ACCESSING MEDICINES IN AFRICA AND SOUTH ASIA (AMASA)

The Foundation for Research in Community Health

Policy Brief

# Inadequately enforced workforce planning norms undermine safety of Indian drugs.

*India's reputation as one of the top ranking global producers of medicines is taking a beating. Its failure to establish a strong drug regulatory mechanism is casting doubt on the safety and quality of Indian drugs. With complaints of sub-standard drugs coming from major international buyers – the US, Uganda, South Africa – there is deep concern within the Indian pharmaceutical industry that the 'black sheep' can tar the credibility of the entire industry.*

India's rapid pharmaceutical industry growth – approximately 10 per cent per year – meets 95percentof domestic needs and has a 10 percent share by volume in the global market. These achievements are jeopardized by the absence of drug inspectors and the failure to follow workforce planning norms for regulation of this industry, which is valued at Rs.100,000 crores.

The central regulatory laws – the Drugs and Cosmetics Act, 1940 and its subsequent amendments –do not specify workforce planning norms. Nevertheless various official committees have highlighted the way in which inspection has been neglected and recommended increasing trained inspector manpower -- the Mashelkar Committee, 2003; the Hathi Committee, 1975; The 59th Parliamentary Standing Committee, 2012.

Consequently, the safety and quality of the drug production process is still in question in states like Maharashtra where 29 per cent of the country's manufacturing and sales units are based. The State commands a 38 per cent share (2008-09) of India's Rs. 42,000 crore export market in medicines.

A study in four districts of Maharashtra – conducted from January to June 2012, by the Foundation for Research in Community Health (FRCH)under the framework of the AMASA project ('Access to Medicines in Africa and South Asia') shows that while there is no paucity of qualified human resources available in the State, the posts for Drug Inspectors are inadequate. In 2009-'10 Maharashtra's sanctioned posts were 161 while the vacancies were 45 per cent (73).But going by the Mashelkar Committee recommendations on workforce norms, the State requires 433 drugs inspectors and the shortfall is 80 per cent.

The study found that only a quarter of manufacturing and sales units were inspected by the Maharashtra FDA, when all should have been inspected at least once in a year as per the Drugs and Cosmetics Act. During 2009-10, 7.94 per cent of the drug samples tested in two state drug regulatory laboratories were found sub-standard.

The 59th Parliamentary Standing Committee report states that the rapid growth of the pharmaceutical industry imposes an annual 20 per cent increase in the workload of the overall drug regulatory mechanism. The Maharashtra FDA has proposed expansion of its sample testing capacity from 8,000 to 80,000 annually– almost double the current sample testing capacity of the country. This will require the appointment of more trained drug inspectors, along with provisions for their career growth, sustained training and efficient deployment.



PARTNERS

http://www.amasa-project.eu/

University of Edinburgh, Edinburgh, UK (Project Coordinator)

The Swiss Tropical and Public Health Institute, Basel, Switzerland

University of Ghent, Ghent, Belgium

Queen Mary University of London, London, UK

Mbarara University of Science and Technology, Mbarara, Uganda

University of the Western Cape, Cape Town, South Africa

Makerere University, Kampala, Uganda

Foundation for Research in Community Health, Mumbai, India

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**The study recommends:**

❖ Amendment of the Drugs and Cosmetics Act and Rules to include workforce planning norms. The Mashelkar Committee recommendations should be included in the rules promulgated under the Act. The legislation needs to be regularly re-assessed to take account of the growth and increasing complexity of the Indian pharmaceutical industry.

❖ Focus on rural areas where funding and capacity building must take account of distances involved in coverage.

❖ Transparency in the functioning of the drug regulatory authority with information made available in the public domain. This would include creation of a central database for the country and by individual states that reveals:

- ➢The number of drugs inspectors and other supporting staff.
- ➢The total number of sales and manufacturing units.
- ➢The number of f inspections conducted and their outcomes.
- ➢The names of repeated violators who manufacture spurious and sub-standard drugs and the action taken.
- ➢The extent of unsafe drugs in the market.

**Table: Number of manufacturing units, sales units, inspections and actual and required numbers of inspectors in India (2011-12) and three study districts ( Dhule, Nagpur, Sangli) 2009-10 (The headline should be in normal bold. Remove capitals)**

| | Number of Manufacturing units (a) | Number of Sales units * (b) | Expected Inspections (Drugs & Cosmetics Act) (c = a+b) | Actual inspections conducted (Actual % of expected) | Number of Drug Inspectors: Actual (Sanctioned posts) | Number of required Drug Inspectors Maharashtra FDA norm ( Shortfall %) | Number of required Drug Inspectors Mashelkar Committee norm (Shortfall %) |
|---|---|---|---|---|---|---|---|
| **India (2011-2012)[1]** | | | | | | | |
| | **10563** | **600000§** | **610563** | **Data not available** | **846 (1349)** | **Not Applicable** | **3211 (74)** |
| **Maharashtra (2009 - 2010)[2]** | | | | | | | |
| | **1523** | **80417** | **81940** | **19195 (23)** | **73 (161)** | **332 (78)** | **433 (83)** |
| **Study districts # (2009 - 2010)[2]** | | | | | | | |
| **Dhule** | 10 | 2094 | 2104 | 238 (11) | 0 (NA) | 8(100) | 11 (100) |
| **Nagpur** | 95 | 4039 | 4134 | 1010 (24) | 4 (6) | 17 (76) | 22 (82) |
| **Sangli** | 32 | 2225 | 2257 | 246 (11) | 1 (4) | 9 (89) | 12 (92) |

NA – Information not available, * Sales Units – Retail and whole sale pharmacies; distributors; carrying and forwarding units.§Estimates. # Segregated data for Mumbai and Mumbai city district is not available.1:59th report on the functioning of the Central Drugs Standard Control Organisation (CDSCO), Department Related Parliamentary Standing Committee on Health and Family Welfare (2011-2012).2: Annual Plan 2011-2012, Medical Education and Drugs Department, Maharashtra, age no. A21.

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