SCHEDULE Y OF THE RULES TO GO UNDER KNIFE!

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The clinical trial on new drugs is regulated under the provision of D&C rule 1945 as amended from time to time. The rule provides that no clinical trial can be initiated without the grant of permission by the licensing authority and the condition prescribed there in. The detailed requirements and guidelines for undertaking the clinical trial are specified under schedule Y of said rule. Similarly, for import/manufacture of new drugs, the Union Health Ministry will soon amend the Note regarding the authenticity of the data or documents to be submitted by the applicant under Schedule Y of the Drugs and Cosmetics Rules, 1945 ("Note"). The Note shall provide that only authentic data should be submitted in the application for permission to import and/or manufacture new drugs for sale or to undertake clinical trials. The data will have to be self certified. Note will also provide that the licensing authority reserves the right to reject any data or any document(s) if such data or content of such document are found to be of doubtful integrity.

Therefore, the Drugs Technical Advisory Board has proposed that the Note be amended to read as under-

"The data requirements stated in this Schedule are expected to provide adequate information to evaluate the efficacy, safety and therapeutic rationale of new drugs (as defined under Rule 122-E) prior to the permission for sale. Depending upon the nature of new drugs and disease(s), additional information may be required by the Licensing Authority. The applicant shall certify the authenticity of the data and documents submitted in support of an application for new drug. The Licensing Authority reserves the right to reject any data or application or debar the applicant for a specific period to make any application to the office of Drugs Controller General (I) as the case may be if such data or contents of such documents are found to be of doubtful integrity."

PSA view – It is good to see that the Drugs Technical Advisory Board has filled up the legislative vacuum. Looking at the sensitiveness of the matter, be it import of drugs or clinical trial, this is a welcome move.

Regulation Specific to Medical Device Sector in the Pipeline

The Task Force on the Medical Devices Sector in India, constituted by the DoP, pursuant to the Prime Minister's Make in India campaign, has recommended enacting the Medical Device Regulatory Act ("Proposed Act") to lay down globally recognized and transparent regulations that specifically cater to medical devices sector.

The Proposed Act shall primarily focus on these concerns (i) simplify procedure relating to import, manufacture and sale of medical devices; (ii) formulate procedure for clinical trial of medical devices at par with international standards; (iii) re-classify the medical devices based on the risk factor upon its usage on

humans; (iv) integrate within MDR Act the regulations pertaining to radiation emitting medical devices; (v) ensure that the standards for safety, efficacy and adverse reaction reporting must be in consultation with Bureau of Indian Standards and National Health Systems Resource Centre; and (vi) set-up and implement single window model for obtaining regulatory clearances for operations pertaining to medical device sector.

PSA view – Implementation of Proposed Act shall aid in setting up a definite guideline for medical device sector ensuring that it is regulated by device relevant laws and not those relevant to drugs. Considering the interest of stakeholders, it is recommended that the new legislations must facilitate transforming the industry from an import dependant sector to a export oriented sector by promoting domestic manufacturers of medical devices and pharmaceutical equipments. Therefore, in our view, an initiative to formulate a industry specific legislation is commendable and it will be interesting to see its impact on the industry upon once implemented.

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