Pharma & Healthcare Update

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RISK CLASSIFICATION OF MEDICAL DEVICES AND IVDS PUBLISHED! COUNTDOWN FOR JANUARY 1, 2018 BEGINS!

- On November 1, 2017, the government published risk classification of medical devices and in-vitro diagnostic products and kits (IVDs) on the basis of their intended use.
- This development is significant because the risk classification of a medical device or IVD determines how it will be regulated after January 1, 2018 when the Medical Devices Rules, 2017 take effect.
- As of now, only those medical devices that are presently regulated have been classified.
- The classification is non-appealable. However, the regulator is open to revise the classification from time to time.
- Presently unregulated medical devices may be regulated and given risk classification in future.

INTRODUCTION

On November 1, 2017, India's central medical device regulator, the Central Drugs Standards Control Organization ("Central Regulator"), published a revised risk classification of medical devices and IVDs on the basis of their intended use. It may be accessed by clicking here. This is an extremely important development for the medical device and IVD industry because, January 1, 2018 onwards, the Central Regulator will regulate all medical devices and IVDs as per their risk classification. A device or IVD with low risk classification will be sparingly regulated. A device or IVD with high risk classification will be tightly regulated.

The revised classification is significantly different from the old classification because it covers only those medical devices that have been already notified as "drug" by the Government of India. The earlier classification covered all medical devices irrespective of whether they were notified by the Government or not. A list of medical devices notified by the Government of India is reproduced at the end of this hotline for reference.

At present, the Central Regulator has classified 328 medical devices into various risk classes. A convenient (but not perfect) way to check whether a company's medical device has been classified or not is as follows : If the device is regulated as on date, i.e. if an import registration / license or manufacturing license for the license has been obtained, then the device in all likely hood has been classified.

With respect to IVDs, the Central Regulator has classified 247 IVDs into various risk classes. All IVDs, excepting IVDs for HIV, Hepatitis B and Hepatitis C, are presently regulated as drugs. The excepted IVDs are presently regulated as notified medical devices. From January 1, 2018, all IVDs will be regulated as medical devices only.

Please note that apart from medical devices and IVDs, the Government has also given a risk classification for surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures and mechanical contraceptives (condoms, intrauterine devices, tubal rings) because from January 1, 2018, these products will be regulated as medical devices under the provisions of the Medical Devices Rules, 2017.

BACKGROUND

The Medical Devices Rules, 2017 ("MDR") will take effect from January 1, 2018 and regulate medical devices, IVDs and other products referred to in the paragraph above as per the risk classification published yesterday (i.e. on November 1, 2017). This is unlike other jurisdictions where the risk class for a product is usually chosen by the company itself and endorsed by the regulator.

Under the provisions of MDR, once a medical device or IVD has been classified for risk by the Central Regulator, the classification is not appealable. This is also why the revised classification assumes great importance for the medical device and IVD industry.

Those who wish to know more about MDR and its impact may refer to our detailed analysis of MDR by clicking here.

ANALYSIS

The decision of the Central Regulator to restrict risk classification at present to only those medical devices that have been notified by Government of India (and therefore are currently regulated) appears to be in line with the provisions of MDR, which grant power to the Central Regulator to regulate only those devices that the Government has notified as "drugs" under the Drugs and Cosmetics Act, 1940.

Though the risk classification is not appealable, it may be pragmatic for the companies in the business of medical devices and IVDs to formally submit their concerns about the present risk classification to the Central Regulator with a request for revision. The formal submission may come-in handy in the next cycle of revision. The Central Regulator

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has itself acknowledged that the classification is dynamic in nature and may be revised from time-to-time.

The relevance of publication of the risk classification is that companies whose products are covered by the classification can now start preparing fresh applications for issuance of license under the MDR in line with the risk classification. In absence of the risk classification, it would have been futile to start preparations because every risk class is regulated differently under the MDR. Different risk classes have different license application forms under the MDR as well. Please note that the Central Regulator and state-level licensing authorities will not have the power to accept application for renewal of existing license and registrations of medical device, IVDs and other products covered in the risk classification from January 1, 2018. This is because all of the existing licenses and registrations for the aforementioned products have been issued under the Drugs and Cosmetics Rules, 1945 which will be superseded by MDR from January 1, 2018. After January 1, 2018, all companies engaged in the business of aforementioned products will have to make applications for issuance of fresh license under MDR. All existing licenses and registrations for these products will be valid until their expiry, post which they will not be renewed.

As a side note, it is worth knowing that the internet portal from where applications under MDR will have to be submitted is not yet operational. Therefore, it is possible that the industry may get some relaxation in time-lines for making the application under MDR after January 1, 2018.

CONCLUSION

With the publication of revised risk classification in line with provisions of MDR, the Central Regulator has made it clear that it is serious about giving effect to MDR from January 1, 2018. All medical devices companies and IVD companies whose products are currently regulated should review the risk classification of their products since the risk classification has the potential to directly impact the process for applying and obtaining a business license as well as the scope of compliances to be undertaken for marketing of the product in India. Those medical devices companies whose products are not currently regulated should also take note of the risk classification because the Government of India may notify other medical devices in future. Upon such notification, the Central Regulator will classify those medical devices in the same manner as it has classified the presently regulated medical devices.

List of categories of medical devices currently notified by the Government of India : Ablation Devices, Bone Cements, Cardiac Stents, Catheters, Disposable Hypodermic Needles, Disposable Hypodermic Syringes, Disposable Perfusion Sets, Drug Eluting Stents, Heart Valves, I.V. Cannulae, In vitro Diagnostic Devices for HIV, HbsAg and HCV, Internal Prosthetic Replacements, Intra Ocular Lenses, Orthopedic Implants and Scalp Vein Set.

– Anay Shukla & Dr. Milind Antani
You can direct your queries or comments to the authors

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