ANTIBIOTICS POLICY BRINGS SCHEDULE HX TO THE ACT

June 2011

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The Ministry has completed drafting of the national antibiotics policy and will insert a new Schedule HX under the Act with a view to preventing the misuse of about 70 antibiotics. This draft has been sent to the Law Ministry before seeking approval of the Drugs Technical Advisory Board . The Drugs Consultative Committee had already given its go-ahead to the proposal. Currently the antibiotics are placed under the Schedule H of the Act. Antibiotics would be categorized as non-restricted, restricted and very restricted. Each category would have a distinct colour code for the benefit of consumers. The policy would include a list of antibiotics that cannot be sold without doctors' prescription. The new Schedule HX that will apply to both public and private health sectors, will require doctors and chemists to retain prescriptions and doctors will have to give two prescriptions to every patient and one copy should be kept for a period of 2 years by the chemists. The Drug Controller General of India can audit it any time and violations will be punished with a fine of INR 20,000 or up to 2 years imprisonment.

PSA view – The new policy is likely to have curbs on doctors who would be allowed to prescribe only selected antibiotics and, if needed, they will have to justify the prescription of the drugs to hospital committees and drug and therapeutic committees that will monitor them. A panel was set up after the superbug New Delhi Metallo-beta-lactamase 1 (NDM1), which was alleged to be resistant to the most powerful antibiotics started affecting India's medical tourism business.

NPPA revising the norms for CC, PC, PL and PM

The NPPA has launched the process of revising and fixing norms for CC, PC, PL and PM for the year 2011 as per the provisions of DPCO. For this NPPA has started collecting inputs from the industry by sending a detailed questionnaire to them. The norms for CC, PC, PL & PM are generally based on the actual cost data and information received from various manufacturers and formulators. The technical and cost details in respect of any new packing/packing material which is not covered under the existing notified norms and has been recently introduced with latest and innovative technology has to be provided separately. A suitable method of indexing the variable & major cost elements, which constitute CC & PC and the appropriate basis for indexing process losses has also been sought from the industry.

PSA view – The PL, CC and PC are considered as per the norms notified in the Gazette vide S.O. 578(E) dated July 13, 1999. The PM cost is allowed as per the actual claim supported by invoices and after referring

to information available with NPPA. The ceiling prices are fixed or revised under Paragraph 9 of DPCO, 1995 for commonly marketed standard pack sizes of price control formulations. The formula to determine the RP of a drug as followed by NPPA is "R. P. = [M. C. +C. C. +P. M. +P. C.] x [1+MAPE/100] +E. D.", where – **R.P**. is retail price, **M.C.** is material cost, and **E.D**. is excise duty. It is this price that is printed on the pack of a DPCO-controlled formulation. This price is not the Maximum Retail Price ("**MRP**"). Local taxes are additional. MRP is the RP that is fixed in accordance with the provisions of the DPCO and includes a ceiling price, at which the drug may be sold to the ultimate consumer and where such price is mentioned on the pack, the words "Maximum or Max. Retail price inclusive of all taxes" shall be printed on the pack. It is obligatory for all, including small scale units, to follow the ceiling prices which are notified in the Gazette of India (Extraordinary).

NAC-SCRT to revise Guidelines for stem cell research regulation

NAC-SCRT has the responsibility to examine the scientific, technical, ethical, legal and social issues in the area of stem cell based research and therapy in the country and every institution involved in any type of stem cell research and therapy should be registered with the NAC-SCRT through their Institutional Committee. Recently, NAC-SCRT has decided to revise the Guidelines for stem cell research regulation in India. NAC-SCRT has to set up standards for safety, quality control, procedures for collection and its schedule, processing or preparation, expansion, differentiation, preservation for storage, removal from storage to assure quality and/or sterility of human tissue, prevention of infectious contamination or cross contamination during processing, carcinogenicity and xenotransplantation.

PSA view – The Guidelines is crucial as stem cell research raises many ethical, legal, scientific, and policy issues that are of concern to the policy makers and general public. The Guidelines for stem cell research regulation came up in 2007 and prescribed strict procedures for souring and the use of stem cells by research institutions. However, several developments have occurred so far making several clauses redundant and essential to amend the Guidelines.

DoP issues UCPMP

In order to control the unethical practice of bribing doctors by the pharma companies for prescribing their drugs, the DoP has issued UCPMP. However, UCPMP shall initially be voluntary and its implementation will be reviewed by the government six months after it comes into force. In case it is found that UCPMP is not being adhered to by the pharma companies, the government shall consider making it statutory code and thus, compulsory. UCPMP shall prohibit pharmaceutical company from giving, offering or promising to give gifts, pecuniary advantages or benefits to persons qualified to prescribe or supply drugs. The DoP has asked the pharma associations and other stake-holders to send their feedback by June 30 this year.

PSA view – The introduction of UCPMP shall assist in curbing the unethical practice of bribing doctors by pharma companies. However, until and unless it is made mandatory, very few pharma companies will follow the voluntary code.

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