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Invitation - Webinar + Square Table (Munich)

Webinar + Square Table (Munich): The Indian Medical Device Industry, Road Ahead

For participation, please email to ruchi.biyani@nishithdesai.com

MONDAY, OCTOBER 23, 2017

4:45 PM - 6:00 PM (CET)

VENUE: MAXIMILIANSTRABE 13, 80539 MUNICH

PRELUDE

The Indian Medical Devices Industry is going through a regulatory churn of sorts. The government recently exercised its extra-ordinary power and fixed prices of knee implants. Unlike coronary stents whose prices were also fixed sometime back, knee implants were not officially recognized as "essential" for the country when their prices were fixed. Many other such "non-essential" medical devices appear to be on the government's radar for price control. On a separate note, earlier in the year, the Government introduced of a completely new regulatory regime for medical devices to be effective January 1, 2018. The new regime is expected to regulate all medical devices without exception, including in-vitro diagnostic devices (IVD) and embedded software. This development is a major departure from the present scenario where the government regulates just 15 categories of medical devices. The new regulatory regime has introduced new provisions for business sensitive areas such as shelf life and mandatory recalls that may impact current operations. Clinical research of medical devices has also been revamped under the new regime. The introduction of the new regulatory regime was quickly followed by a major change in labelling requirements for presently regulated medical devices, that will also be effective from January 1, 2018.

There is no denying that a quick brush-up of the regulatory developments in the Indian Medical Devices Industry is now unavoidable. Please join us and our experts from India in the session during which they will apprise you of the business-critical developments in the regulatory framework of medical devices in India.

The event is 'by invitation only' due to limited capacity at the venue. To confirm your interest, kindly register.

FOCUS AREA

- Making sense of the extra-ordinary application of the Indian price control framework
- Medical Devices Rules, 2017 A totally new regulatory regime for medical devices, effective January 1, 2018
- Major new features
- Grandfathering
- Aligning business operations
- New labelling requirements for currently regulated medical devices, effective January 1, 2018

Venue:

MAXIMILIANSTRABE 13, 80539 MUNICH.

TEL: +49 89 203006268

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ANY QUESTION?

Email:ndaconference(at)nishithdesai.com

WEBEX DETAILS:

Video Link: Click Here

Dail-In Details:

Primary Number: +912239381004 (8:30 PM

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Germany: 0080014243444 (5:00 PM CET)

UK: 08081011573 (4:00 PM BST) USA: 18667462133 (8:00 AM PDT)

THERE IS NO PARTICIPATION FEE FOR THIS EVENT

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Event and Calendar

ABOUT NISHITH DESAI ASSOCIATES

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Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Silicon Valley, Singapore, Mumbai-BKC, New Delhi, Munich and New York. It specializes in strategic legal, regulatory and tax advice coupled with industry expertise in an integrated manner.

Our core practice areas include International Tax, Succession and Estate Planning, International Tax Litigation, Mergers & Acquisitions, JVs & Restructuring, International Litigation & Dispute Resolution, Capital Markets, Corporate & Securities Law, Fund Formation, PE/VC Fund Investments, Real Estate Fund Formation, Real Estate Investments, Employment and HR, Intellectual Property, Competition Law, International Commercial Law. Our specialized industry niches include financial services, IT and telecom, education, pharma and life sciences, media and entertainment, real estate and infrastructure

PROGRAM

4:45 PM - 5:00 PM : REGISTRATION

5:00 PM - 6:00 PM : SESSION

6:00 PM ONWARDS: COCKTAILS & INTERACTION

SPEAKERS

DR. MILIND ANTANI

Leader - Pharma-Life Sciences and Healthcare Practice, Nishith Desai Associates

Dr. Milind Antani is Leader in charge of Pharma-Life Sciences and Healthcare Practice at the multi-skilled, research-based international law firm, Nishith Desai Associates with offices in Mumbai- Nariman Point, Silicon Valley, Bangalore, New York, Singapore, New Delhi, Mumbai – BKC and Munich. He is also in charge of the Social Sector Practice Group and an integral member of the Education Sector Practice Group.

Dr. Antani practiced as an ENT surgeon for 14 years prior to joining Nishith Desai Associates. Dr. Antani received a Doctorate from Baroda Medical College, Vadodara, Gujarat and a Bachelor of Law from Sardar Patel University, Vallabh-Vidyanagar, Gujarat.

Dr. Antani represents clients in matters including corporate mergers and acquisitions, investments, regulatory and transactional matters, intellectual property prosecution and litigation, joint ventures and formation of new companies.

Dr. Antani has been nominated as one of the world's leading practitioners in 'Who's Who Legal' for Life Sciences 2015, 2016, 2017 in the 'Regulatory' section. Dr. Antani and his team's efforts resulted in Nishith Desai Associates being declared as ASIAN-MENA COUNSEL 'IN-HOUSE COMMUNITY FIRM OF THE YEAR' in India for Life Sciences practice 2012.

Dr. Antani has authored and co-authored many articles, publications related to the pharma industry including a book on Contract Research and Manufacturing Services (CRAMS) in India: The Business, Legal, Regulatory and Tax environment in the Pharmaceutical and Biotechnology sectors published by Woodhead Publishing Limited and Legal & Tax Framework: Indian Pharmaceutical Industry, published by CCH, 2008. He has been invited by national and international forums to speak at various conferences, seminars and webinars on the subjects of pharma, biotech, IP, clinical trials, healthcare etc. Dr Antani has been a visiting faculty at various academic institutions.

Dr Antani is also the member of the Committee of Telemedicine Society of India and involved in drafting of the Telemedicine Act of India.

ANAY SHUKLA

Senior Member - Pharma-Life Sciences and Healthcare Practice, Nishith Desai Associates

Anay Shukla is a senior member of the Pharma, Medical Device and Healthcare team at Nishith Desai Associates.

His practice particularly focuses on medical devices, pharmaceutical and healthcare related regulations, intellectual property laws, litigation and dispute resolution. He has been regularly advising MNCs on regulatory issues affecting the medical devices sector and has represented medical device companies in high stakes regulatory litigation.

Anay graduated from National Law School of India University, Bangalore in 2012.

SUGGESTED NDA LITERATURE

- 1. Knee Implants Go Under Scapel Of Price Control In India
- ${\bf 2.} \ {\bf Regulated} \ {\bf medical} \ {\bf devices} \ {\bf in} \ {\bf India} \ {\bf to} \ {\bf lose} \ {\bf exemption} \ {\bf from} \ {\bf labelling} \ {\bf requirements}$
- 3. The Indian Medical Industry

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