Jan Swasthnya Abhiyan
(People's Health Movement – India)

Health for All - Now!  Health is a Basic Human Right!

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All India People's Science Network (AIPSN)
All India Drug Action Network (AIDAN)
All India Democratic Women's Association (AIDWA)
Bharat Gyan Vigyan Samiti (BGVS)
Breast Feeding Promotion Network in India (BPNI)
Catholic Health Association of India (CHAI)
Centre for Community Health and Social Medicine, JNU
Christian Medical Association of India (CMAI)
Forum for Creche and Child Care Services (FORCES)
Fed. of Medical Representative Assns. of India (FMRAI)
Health Watch
Joint Women’s Programme (JWP)
Medico Friends Circle (MFC)
National Alliance of People’s Movements (NAPM)
National Federation of Indian Women (NFIW)
National Association of Women’s Organisations (NAWO)
Public Health Resource Network (PHRN)
SAMA – Resource Group on Women’s Health
SATHI – CEHAT
Society for Community Health Awareness Research and Action (SOCHARA)

Participating Organisations:
Over 1000 organisations concerned with health care and health policy from both within and outside the above networks

PRESS RELEASE

Public Health Must Prevail Over Corporate Profits

The Jan Swasthnya Abhiyan compliments the Government for notifying a list of over 300 drug formulations, available as fixed-dose combinations (FDCs) of two or more drugs, which are to be banned with immediate effect on the grounds of lack of “lack of therapeutic justification”. This is a long pending measure and needs to be followed up by further action to weed out a huge number of formulations, that should not have received marketing approval in the first place.

While we support the current move of the Central Drug Standard Control Organization (CDSCO), it must also be noted that the agency has sat on a huge body of evidence for decades, which has consistently shown that a significant proportion of drug formulations available in India have no scientific validity. It may also be recalled that for well over a decade the CDSCO has been cognizant of the fact that many formulations marketed in India have not been approved by it but had merely received manufacturing approval from state drug authorities. As state drug controllers have no authority to provide marketing approval, these formulations have been illegally marketed for years.

The 344 drugs that have now been banned constitute a fraction of the large number of irrational and unscientific formulations available in India. We urge the CDSCO to take proactive measures to weed out all irrational and hazardous formulations that are not validated by current scientific literature. Currently the CDSCO has chosen to scrutinize specific formulations while deciding on their future status. This drug by drug approach, where each FDC is scrutinized for scientific validity, is cumbersome and unnecessary and is likely to leave out a significant proportion of medicines that ought to be taken off the market. Instead the CDSCO should specify inclusion criteria based on clear scientific evidence for FDCs, and all FDCs that do not fulfill the criteria should be banned. It may be noted that the WHO List of Essential medicines contains 370 drugs, of which only 25 are FDCs. There is abundant internal capacity available in India to draw up inclusion criteria for the Indian drug market.
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FDCs are needed only in very specific cases -- when the combined drugs have clear synergistic effect to enhance efficacy, or when a treatment regime specifically requires drugs to be combined (viz. in HIV/AIDS, TB) to reduce emergence of drug resistance, or the combination decreases side-effects or when the two medicines are always required together or if the combination increases compliance by the patient. In all other cases availability of FDC is contrary to public health goals. Irrational FDCs push up treatment cost, multiply the possibility of adverse reactions and limit therapeutic choice. Irrational FDCs of antibiotics, further, contribute to the growth of antimicrobial resistance, a serious threat that would nullify the efficacy of many antibiotics within the next few years.

It is of grave concern that several injunctions have been granted by courts against the ban order. Courts need to be cognizant of the public health impact of continued marketing of thousands of irrational FDCs. Companies have complained that their profits will be jeopardized. The pharmaceutical industry reported a profit in excess of Rs.40,000crores in 2015-16, well in excess of the total Central outlay for the Ministry of Health and Family Welfare. Surely concerns need to prevail over attempts to profiteer at the expense of public health. Some of the major brands that have been banned, and for which injunctions have been granted, are manufactured by prominent MNCs. None of these banned formulations would be allowed in the home countries of the concerned MNCs. All the companies concerned had access to information showing their formulations were unscientific. Their marketing of these drugs is in all cases unethical, and in many cases illegal. The distorted business model of large companies has also been laid bare by the pleas of some of these companies. Pfizer and Abbott, two US based MNCs who take pride in claiming that they are 'innovator' companies, now lament that a ban on their unethical cough syrups -- Corex and Phensedyl -- will jeopardize their entire operations in the country. Surely giant MNCs should not depend on simple remedies like cough syrups to sustain operations in a developing country.

**The Jan Swasthyaa Abhiyan urges the government to aggressively pursue the court cases so that the injunctions are expeditiously vacated. We also urge the government to not view the current measure as a one-off exercise but to initiate a systematic review of all irrational formulations in the market.**

Issued on behalf of Jan Swasthyaa Abhiyan