Govt Sets New Guidelines For Medical Device Grouping To Streamline Licensing Process (21-03-2018)

New Delhi, 21 March 2018: The Union health ministry has issued a set of *comprehensive guidelines for grouping medical devices* which is expected to streamline the application process for obtaining manufacturing or import licence. The norms will come in handy for individuals or companies applying for a licence and are aimed at regulating medical devices industry in the country on par with international standards.

The guidelines, prepared in accordance with the Medical Devices Rules, 2017, categorise medical devices into six brackets -- Single, Family, IVD Test Kit, System, IVD Cluster and Group. An applicant is allowed to group medical devices having same or similar intended uses or commonality of technology and submit a single application for a licence to manufacture or import it.

According to the notification, a single medical device is a product sold as a distinct packaged entity and does not meet the criteria for other specified categories. It may be sold in a range of package sizes but must be licensed separately. Even if the devices are a part of a Group, it must be licensed separately before it is sold in the market, the guidelines say.

For instance, condoms are sold in packets of 3, 10 or 16 but can be licensed as a single medical device application. However, if a company that assembles a first aid kit decides to supply each of the devices in the kit individually, each product supplied separately must be licensed as a single medical device.

A medical device Family is a collection of products from the same licence holder, have same risk classification class, have a common intended use, have the same design and manufacturing process and their variations should be within the scope of the permissible variants.

To give an example, spherical contact lens with additional features of UV protection can be licenced as part of a Family, as this feature does not affect the basic design or manufacturing of the lens. But contact lenses are available as toric lens and spherical lens. These products have different intended purposes and performances. They are designed and manufactured differently and cannot be considered as members of a Family.

Regarding In Vitro Diagnostics Test Kit, the guidelines state that it is a device that consists of reagents or articles which are from same licence holder, intended to be used in combination to complete a specific purpose, sold under single proprietary test kit name and compatible when used as a test kit. An In-Vitro Diagnostics Kit does not include the instruments such as analysers needed to perform the test.

By way of illustration, an Enzyme Linked Immunosorbent Assay (Elisa) Test Kit, used to check presence of Human Immunodeficiency Virus (HIV) infection, may contain controls, calibrators and washing buffers. All the reagents and articles are used together to detect HIV and therefore can be licenced as Test Kit. These reagents and articles can be supplied separately as replacement items for that particular test kit.

A set of medical devices belongs to the System category if they are intended to be used in combination to complete a common purpose, compatible when used as a system and are sold under single proprietary system name.

An In Vitro Diagnostics Cluster comprises a number of in-vitro diagnostics reagents or articles which are from same licence holder, of a common methodology, are sold under single proprietary name and are compatible when used as a test kit.

A medical device Group is a collection of two or more products, supplied in a single package by same license holder, may have different proprietary names and intended purposes. They might be designed and sold by different licence holders.

The collection of medical devices in a Group may differ in the number and combination of products, while maintaining the same proprietary name and intended purpose. To give an instance, a first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package, can be licenced as a Group.