NPPA TO START SMS SERVICE FOR SENDING BRAND NAME OF DRUGS WITH PRICES

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The Government is in the process of rolling out a SMS service whereby which consumers can choose the cheapest brand of a drug prescribed by doctor by sending the brand name of a prescribed drug in a text message. The consumer shall receive a SMS from the NPPA listing out the brands of the same medicine along with their prices, thus providing an option to the consumer to choose the cheapest brand. The programme is being executed by the NPPA along with the department of pharmaceuticals. There is a significant difference in the price of the costliest brand of a medicine and its cheapest alternative. A recent survey by NPPA found that prices of the expensive brands can be ten times higher than the cheapest alternative of the same medicine.

PSA view – Drugs are not allowed to be advertised, which is why many pharma companies indulge in illegal and unethical practices to ensure that doctors prescribe their drug. This move by the NPPA shall help in reducing healthcare costs for the masses; however, it is not advisable to sell substitute brands for prescription medicines as brand substitution can be harmful.

CDSCO draft guidance for industry in reporting SAEs in clinical trials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 an 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). The guidance document specified that "*at present various pharmaceutical companies and contract research organizations (CROs) are using multiple / different formats and procedures for reporting SAEs to CDSCO. Though most reports adhere to Appendix XI of Schedule Y, multiple formats and missing information, including improper referencing for submission of follow-up reports have lead to difficulties in segregation and further processing of these reports by this office. Hence, this guidance document has been developed to achieve uniformity and completeness of data*

received by this office with respect to SAE reporting in clinical trials." The adverse event has been defined as "any untoward medical occurrence (including a symptom/disease or an abnormal laboratory finding) during treatment with a pharmaceutical product in a patient or a human volunteer that does not necessarily have a relationship with the treatment being given." And a serious adverse event is "an adverse event that is associated with death, in-patient hospitalization (in case the study was being conducted on out-patients), prolongation of hospitalization (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening."

PSA view – 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 recent past Drug Controller General of India ("**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 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 Drugs and Cosmetics Rules, 1945 ("**DCR**"). According to recent 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 rates 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.

PSA view – 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 DCR 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. It is essential to implement and enforce strict compliance requirements as well as periodic audits of the CROs and other agencies associated with clinical trials in India in order to bolster the image of India as a clinical trial destination and to give more validation to the clinical trials conducted here. It is also imperative that the DGCI enforce strict penalties against violators of the compliance requirements and for any flouting of the DCR and its provisions.

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