Newsletter

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June 2014

Welcome to the June edition of the newsletter. This edition brings to our readers a featured article on "*Medical devices in India*".

Medical devices have now become an integral and important part of the pharmaceutical industry. They are treated at par with drugs in terms of therapeutic uses and efficacy and as such are subject to stringent regulatory norms across the world. India has been recognised as one of the countries where the pharmaceutical sector has seen a lot of dynamic growth and is expected to continue to grow at an astonishing rate. All the growth and development patterns only lead to one logical conclusion- increased regulatory controls. The regulatory controls as applicable to medical devices in India still have grey areas in terms of applicability thereof to devices across the board. The instant article is but an overview of how and where these regulatory controls apply to medical devices in India.

Recently, as of June 9, 2014 the Ministry of Corporate Affairs has issued a notification pursuant to which it has restored the requirement of all companies, including private companies having paid up capital of INR 50 million or more to appoint a whole-time company secretary. Prior to this notification, the private companies were exempted from this requirement.

We continue to highlight certain key judgements passed by the Hon'ble Supreme Court of India as well as changes in corporate and commercial matters, case laws in indirect taxation.

Your inputs and feedback are always welcome and we look forward to our interactions with you.

For further information, contact:
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Pharmaceutical / healthcare update

Medical devices in India

Definition of medical devices under the Drugs and Cosmetics Act, 1940.

Medical Devices per se do not have a separate and distinct definition under India Laws. Medical devices covered under the definition of "*drug*" as has been defined in the Drugs and Cosmetics Act of 1940 (**Act**) read together with the Drugs and Cosmetics Rules (**Rules**).

Section 3(b)(iv) of the Act includes certain devices under the definition of a Drug stating:

"…*"drug" includes…..*

(iv) …such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board".

As the above definition indicates, Medical Devices that are notified and identified so by The Indian Ministry of Health and Family Welfare (**Ministry**) have to be so identified and notified as a Drug under Section 3(b) (iv) of the Act.

Given the above, there is ambiguity regarding the regulatory regime applicable to devices that have not been so expressly classified. The but logical conclusion to draw therefore is that Medical Devices that are not classified as or do not fall under the definition of Drug as above, there is nothing under the Act pertaining to Medical Devices which would appear to hinder imports (into India) of Medical Devices that are not expressly identified and notified by the Government.

Central Drugs Standard Control Organization guidelines

The Central Drugs Standard Control Organization (**CDSCO**), part of the Directorate General of Health Services within the Ministry, is the regulator responsible for regulating medical devices in India. It is the responsibility of the CDSCO to monitor regulatory approvals granted Medical Devices in India and in furtherance of this purpose, the CDSCO has issued specific guidelines that pertain to certain identified devices primarily in the area of blood and blood products, IV fluids, vaccines and heart stents. The CDSCO has promulgated draft guidelines that identify a Common Submission Format for Import Licenses for medical devices in India. In addition, the CDSCO has also drafted a Guidance Document on the "*Common Submission Format for Registration of Medical Devices in India*". While these are at best guidance documents, they may be considered as an outline of the pathway for future medical device regulation in the country, an indicative guidance regarding the direction which CDSCO is likely to take in establishing its import and registration requirements for medical devices in the future

In addition to existing regulations and guidelines, there has been an attempt to amend the Act as well. In the proposed revisions to the Act, the Central Licensing Approval Authority, a branch of CDSCO, has been identified as the central approval authority for medical devices in India.

Registration and import licenses under the Act

Registration and import license are subject to the control of the Central Government.

Registration and import licensure requirements under the Act are limited to Medical Devices that are included in the above noted classification as drugs. To the extent that a device is not identified and notified, it could be inferred that such Medical Device would not come under the definition of drug as under the act and as such regulatory requirement might not apply. It may however be noted that, if a device is, at a later date identified as a Medical Device, falling under the definition of the term "*drug*", vide a Government notification to that effect, in such a scenario, the applicability (retrospective or prospective) of such notification would be based on the text of such notification and as such regulatory approval could very possibly be required at that time. There is usually a grace period given in case applicability of a notification is retrospective in nature.

Marketing and distribution licenses

Marketing and distribution licenses are subject either to the control of the State or Central Government, depending on specific circumstances.

Part VII of the Rules deals with licensure requirements for the "*Manufacture for sale or for distribution of drugs other than homeopathic medicines.*" Relevant licenses are applied for under Form 20 (Rule 61(1)) and Form 24(Rule 69(1) (c).

However, if a device does not fall within the category of devices that have been classified as a drug, it could very well be inferred that these requirements will not apply. However it may be kept in mind that if a device is, at a later date identified as a Medical Device hence falling under the definition of the term "*drug*", vide a Government notification to that effect, in such a scenario, the prospect or retrospect applicability of such notification would be based on the text of such notification and as such regulatory approval could very possibly be required.

Conclusion

If a device is not included within the definition of a drug, the provisions of the Act and Rules would not apply as far as regulatory requirements under the Act and Rules are concerned.

If the proposed revisions to Schedule M-III result in enlarging the scope of the definition of Drug under the Act to include additional devices. The amendment proposes the following revision:

"*For the purposes of this Schedule any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article shall be deemed to be a Device under the meaning of Section 3 (b) (iv), which is:*

(a) intended by the manufacturer to be used alone or in combination for human beings for one or more specific purpose(s) of;

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process,

(iv) supporting or sustaining life,

(v) control of conception,

(vi) disinfection of medical devices,

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means."

However the above amendments will only be applicable if and when they are notified in the Official Gazette of India or otherwise form a part of a suitably titled Law.

The enlargement of the scope of medical devices falling within the category of drugs can at most be taken as indicative of where the government and the industry might be headed when it comes to regulations affecting Medical Devices in India.

Import of a device that is not identified and included under the definition of Drug under the Act and Rules would be subject to Indian Customs Laws and procedures. That said, it may also be kept in mind that a customs official, at the port of entry in India, could possibly exercise his powers of seizure and seize the imported item for want of more information as regards the regulatory status of the device at the time of import.

For any clarification or further information, please contact **Mr Ashwin Sapra**, Practice Head at ashwin.sapra@clasislaw.com

Legal alert
Recent judgements

Reliance Industries Limited and Another versus Union of India, Civil Appeal No. 5765 of 2014 (Arising out of SLP (C) No. 20041 of 2013)

The Hon'ble Supreme Court on May 28, 2014 allowed the appeal filed against the order dated March 22, 2013 passed by the Hon'ble Delhi High Court.

The Hon'ble Delhi High Court held that, even though the arbitration agreement is governed by the laws of England and the juridical seat of arbitration is in London, Part I of the Arbitration & Conciliation Act, 1996 is still applicable as the laws governing the substantive contract are Indian Laws and the issues involved in the matter relates to public policy of India.

The Hon'ble Supreme Court while setting aside the High Court's order held that applicability of Part I of the Act is not dependent on the nature of challenge to the award. Whether or not the award is challenged on the ground of public policy, it would have to satisfy the pre-condition that the Act is applicable to the arbitration agreement. The parties, by providing the juridical seat in London, understood that the arbitration law of England would be applicable to the arbitration agreement and not Indian law.

M/s. Kone Elevator India Private Limited versus State of Tamil Nadu and Others, Writ Petition (Civil) No. 232 of 2005

The Constitution Bench of the Hon'ble Supreme Court on May 6, 2014 overruled the decision of three-Judge Bench in State of Andhra Pradesh versus Kone Elevators (India) Limited on the ground that the three-Judges Bench had not taken into consideration the decisions rendered by the Supreme Court in various precedents in relation to "*works contract*".

The Hon'ble Supreme Court has set out four concepts related to works contract: (i) the works contract is an indivisible contract but, by legal fiction, is divided into two parts, one for sale of goods, and the other for supply of labour and services; (ii) the concept of "*dominant nature test*" or the "*degree of intention test*" or "*overwhelming component test*" for treating a contract as a works contract is not applicable; (iii) the term "*works contract*" as used in the Constitution takes in its sweep all genre of works contract and is not to be narrowly construed to cover one species of contract to provide for labour and service alone; and (iv) once the characteristics of works contract are met with in a contract entered into between the parties, any additional obligation incorporated in the contract would not change the nature of the contract.

Indirect taxation
Case laws

Not providing opportunity of cross examination is violation of principles of natural justice

The Allahabad HC has held that if the department has relied on the statement of any witness, the assesee has the right to cross examination the witness. Not providing the assesse with an opportunity to cross examine the witness amounts to violation of the principles of natural justice.

[CCE vs M/s Kurele Pan Products Pvt Ltd & others (2014-TIOL-690-HC-ALL-CX)]

Demand raised upon automatic vacation of stay previously granted not tenable

The Rajasthan HC has held that the department cannot initiate proceedings against an assesse where stay has been granted earlier and the appeal could not be disposed off within the period of stay, for no fault of the assesse.

[M/s Chhote Lal Virendra Kumar Jain vs Union of India & Others (2014-TIOL-647-HC-RAJ-ST)]

Manufacture, erection, installation and commission of lifts is works contract

The Constitutional bench of the Hon'ble Supreme Court, over-ruling the earlier decision of three-member Bench, has held that the activity of manufacture, erection, installation and commissioning of lift is indeed a '*works contract*' and not a '*contract for sale of goods*'.

The Apex Court held that the dominant nature test may not be applicable if the contract is a composite one falling under the definition of works contracts under clause (29A)(b) of Article 366 of the Constitution.

[M/s Kone Elevators Pvt Ltd vs State of Tamil Nadu & Ors (2014-VIL-12-SC-LB)]

Corporate and commercial

Restoration of requirement of appointing whole-time company secretary by all companies having paid up share capital of INR 50 million and above

Following representations by the Institute of Company Secretaries of India (**ICSI**), the Ministry of Corporate Affairs has issued a notification on June 9, 2014 which amends the Companies (Appointment and Remuneration of Managerial Personnel) Rules, 2014, pursuant to which now all companies having paid up share capital of INR 50 million and above are required to appoint a whole-time company secretary.

Prior to this amendment the said Rules provided for mandatory appointment of whole-time key managerial personnel (including company secretary) by all listed companies and by public companies having paid up capital of INR 100 million or more. Accordingly, all unlisted public companies having paid up share capital below INR 100 million and all private companies, irrespective of their paid up share capital, were exempted from appointing a whole-time company secretary.

Government proposes liberalisation of the foreign direct investment (FDI) scheme

For easing the inflow of FDI, the Ministry of Finance has put in a proposal for liberalising the FDI policy. For the sectors that are regulated by the FDI policy and having sectoral conditions and caps in place, the ministry has proposed a composite 49% FDI cap under the automatic route (barring a few strategic sectors), which cap would include all types of investments such as FDI, foreign institutional investment, investment by non-resident Indians. The said cap is likely to be imposed in sectors such as railways, defence and e-commerce.

Proposals are also under consideration by the Government for raising the FDI limits in insurance sector from 26% to 49%, subject to certain conditions and also in the defence sector from 26% to 100% through the approval route subject to strict riders.

Reserve Bank of India (RBI) simplifies the procedure for raising external commercial borrowings (ECB) from foreign equity holder

The RBI has simplified the procedure for raising of ECB from foreign equity holder under the ECB policy, which were earlier considered both under the automatic route as well approval route. Now, the following cases which were earlier under the approval route have been placed under the automatic route and powers have been delegated by the RBI to Authorised Dealer banks to approve the same:

- Proposals for raising ECB by companies belonging to manufacturing, infrastructure, hotels, hospitals and software sectors from indirect equity holders and group companies.
- Proposals for raising ECB for companies in miscellaneous services from direct / indirect equity holders and group companies. Miscellaneous services mean companies engaged in training activities (but not educational institutes), research and development activities and companies supporting infrastructure sector. However, companies doing trading business, companies providing logistics services, financial services and consultancy services are not covered under the facility.
- Proposals for raising ECB by companies belonging to manufacturing, infrastructure, hotels, hospitals and software sectors for general corporate purpose. ECB for general corporate purpose (which includes working capital financing) is, however, permitted only from direct equity holder.
- Proposals involving change of lender when the ECB is from foreign equity holders (direct/indirect) and group company.

All the other conditions under the ECB policy remain unchanged.

Recent events

France India Legal Knowledge Partnership Ceremony

27 May 2014, Paris-France

Vineet Aneja, Partner, Clasis Law recently attended the France India Legal Knowledge Partnership Ceremony organized by Chamber of Commerce and Industry France-India held on 27 May 2014 at Paris, France.

2014 INTA Annual Meeting

10-14 May 2014, Hong Kong

Ashwin Sapra, Practice Head, Clasis Law attended "*2014 International Trademark Association (INTA)*" from 10-14 May, 2014 held at The Hong Kong Convention and Exhibition Centre, Hong Kong. It was the largest Annual IP conference of its kind, attended by over 8,000 IP lawyers from across the globe.

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