Following strong objections from drug manufacturers to the new spurious drugs law as per the Drugs & Cosmetics (Amendment) Act, 2008, the Union ministry of health has come out with a set of guidelines for the state drug control organisations to act on offences by ensuring justice to law abiding manufacturers and traders.

The guideline, issued early August 2009 for framing a standard operative procedures in each state to examine and process various violations of the amendment act, suggests the state drug control organisations to have internal mechanism of checks and balances to ensure that law abiding manufacturers and traders of drugs are not harassed or put to a disadvantageous position.

The guideline classifies the defects in pharmaceutical products as three categories, A, B and C. The spurious and adulterated drugs under category A, grossly substandard drugs as category B and minor defects like broken or chipped tablets, cracking of emulsions, change in colour of the formulation under category C. The Category B and C are defined further in order to avoid false categorisation of defects.

In case of not of standard quality reports based on minor defects arising out of variations from the prescribed standards of contraventions, the authority may be resorted to measures including suspension, cancellation or compounding offences and launch prosecution only if it is justifiably felt that above measures would not meet the ends of justice.

"Section 36 AC which makes certain offences under the Act cognizable and non-bailable has been inserted to facilitate the arrest of anti-social elements involved in the manufacture of spurious or adulterated drugs. The section should therefore be invoked with utmost care and only in cases where it is justifiably felt that it is essential to book the culprits for proper investigations in the case," explains the guideline, prepared after the hues and cries of the manufacturers alleging that the stringent actions would malign the legitimate and genuine pharma companies, to the state drug control officials.

The guideline also asks the state drug control departments to constitute screening committees comprising of at least three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are proposed to be launched. The committee will have the onus to submit written opinion on the investigation reports regarding their feasibility of taking legal action, by considering various factors.

The inspectors should launch prosecutions on the basis of written permissions of the controlling authority and this authority in turn shall consider the recommendations of the screening committee while taking final decision in the matter, according to the guideline.
Further, as an effort to bring in co-ordination between the regulatory authorities, the state drug control organisations should notify a nodal officer with telephone and fax number at the headquarters as well as circle levels, which could be contacted by other regulatory authorities for exchange of information and co-ordination in search, seizures, raids or investigations in the spurious drug cases. Details of these officers should be forwarded to the office of DCGI.

The pharma industry in the country, which missed to give its suggestions on the law at the allotted period of 45 days after notification of the draft amendment act, has later raised its concerns over the provisions in the regulation. The new guideline comes as a result of several meetings conducted by the DCGI and other officials with the pharma companies and various related associations.

Source:- Pharmabiz