BAR CODES ON INDIAN MEDICINES TO CURB FAKE

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Early in 2011, the Drug Consultative Committee ("**DCC**") had approved the proposal for every strip of medicine in India to have a 2D bar code and a unique randomly generated numeric code. The proposal came into effect on October 1, 2011 and as per this proposal, it become compulsory that a phone number be mentioned above the bar code allowing a consumer to SMS the code to verify the authenticity of the medicine by receiving a returning SMS. However, it seems that the implementation of barcoding on secondary level packaging has run into deep waters. The Madras High Court has ordered a stay on the implementation of barcoding, which means that until further notice, the exporters are not required to implement barcoding on secondary level packaging.

Ministry issued Knowledge Management Policy

The Department of Health Research under the Ministry had issued the draft Knowledge Management Policy for Health – services, education and research which aims to change the focus from the people who manage knowledge to those whose health is managed. The core objectives of this policy are: (**a**) to make authentic information about health knowledge services available to health professionals, planners, managers, policy makers and common man; (**b**) to promote sharing of health resources in health services delivery, education and research; (**c**) to manage health aspects of disasters effectively using knowledge management tools; (**d**) to enable access to high quality health and medical education; (**e**) to contribute towards development of an efficient health research system; and (**f**) to ensure health equity across the different social sections of the community. The policy primarily proposes the establishment of a 'Authority for Knowledge Management' which will develop and implement a comprehensive plan for utilization of the knowledge network for health service delivery, medical education and research. Additionally, the responsibility for strategic planning, implementation and review of progress from time to time for the plan would also remain on the body so created. By developing a roust and efficient knowledge management system, the policy will allow scientists, researchers, students, specialists, and other stakeholders to work closely for advancing medical development in critical areas. The efficiencies reached due to the implementation would harmonize the health service sector and its interaction with the public vis-à-vis providing services and disseminating knowledge as well as increase the accountability of healthcare professionals and services towards human life.

Schedule HX to the Act

During 2011, the Ministry also completed drafting the national antibiotics policy to insert a new Schedule HX under the Act to prevent misuse of approximately 70 antibiotics. The draft policy was forwarded to the Law Ministry before seeking approval of the Drugs Technical Advisory Board as opposed to the DCC which has already given its go-ahead to the proposal. At present, antibiotics are covered under the Schedule H of the Act. Under the proposed policy, antibiotics would be categorized as non-restricted, restricted and very restricted and 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 will also require doctors and chemists to retain prescriptions and an additional obligation on the chemist to retain the prescription for a period of 2 years. This would be subject to audit by the DCGI at any time and violations are made punishable with a fine of INR 20,000 or up to 2 years imprisonment. The proposed policy is a good measure to check doctors and physicians who prescribe antibiotics with an open hand and also on chemists and pharmacists that sell antibiotics without prescriptions. In addition to this, doctors 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. This policy is however yet to see implementation.

National Pharmaceutical Pricing Authority revising the pricing norms

In mid 2011, the NPPA launched the process of revising and fixing norms for Conversion Cost ("**CC**"), Packing Charges ("**PC**"), Process Loss ("**PL**") and Packing Material ("**PM**") for the year 2011 under the DPCO. The NPPA had started collecting inputs from the industry by sending a detailed questionnaire to them. The norms for CC, PC, PL and 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 was also been sought from the industry. PL, CC and PC are taken into considered under 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 the DPCO 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 scheduled 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).

DoP issues Uniform Code of Pharmaceuticals Marketing Practices ("UCPMP")

In order to control the unethical practice of bribing doctors by the pharma companies for prescribing their drugs, the DoP has issued UCPMP. The compliance with the UCPMP initially is voluntary and its implementation would be reviewed by the government after it comes into force. While not in force at present,

where the government is of the opinion that UCPMP is not being complied with, the government shall consider making it's adherence mandatory. UCPMP prohibit pharmaceutical company from giving, offering or promising to give gifts, pecuniary advantages or benefits to persons qualified to prescribe or supply drugs. 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.

CDSCO draft guidance for industry in reporting SAEs in clinical trials

In order to further streamline the clinical trials sector in India, CDSCO has framed guidelines for reporting SAEs occurring during the clinical trials with the intent to bring uniformity and completeness of data in the process of reporting SAEs. Pursuant to Schedule Y of Drugs & Cosmetics Rules all unexpected SAEs have to be reported to CDSCO within 14 calendar days and there is no format for such reporting. Every report (*both initial as well as follow-up reports*) should be submitted along with a covering letter. Unexpected SAEs have to be submitted to this office as per Schedule Y of Drugs and Cosmetics Rules, 1945. The assessment report should clearly mention whether the SAE occurred is related or not related (*Situations like unlikely, possibly, suspected, doubtful etc. should not be used*). This is seen as an attempt to collect data to get a better idea of the number of deaths occurring during clinical trials as in the past the DCGI had to face numerous queries from Parliament on the increasing number of trial-related deaths wherein it was also accused of approving trials without ensuring that the study protocol addresses patient safety issues sufficiently. It is crucial to note that the DCGI has already been advising stakeholders to include a line in the informed consent form, assuring the patient/volunteer that he will be provided complete medical care and compensation for any clinical trial-related injury.

DGCI commences audit of CROs

The DGCI has commenced and is carrying out systematic auditing of all CROs across India. These audits are being conducted primarily to ensure the bio-availability and bio-equivalence ("**BA/BE**") studies are carried out in strict compliance with the applicable regulatory guidelines and Schedule Y of the Act. According to news reports, the DGCI has completed the audit in two states and plans to intensify the audit process in other states. The call for audit of CROs was initiated by the DGCI after receiving several complaints against a Hyderabad based CRO that was carrying out clinical trials for a breast cancer drug. It was alleged that CRO was carrying the clinical trials on illiterate agricultural laborers by luring them with an offer of INR 10,000, instead of carrying out the study on rats or guinea pigs in flagrant violations of the DCR. The DGCI in that case had found irregularities and had suspended approvals for all BA/BE studies in Hyderabad.

National vaccine policy finalized

In order to strengthen the Universal Immunization Program, the Ministry has finalized a Policy that aims to strengthen the institutional structure, processes and framework required for decision making for strengthening the UIP. While trying to streamline the decision-making process involved in introduction of new and under-utilized vaccine, the Policy also addresses the issues of vaccine security, regulatory guidelines, vaccine research and development and product development. It is to be noted that the date of implementation of this Policy is yet to be notified by the Ministry. The success of immunization program in

any country depends more upon the effectiveness of its policies. Though, this Policy holds a lot of promises, what needs to be seen is how effectively will the Policy be implemented. As per a report published by the World health Organization in 2002, the main problem with the UIP was the delay in delivery of vaccination. Though, the Infrastructure in the health care sector has improved since 2002, the question that needs to be answered is that will the Policy be able to reach out on time to the majority in need, if not all.

DCGI to issue guidelines on compensation to clinical trial victims

Due to ambiguity on the law on compensation to clinical trial victims, the DCGI has announced that they will soon be issuing guidelines on providing proper compensation to the victims of the trials. Though the Indian Council for Medical Research ("ICMR") Ethical Guidelines for Biomedical Research on Human participants, 2006 have specified the need for provision of compensation of participants for research related injuries, due to a lack of clear guidelines in this regard, the sponsors of the trials very often exploit the participants by simply providing some treatments. In absence of a binding law for providing compensation to such victims and due to a public outcry on the same, the issue has caught the attention of the drug authorities in the country. In November 2008, the ICMR issued a draft guideline for compensation to participants for research related injury. The draft guideline would bring uniformity in giving compensation to the participants and apply to all clinical research uniformly. However, the draft is still to be released. It is sad that even after 22 trial related deaths in 2010, no concrete guidelines exist on compensation to trial victims. There is a lot of expectation from the DCGI and it is hoped that these guidelines are enforced and made mandatory.

Food Security Bill ("Bill") to be introduced in Parliament

The Bill has received Cabinet approval and is to be presented to the Parliament at its current session in December 2011. Once the law is implemented, the food subsidy bill is expected to rise by Rs 27,663 crore at nearly Rs 95,000 crore, while food grains requirement would go up to 61 million tonnes from 55 million tonnes, as per the Cabinet proposal. The Bill provides that that the government would reimburse the states in case there is any shortage of food grains due to fall in production caused by natural calamities such as drought and floods. Where food grain or meals are not provided to entitled persons, the concerned State would be required to provide "food security allowance" in terms of monetary compensation. Further, a three tier grievance redressal mechanism has also been provided for under the Bill to deal with issues related to enforcement of entitlements. The Bill stipulates a penalty up to Rs 5,000 on public servants or authority if found guilty of non-compliance.

PSA view 2011 – The year 2011 has seen rapid development of regulations in food and pharma sector with several more in the pipeline. The Biomedical Research Bill, Transplantation of Human Organs and Tissues Act, Task force to develop software for drug manufacturing & tracking system, Drugs and Cosmetics (First Amendment) Rules, NAC-SCRT revising the stem cell research guidelines, reward scheme for whistle blowers, legislation to regulate fertility clinics and policy to curb imported drug prices are some of the regulatory changes in the offing. Specifically, the measure by the DGCI for auditing the CRO is a beneficial step in ensuring that innocent and illiterate individuals are not taken advantage of and compliance with the consent and ethical requirements for clinical trials under the Act and corresponding Rules are met. The DGCI should implement stringent compliance requirements, especially in clinical trials as India is seen as a viable and relatively cheap market for conducting clinical trials due to its vast population, and to a certain extent, lack of education amongst a majority of the populations.

The food sector is also streamlining itself to the changing needs of the industry with Food Safety and Standards Rules, 2011 and the Food Safety and Standards Regulations 2011. The Food Safety and Standards Authority of India is constantly laying down science based standards for articles of food. While the intention of the latest Bill is clear and necessary, and the fact that it provides consideration for special groups such as women, children, destitute and people affected by natural disasters, considering the insurmountable fiscal implications, it remains to be seen whether implementation of the Bill would actually provide any respite. Hopefully, we will enter the new year with the needs of the citizens below poverty line and destitute citizens been addressed under the Bill.

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