ASIA ACTUAL

RECENT PUBLIC NOTICES FROM THE CDSCO (updated Nov 2019)

Notice Date	Subject	Impact	Next steps
08 Nov 2019	Exemption for requirement of wholesale and retail drug license provided to hi-tech equipment like MRI, PET, X-ray, CT etc.	Positive impact. Most sale of hi-tech equipment is directly to hospitals and the requirement of a drug license for wholesale and retail was a redundant requirement.	Inform importers of such devices to maintain records of transactions, installations, maintenance, agreements etc. Final decision will be taken by the CDSCO in the DTAB.
08 Nov 2019	Definition of "All Implantable Devices" released and remains the same as defined in Medical Device Rules 2017.	Fifth Schedule - Quality Management System for medical devices and in vitro diagnostic medical devices: **Implantable medical device. -** Medical device intended: a. to be totally or partially introduced into the human or animal body or a natural orifice; or b. to replace an epithelial surface or the surface of the eye by surgical intervention, and which is intended to remain after the procedure for at least thirty days, and which can only be removed by medical or surgical intervention.	Notice seeks to bring clarity over what constitutes an 'implantable device'
08 Nov 2019	Environment control for Medical Equipment and other soon to be regulated medical devices.	The notice clarifies that the environmental conditions required include those as per Vth Schedule, MDR 2017 such as **well-ventilated area with neat and clean environment, free from dust and other particulate matter, with air-conditioning.**	The change is pending approval of the DTAB and stakeholder comments are invited.
13 Nov 2019	Exemption to composite devices that measure temperature and BP despite having another different primary purpose.	Composite Devices that include Digital thermometer, Blood Pressure monitors but whose primary intended purpose is composite and not to specifically measure temperature or blood pressure are being exempted from the registration requirements.	The notice provides much needed clarity to manufacturers and importers of such devices.