

# CAMPAIGN FOR AFFORDABLE TRASTUZUMAB

**Hon'ble Shri Manmohan Singh,  
Prime Minister of India  
Room No. 148-B  
South Block  
New Delhi – 110 001  
Tel: 23012312  
Fax: 23016857**

**New Delhi, November 5, 2012**

## **Subject: Access to Trastuzumab – a life-saving breast-cancer drug**

Respected Prime Minister,

We the undersigned cancer survivors and patients, women's groups, public interest organisations, health rights groups and treatment activists are writing to urge you to take immediate steps to make the cancer drug trastuzumab available free at public cancer treatment facilities, and at an affordable price in the private market.

Trastuzumab is used in treatment of HER2+ type of breast cancer, which affects around about one in four patients diagnosed with the disease.

### **Some facts about breast cancer in India**

You may be aware that as many as one lakh women in India are diagnosed with breast cancer every year. One out of every 22 Indian women is likely to get breast cancer during her lifetime. One Indian woman succumbs to breast cancer every ten minutes. Breast cancer is now the most common form of cancer in urban areas, and the second most common cancer in rural areas in India. ICMR data suggest some extremely worrying trends – breast cancer is becoming more common in younger women, with almost 50% of patients being women under 50. Younger women are showing an increased incidence of HER2+, a particularly aggressive form of breast cancer.

### **Trastuzumab: hope for women with HER2+ breast cancer**

Clinical trials have demonstrated that trastuzumab has a strongly positive impact on HER2+ metastatic breast cancer in terms of reducing the rates of recurrence and improving the chances of disease-free survival. In 2006, the US Food and Drug Administration approved trastuzumab for treatment of all HER2+ breast cancers. It is now the standard practice to prescribe Trastuzumab along with post-surgery chemotherapy for women with metastatic breast cancer. Treatment consists of 12 intravenous doses of the drug, administered every three to four weeks over the course of a year.

### **High costs block access to treatment**

Roche, the Swiss drug major (the originator company) has been marketing trastuzumab in India under the trade name 'Herceptin'.

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Indian companies are still to register and market a biosimilar version of trastuzumab. As a result Roche has a complete monopoly over both the private market and the public sector purchases made by the Central Government Health Service and Indian Railways.

When Herceptin first became available in India, it was priced at around Rs. 1,10,000 (2000 \$) per vial, making it unaffordable to all except the very wealthy. In March 2012, soon after the decision of the Indian Patent Controller to grant a compulsory license on Sorafenib (a drug used in the treatment of liver and kidney cancers), Roche announced a cut in the price of Herceptin from Rs.1.08 lakh (1964\$) per dose to Rs.92,000 (1673\$) per dose – a reduction of about 15%. Roche also signed a commercial agreement with Emcure Pharma. As of August 2012, Emcure is offering a repacked and renamed version of trastuzumab (Herclon) to patients at a price of Rs.72,000 (1310\$) per dose – a reduction of around 33% from the price in 2011.

While Roche is using the deal with Emcure and its “voluntary” price reductions to claim that it is concerned about access issues, it is clear that the company's pricing policy is motivated by greed for profits and the determination to retain control of the Indian market. The price cuts are defensive and pre-emptive measures to preserve its monopoly in India against the issuance of compulsory licensing and price control measures by the Indian government.

The agreement between Roche and Emcure does not involve any transfer of technology or create any possibility for the entry of other players into the market - Roche will continue to produce the drug at its plants in the US, Singapore and Germany and ship vials to Emcure for packaging.

The patent on trastuzumab expires in 2014, but Roche is attempting to maintain its market monopoly by filing several new patent applications in the four different patent offices in India. If granted, these patents can be used to file IP infringement suits claiming damages of crores of rupees against Indian companies who develop and launch a bio-similar of trastuzumab. This strategy has already been employed by Roche to discourage the entry of a bio-similar of a pegylated interferon (Alpha-2a) used in the treatment of Hepatitis C.

## **Competition can bring down prices and ensure access**

Experience shows that competition from Indian companies can bring down the price of essential drugs far more effectively than discounts or differential pricing schemes controlled by companies. In 2001, the cost of first line antiretroviral therapy for HIV treatment was brought down from over Rs. 5,00,000 (10,439 USD) (which was a discounted price for MSF) to Rs. 17,000 (350 USD) per patient per year (PPY) when Indian companies started manufacturing affordable generic versions. Similarly, in the area of biotechnology, the local development and registration of recombinant Hepatitis B vaccine by Indian companies has brought prices down from over Rs. 1000 per dose to less than Rs. 50 a dose.

More recently, the landmark decision in March by the Patent Controller to allow generic competition on the cancer drug sorafenib tosylate (Sorafenib) via a 'compulsory licence' issued to an Indian company brought the price of this patented cancer drug down by 97% (from over Rs 280,000 to Rs. 8,800 per month) (5090\$ to 160\$ per month).

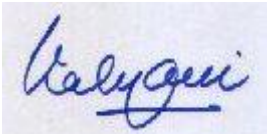
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**We therefore urge the government** to immediately institute measures for the local development of biosimilars of trastuzumab so that competition can bring down prices effectively for patients in India and other developing countries.

**Specifically, we request your government to:**

- ⤴ Make trastuzumab available free of cost to patients in government hospitals, and at a reasonable and affordable cost in the open market.
- ⤴ Constitute a High-Level inter-Ministerial Task Force in the Health Ministry involving biotechnology experts from public funded research organisations and civil society organisations to address the technological issues that may be involved in production of trastuzumab.
- ⤴ Take effective measures to ensure that no secondary patents on trastuzumab are granted or enforced in India.
- ⤴ Issue compulsory licenses (as allowed by the Indian Patents Act, 2005) in case there are existing process or product patents that block the development of bio-similars of trastuzumab,
- ⤴ Provide adequate resources for research and development, manufacture and clinical trials of a bio-similar of trastuzumab, and ensure a fast track process for regulatory approval.

Respected Prime Minister, we look forward to your urgent actions in response to this letter.



**Kalyani Menon-Sen**  
**(Campaign Coordinator)**

**Cc:**

Mr. Anand Sharma, Hon'ble Minister of Commerce & Industry  
Mr. Ghulam Nabi Azad, Hon'ble Minister of Health and Family Welfare  
Mr. S Jaipal Reddy, Hon'ble Minister of Science and Technology  
Mr. M K Alagiri, Hon'ble Minister of Chemicals and Fertilizers  
Ms. Krishna Tirath, Hon'ble Minister for Women and Child Development

Ms. Sonia Gandhi, Chairperson, National Advisory Council  
Ms. Sushma Swaraj, Leader of Opposition, Bhartiya Janata Party

Mr. Shanta Kumar, Chairman, Parliamentary Standing Committee on Commerce  
Mr. Brajesh Pathak, Chairman, Parliamentary Standing Committee on Health and Family Welfare  
Mr. Gopinath Munde, Chairman, Parliamentary Standing Committee on Chemicals & Fertilizers  
Ms. Chandresh Kumari Katoch, Chairperson, Parliamentary Standing Committee on Empowerment of Women

Mr. Pulok Chatterjee, Principal Secretary, Prime Minister's Secretariat

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Mr. P K Pradhan, Secretary, Dept of Health & Family Welfare, MoHFW  
Dr. V M Katoch, Secretary, Dept of Health Research, MoHFW  
Mr. S R Rao, Secretary, Department of Commerce, MoC  
Mr. Saurabh Chandra, Secretary, Department of Industrial Policy and Promotion (DIPP), MoC  
Dr. M.K.Bhan, Secretary, Department of Biotechnology, Ministry of Science & Technology  
Dr. T. Ramasami, Secretary, Department of Science & Technology  
Prof. Samir K. Brahmachari, Secretary, Department of Scientific and Industrial Research, Ministry of Science & Technology  
Mr. Prem Narain, Secretary, Ministry of Women and Child Development  
Mr. Keshav Desiraju, Special Secretary, Dept of Health & Family Welfare, MoHFW  
Mr. R K Jain, Additional Secretary, Ministry of Health and Family Welfare  
Dr. G.N. Singh, Drug Controller General of India

# CAMPAIGN FOR AFFORDABLE TRASTUZUMAB

## SIGNATORIES

### Health rights and human rights organisations and campaigns (India)

1. Jan Swasthya Abhiyan, India
2. Asha Parivar, India
3. All India Drug Action Network
4. Centre for Trade & Development, India
5. Citizen News Service (CNS), India
6. Diverse Women for Diversity, India
7. Economic Research Foundation, New Delhi
8. Foundation for Research in Science Technology & Ecology, India
9. Indian Social Action Forum (INSAF)
10. Vote For Health (V4H) campaign, India
11. Abhinav Bharat Foundation (ABF), India

### Health rights and human rights organisations and campaigns (global)

12. People's Health Movement
13. Asia Pacific Network of people living with HIV (APN+), Thailand
14. Egyptian Foundation for Health for All
15. Fix the Patent Law Campaign, South Africa
16. Health Education and Research Association, Skopje, Macedonia
17. Initiative for Health & Equity in Society, Thailand
18. Initiative For Medicines, Access and Knowledge, USA
19. Instituto Vida Nova, Brazil
20. MOPAIDS (Movimento Paulistano e Luta Contra a AIDS), Brazil
21. Pink & Steel Pilates Trust, New Zealand
22. SEA-AIDS (global)
23. Stop-TB eForum (global)
24. The Positive Malaysian Treatment Access & Advocacy Group, Malaysia
25. Third World Network, Malaysia
26. Treatment Action Campaign, South Africa
27. Works for a Better Bangladesh (WBB Trust)

### Cancer survivors and patient organisations

28. Alka Nagpal, development professional, New Delhi
29. Bindia Thapar, artists and writer, New Delhi
30. CanSupport, New Delhi
31. Chaitali Haldar, development worker, New Delhi
32. Koh Miyaoi, development professional, Japan
33. Lalita Ramdas, anti-nuclear and anti-war activist, India
34. Leela Menon, Editor, Janmabhumi, India
35. Lynn Cartwright, homemaker, South Africa
36. Nicki Glossop Jones, health activist, UK
37. Priya Ravish Mehra, New Delhi
38. R Anuradha, media professional, India
39. Sandra Flower, health activist, UK
40. Sarbari Sen, teacher and blogger, New Delhi

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## Indian women's movement organisations

41. Feminist Approach to Technology, Delhi (Gayatri Buragohain)
42. Forum against Oppression of Women, Mumbai (Sabala)
43. Jan Abhiyan Sanstha, Shimla (Richa Minocha)
44. Jeevika Development Society, Kolkata (Dolon Ganguly)
45. Lesbians and Bisexuals in Action, Mumbai (Chayanika Shah)
46. Manasi Swasthya Sansthan, Indore (Kalpana Mehta)
47. Olakh, Ahmedabad (Nimisha Desai)
48. PWESCR, Delhi (Preeti Darooka)
49. Sahayog, New Delhi (Jashodhara Dasgupta)
50. Saheli, Delhi
51. Sahiyar, Ahmedabad (Trupti Shah)
52. SAHRWARU, Baroda (Sheba George)
53. SAMA, New Delhi (NB Sarojini)
54. Sangram, Sangli (Meena Seshu)
55. Stree Mukti Sangathana, Mumbai (Jyoti Mhapsekhar)
56. Swayam, Kolkata (Anuradha Kapoor)
57. Vimochana, Bangalore

## Individual women's rights activists (India)

58. Abha Bhaiya, Jagori Grameen, Himachal Pradesh
59. Dr Anjali Dave, TISS
60. Ajita, Anweshi, Kerala
61. Ammu Abraham, Women's Centre, Mumbai
62. Anandhi Shanmughasundaram
63. Anuradha Pati, independent researcher, Mumbai
64. Archana Sivaramakrishnan, Keystone Foundation
65. Aruna Rao, Gender At Work, Washington DC
66. Dr Aswathi Ravindran, TIFR, Mumbai
67. Chandita Mukherjee
68. Prof Chaya Datar, researcher and writer (former Head of Women's Studies, TISS)  
Mumbai
69. Prof Devaki Jain, Singamma Srinivasan Foundation, Bangalore
70. Dyuti Ailawadi, development worker, New Delhi
71. Dr Jayasree AK, HoD Community Medicine, Kannur Medical College
72. Jaya Srivastava, writer and musician, New Delhi
73. Jayashree Subramaniam, TISS, Hyderabad
74. Kabi Sherman, journalist, Mumbai
75. Kameshwari Jandhyala, Member UGC Committee on Women's Studies, Hyderabad
76. Kaveri Indira, Bangalore
77. Kranti, women's health activist, Mumbai
78. Lakshmi Menon, writer, Mumbai
79. Dr Lata Singh, Maitreyee College, New Delhi
80. Leena Menghaney, lawyer and health rights activist, New Delhi
81. Mini Mathew, Advocate
82. Nandini Rao, independent activist, New Delhi
83. Nandita Shah, Akshara, Mumbai

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84. Pamela Philipose, writer and journalist, Women's Feature Service, New Delhi
85. Ponni Arasu, writer, Chennai
86. Prof Jayati Ghosh, economist, Jawaharlal Nehru University, New Delhi
87. Prof Kannamma Raman, Mumbai University
88. Prof Nivedita Menon, political scientist, Jawaharlal Nehru University, New Delhi
89. Dr Pratiksha Baxi, legal researcher
90. Rajashri Dasgupta, journalist, Kolkata
91. Dr Richa Nagar, writer and Professor of Women's Studies, University of Minnesota
92. Ritu Menon, writer and publisher, New Delhi
93. Rohini Hensman, independent writer and researcher
94. Sabala, women's health activist, Mumbai
95. Saumya Uma, Advocate, Mumbai
96. Shalini Krishnan
97. Shrutipriya, Centre Square Foundation, New Delhi
98. Soma K P, independent researcher, New Delhi
99. Soumita Basu, Kolkata
100. Suneeta Dhar, Jagori, New Delhi
101. Teena Gill, journalist and filmmaker
102. Prof Uma Chakravathy, historian and writer
103. Vasanth Kannabiran, writer and researcher, Hyderabad
104. Dr Veena Poonacha, Head Women's Studies, Univ of Mumbai
105. Dr Veena Shatrughna, public health activist (former Professor National Institute of Nutrition), Hyderabad
106. Prof Zoya Hasan, historian, Jawaharlal Nehru University (former Chairperson Minorities Commission), New Delhi

## **Individual human rights activists (India)**

107. Anant Phadke, health rights activist, Pune
108. Anil Chaudhary, PEACE, New Delhi
109. Chittaranjan Singh, People's Union for Democratic Rights, UP
110. Devaki Nambiar, public health researcher, New Delhi
111. Dr Ambika Rajvanshi, CanSupport, New Delhi
112. Dr Anant Phadke, public health activist, Pune
113. Dr Mira Shiva, public health activist, New Delhi
114. Dr Neera Burra, independent researcher and child rights campaigner, New Delhi
115. Dunu Roy, urban rights activist, New Delhi
116. G Balagopal, child rights campaigner, Kerala (former UNICEF Country Director, Democratic People's Republic of Korea)
117. Gautam Chaudhury, disability rights activist, Kolkata
118. Harmala Gupta, CanSupport, New Delhi
119. Hassath, IT professional and film-maker, New Delhi
120. KM Gopa Kumar, lawyer and health rights activist, New Delhi
121. KT Suresh, human rights activist, Mumbai
122. Malini Aisola, health activist, New Delhi.
123. Shankar Ghosh, Director, Charkha, New Delhi
124. Suranya Aiyar, lawyer and human rights activist, New Delhi
125. Tulika Das, disability activist, Kolkata



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## Concerned citizens

126. Justice Mukul Mudgal, former Chief Justice, Punjab and Haryana High Court
127. Justice VR Krishna Iyer, former judge, Supreme Court
128. Arundhati Ghosh, retired diplomat, expert on nuclear disarmament, New Delhi
129. Ardhendu Sen, retired civil servant, former Chief Secretary, West Bengal
130. Prof Alok Bhattacharya, School of Life Sciences, Jawaharlal Nehru University
131. Prof Sudha Bhattacharya, Dean School of Environmental Sciences, New Delhi
132. Abhijit Menon-Sen, software consultant, New Delhi
133. Dr Alpana Niyogi, Dept of English, Ramlal Anand College, Delhi
134. Amit Chandra, Bank of America, New Delhi
135. Anushree Menon, Kaplan India, New Delhi
136. Asha Devi, SUS Office, Ambedkar University, Delhi
137. Ashique Ahmed, New Delhi
138. Prof B Ekbal, former professor of Neurosurgery, JSA
139. Col Deepak Gopinath, retired army officer, Bangalore
140. Dr Dwijen Rangnekar, School of Law, University of Warwick
141. Dr Leon Morenas, urban designer, New Delhi
142. Geeta Gopinath, homemaker, Bangalore
143. Jayanta Niyogi, author and IT expert
144. Minakshi Ibrahim, businesswoman, Delh
145. Nirmala Satyanaryana, homemaker, Coimbatore
146. Nitya Satyanarayana, investment consultant, Coimbatore
147. Rajni Sharma, tax consultant, New Delhi
148. Dr Sayandeb Choudhury, Ambedkar University, Delhi
149. Dr Shailaja Menon, historian, Ambedkar University, Delhi
150. Shreya Khemani, Hoshangabad
151. V.Satyanarayana, retired banker, Coimbatore

## African women's movement organisations

152. Akina Mama wa Afrika, Kampala, Uganda (Leah Chatta-Chippepa)
153. Association for Women in Self-Employment, Addis Ababa, Ethiopia (Tsigie Haile)
154. Rwandan Women's Network, Kigali, Rwanda (Mary Balikungeri)
155. Trade Collective, South Africa (Liepollo Pheko)
156. Young Women's Leadership Institute, Nairobi, Kenya (Kathambi Kinoti)

## Individual women's rights and health rights activists (global)

157. Dr. Germán Holguín, Director Misión Salud (Colombia) and Coordinador de la Alianza LAC Global por el Acceso a Medicamentos
158. Professor Brook K. Baker, Health GAP (Global Access Project)
159. Catherine Tomlinson, Treatment Action Campaign, South Africa
160. Aurea Abbade, health activist, Brazil
161. Aster Zaude, Addis Ababa (former Director Gender Unit, UNDP New York)
162. Cheryl Francisconi, Director, International Institute of Education, Addis Ababa
163. Dr Abinet Tasew, Director Gender Office, Addis Ababa University, Ethiopia
164. Ellen 't Hoen, lawyer, Netherlands
165. Immaculee Ingabire, Polyclinics of Hope, Kigali, Rwanda
166. Liepollo Lebohang Pheko, economist, Four Rivers, South Africa
167. Lieve Vanleeuw, Treatment Action Campaign, South Africa



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168. Mahlet Mekbib, Institute of International Education Regional Centre, Addis Ababa
169. Marcus Lowe, Fix the Patent Laws Campaign, South Africa
170. Melat Tekletsadik, Institute of International Education, Addis Ababa
171. Nicole Chesoni, Young Women's Leadership Institute, Nairobi, Kenya
172. Patience Ayebzibwa, African Women's Leadership Institute, Kampala, Uganda
173. Breast Cancer Initiative East Africa (Philippa Kibugu-Decuir)
174. Raminta Stuikyte, Member, UNAIDS reference group on HIV and Human Rights, Lithuania
175. Workneh Degefu, environmentalist, Ethiopia
176. Yilma Teguest, journalist and Editor-in-Chief, Capital newspaper, Addis Ababa