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Pitkar Orthotools and Quality – an Ongoing Commitment

- We are glad to inform you that Pitkar Orthotools has been granted the **FDA Drug Manufacturing Licence (Form 28)** for it's manufacturing and selling activities in relation to orthopedic implants and medical devices.

- SHPOPL was the **first company to submit an application** for having its manufacturing facilities evaluated and certified, under the Drugs Control Act, as we were confident of our facilities, processes, and products.

- This confidence has been justified as we have been granted the licence without any changes being required in our manufacturing activities.

- Our approach to quality always been a pro-active one and we have had our implant range certified by the CE and relevant ISO marks even before any kind of certification was mandatory in the Indian scenario.

- This drive towards self-improvement, despite the higher costs involved in attaining these benchmarks, was driven by our commitment to the motto “Quality will be our topmost priority”.

- Therefore, even before it became mandatory to do so by law, our manufacturing facilities met the high standards set out by the European Union, in terms of GMP (Good Manufacturing Practice). Post – manufacture, our implant cleaning and packing departments were of a standard that was dictated by international standards, and included HEPA filtered air, microbiological monitoring to keep a low bacterial load even in the unsterile implants.

- Our implants and instruments were and are manufactured of materials that met or surpassed internationally accepted, relevant specifications like the ISO, and ASTM

What this certification means to us:

- We are happy that our users – Doctors, and the end consumer – the patient will benefit by the proper application of quality standards to the Implant Industry in general.

- We are glad that we have had yet another independent body looking at our facilities and giving a stamp of approval to our facilities, and processes.

- Our products have been legally safe, right from the day that the application was made for the licence, as required by the DCGI notification in 2006, since the notification specifies that units that have been in the business can continue to work, pending their application being processed.

- Now, with the grant of the licence, implants manufactured by SHPOPL meet all the legal requirements in India, in addition to international quality requirements that they have met even before this.

What this certification means to our partners/distributors:

- They do not need to worry about being accused of dealing in “spurious drugs”; as under the Act, “drugs” (implants in this case) manufactured by a non-licenced manufacturer, are considered “spurious drugs”, with relevant action/punishments provided in the Act.

What this means to Hospitals and Doctors who directly purchase our implants for use on patients:

- As mentioned above, implants manufactured by SHPOPL **meet all the legal requirements in India today**, so there is no worry for end users re: any possible problems of contravention of the DCA.

- While the law has not been strictly applied in the case of implants as yet, because of lack of awareness and possibly ongoing processes of implementation, ultimately it is our belief that **this law will be applied to implants as strictly as it is applied to other drugs today**.

Clarification:

Some companies are claiming that there is confusion in the law, as it applies only to "sterile implants", and that there is a court stay on the application of the law. **This is not true. The facts are as follows**:

- About 21 manufacturers from tiny industry sector in & around Bhynder, Mumbai have submitted a writ Petition **upon receiving notices from local FDA office to stop activity of manufacturing till application for Licence is submitted**.

- The honorable Court has advised status quo to them **till other party namely local FDA is heard**. Thus, there is no stay on such procedure or licensing per se.

- The position regarding whether the notification refers to sterile or unsterile implants is cleared by clarification given on the CDSCO (Central Drugs Standard Control Organization) at http://cdsco.nic.in

A copy of the public notice regarding registration, and the clarification are included and are self-explanatory.
http://cdsco.nic.in/Medical%20devices.pdf
http://cdsco.nic.in/clearification.pdf