LETTER TO EDITOR

Substandard, Spurious, Falsely-Labelled, Falsified and Counterfeit (SSFFC) Drugs: Time to Take a Bitter Pill

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Abstract:

Substandard, Spurious, Falsely-Labelled, Falsified and Counterfeit (SSFFC) drugs are an emerging public health concern in India. With one of the huge pharmaceutical sectors in the world, India has a varied prevalence of SSSFC drugs ranging from 0.04% to 34% according to various studies. Apart from severe health consequences, SSSFC drugs also weaken community's trust in the health care system. India is tackling the epidemic of SSSFC drugs through various existing and new regulatory measures. Considering the calamitous consequences of this silent epidemic, it is time to prescribe a bitter pill.

Keywords: Counterfeit Drugs, Substandard Drugs, Spurious Drugs, SSSFC, Pharmacovigilance

Dear Editor,

Substandard, Spurious, Falsely-Labelled, Falsified and Counterfeit (SSFFC) drugs are an emerging public health concern in India. With a share of 8% of global pharmaceutical production and 2% of world pharmaceutical market, India's pharmaceutical sector is huge. The nation meets 95% of domestic drug demands through native production and exports 40% of the production, ranking among top 20 countries in exporting pharmaceutical products [1].

The term SSFFC drug subsumes both branded and generic products containing wrong or inactive or insufficient ingredients or come with poor packaging [2]. Some of these products may be toxic with excess amount of active or wrong ingredient or contaminants such as corn starch, potato starch or chalk causing disastrous health consequences [2]. They are often prepared and stored in unhygienic, contaminated environment contributing to a potential public health problem [2]. Besides harmful health effects, SSFFC products also weaken peoples' trust in the health care system and health professional [2]. Hence, the acts of manufacture and distribution of SSFFC products warrant emphatic regulatory efforts, whether intentional or accidental [2].

According to World Health Organization (WHO) estimates, prevalence of counterfeit medicines ranges from less than 1% in developed countries, 10 to 30% in developing countries to a maximum of 50% or more from illegal internet pharmacies [3]. A pilot study in 2008 in Delhi and Chennai revealed 12% and 5% substandard samples respectively [4]. A nationwide survey involving 100 pharmacy outlets from various regions of India, found 0.046% of drugs to be spurious and 4.75%, substandard [4]. Two nationwide surveys across metro-cities, other big cities, district headquarters and villages between 2007 to 2009 present an estimate of drugs belonging to Not of Standard Quality (NSQ) between 0.1 to 0.3% [5]. Khan AN *et al* in their pilot study observed that 28.26% of generic Amoxycillin products bought over-the-counter and 34.37% of diclofenac sodium did not comply with Indian Pharmacopoeia (IP) standards [4].

The World Health Assembly (WHA) has called for coordinated action of international community to curb SSFFC drugs as early as 1988 [3]. The WHO along with other international organisations like United Nations Organization for Drugs and Crime (UNODC), Interpol and the World Customs Organization (WCO) endeavours to address the growing concern of counterfeit and fraudulent drug markets [3]. In India, the Central Drugs Standards Control Organization (CDSCO), in 2008 amendment of Drug and Cosmetics (D and C) Act, 1940 considers the issue under NSQ products and classifies them under 3 categories- Category A: spurious and substandard drugs; Category B: grossly substandard drugs and Category C: products with minor defects [4]. This amendment also prescribes severe penalties and rigorous imprisonment for related offences and provides for establishment of special designated courts for the purpose. The term of imprisonment has been enhanced to not less than 10 years which may be extended to life term with or without a fine not less than one lakh rupees or thrice the amount of drugs confiscated whichever is more. Some of the offences could be considered cognizable and non-bailable [6]. Despite existing enforcement measures the problem of SSFFC drugs is on the rise.

The high cost of branded drugs, heavy taxes levied on drugs and medical products, increased access to unregulated internet pharmacies are identified to be important factors promoting unsafe drug buying practices [3]. The Jan Aushadhi scheme launched by the Government of India motivating the use of generic medicines is a good beginning [4]. The prohibition of fixed dose combination of drugs for human use under section 26A of D and C Act, 1940 by the CDSCO in March, 2016 is an effective step towards promoting rational drug use [7]. CDSCO publishes and updates a monthly list of drugs and cosmetics identified to be NSQ [5, 8]. A "Whistle blower scheme" has been introduced to motivate officials and encourage active public participation to report NSQ drugs [1, 5]. The Indian Medical Association (IMA) has started a nodal centre under its IMA - Pharmacovigilance Programme of India (PvPI) initiative for timely reporting of adverse drug reactions or adverse events by health care professionals using the newly launched helpline 9717776514 or 18001803024 [9].

In future, there is need for a sound National criminal and regulatory legislative framework to address SSFFC medical products in a consistent way, and create an environment free of its threat [2]. State drug quality evaluation services should be improved emulating the successful models in Tamil Nadu and Kerala [5]. The Pharmaco-vigilance programme of India (PvPI) needs strengthening [10]. Reporting of suspected and adverse reactions by the pharmaceutical companies should be made imperative. There is an essential requirement for active contribution of suspected reactions to VigiBase, the WHO database [10]. Treating physicians and other medical personnel should be educated to monitor and report adverse drug reactions resulting from SSFFC drugs as part of curriculum and through refresher programmes [10]. Doctors should be encouraged to refer authenticated resources for drug references such as National Formulary of India (NFI), British National Formulary (BNF), United States Pharmacopeia- National Formulary (USP-NF) and The Merck Manuals- Online Medical Library [10]. Without stringent regulatory measures the SSFFC drug sector could evolve into epidemic proportions. Considering the calamitous consequences of this silent epidemic, it is time to prescribe a bitter pill.

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