welfare
4. Mr. Pranab Mukherjee, Hon'ble Minister for Finance
5. Mr. M. Veerappa Moily, Hon'ble Minister of Law & Justice
6. Mr. M K Azhagiri, Hon'ble Minister of Chemicals and Fertilizers
7. Mr. Anand Sharma, Hon'ble Minister of Commerce & Industry
8. Mr. Rahul Khullar, Secretary, Department of Commerce
9. Mr. Rajinder Pal Singh, Secretary, Department Of Industrial Policy & Promotion
10. Ms. Sonia Gandhi, President, Indian National Congress
11. Mr. Prakash Karat, General Secretary, Communist Party of India (Marxist)
12. Mr. Nitin Gadkari, President, Bharatiya Janata Party
13. Mr. D. Raja, Secretary, National Council, Communist Party of India
14. Members, National Advisory Council
15. Dr. Margaret Chan, Director-General, World Health Organization
16. Dr. Samlee Plianbangchang, Regional Director, South East Asia Regional Office, World Health Organization
17. Dr. Michel Kazatchkine, Executive Director, The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)
18. Dr. Charles Gilks, Country Coordinator, UNAIDS India
19. Mr. Anand Grover, UN Special Rapporteur on Health