PRESS RELEASE

Jan Swasthya Abhiyan Expresses Concern and Shock at the Lifting of the ban order on 344 FDCs

The Jan Swasthya Abhiyan (JSA) expresses its deepest concern and shock at the verdict of the Delhi High Court, lifting the ban imposed on 344 Fixed Dose Combinations (FDCs) of drugs by the Government a few months back. This is a huge setback to efforts aimed at bringing a semblance of order into the absolute anarchy that exist in India’s pharmaceutical market.

No Scientific Rationale

All the 344 FDCs that were banned are irrational and there is no scientific rationale for their continued use. Most of them are being manufactured in gross violation of regulatory procedures and should not have been allowed to be marketed in the first place. Medical students are not taught about their use as no text book of Medicine or Pharmacology recommends the use of these combinations. There is also a large volume of evidence from across the world that speaks to the necessity of discontinuing the use of these FDCs. In fact the 344 FDCs banned constitute the proverbial tip of the iceberg, and there are thousands of other FDCs that also need to be banned. The use of FDCs is generally discouraged except in a handful of cases, none of which are addressed by the FDCs that were banned. The World Health Organization’s Model list of Essential Medicines includes only 24 FDCs (out of 358) and India’s National list of Essential Medicines includes only 16 FDCs (out of 348). Yet, an estimated 40% of the Indian market for drugs comprises of FDCs.

The challenge of the ban order by drug companies, including by some of the largest MNCs like Pfizer, Glaxosmithkline and Abbott, was a disingenuous attempt by them to preserve their profits and to profiteer at the expense of public health. Most of these FDCs are not even registered in countries with strong regulatory systems. Further, as these drugs have no therapeutic validity their sales are driven by unethical marketing practices of drug companies, such as financial and other inducements offered to prescribers.
FDCs a threat to public health

The use of FDCs increase cost of medication, exposes populations to a larger array of adverse effects and limits the choice of therapy as they may combine drugs with different dosage schedules. Expenses borne by patients account for more than 70% of all healthcare costs and within these, 70% is accounted for by expenses incurred in buying medicines. The continued use of FDCs contributes to a big drain on the finances of individual patients. Further, some of the cough syrups in the ban order are primarily being used as addictive substances and not as therapeutic agents. Criminal investigation agencies and the narcotics bureau have filed several cases on charges of smuggling of the addictive cough syrup Phensedyl (one of the drugs in the banned list), manufactured by the MNC Abbott.

Access to essential, rational and affordable medicines is a core component of right to health care. In several judgments the Supreme Court of India and High Courts have upheld the fundamental right to health as part of the right to life with dignity over technical procedural issues. However, the lifting of the ban seems to be predicated on perceived procedural issues which fundamentally abrogate the right to life and health care. Besides, the Delhi High Court order does not appear to address the issues of rationality of the FDCs and the resultant adverse effect on public health. Drug companies should not see this order as a vindication of their stand that these FDCs are rational. JSA calls upon the esteemed judiciary of the highest courts to support and uphold people’s fundamental right to access affordable and rational medicines over the interest of the profiteering corporations who might see the lifting of the ban as a renewed opportunity to inundate the market with irrational FDCs.

Appeal to physicians not to prescribe these FDCs

The JSA appeals to all individual physicians, associations of medical professionals and hospitals not to prescribe the FDCs concerned. The JSA also strongly urges the Government to appeal against the order lifting the ban in the Supreme Court of India. It must also, where appropriate, plug legal and regulatory loopholes so that the ban order can be restored. It is of utmost importance that the government, as a custodian of public health, act decisively to defend it and strengthen regulatory mechanisms. Many of the FDCs covered by the earlier ban are sold over the counter and nothing short of a complete ban can address the threat to public health posed by these drugs. The JSA also appeals to the judiciary to take a broad and informed view of while adjudicating on issues where the private commercial interests of companies come in direct conflict with public health.

Issued on behalf of Jan Swasthya Abhiyan

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