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LEGAL AND TAX COUNSELING WORLDWIDE

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Analysis of Medical Devices Rules, 2017

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Contents

Medical Device Rules 2017 – An analysis

The Indian Government has finally introduced the Medical Device Rules, 2017 (**"2017 Rules"**). The rules have been drafted with the intention to distinguish medical devices from pharmaceuticals for the purpose of regulation. They will come into effect on January 1, 2018 unless a later date is notified by the government.[1]

The key highlights of the 2017 Rules are:

I. Definition of Medical Devices

Under the 2017 Rules, medical devices mean[2] :

a. Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time to time under the Drugs and Cosmetics Act, 1940 (**"D&C Act"**). Some categories of devices have already been notified by the government. A list of classes of currently notified medical devices is annexed as Annexure D.

b. Specific substances intended to affect the structure or any function of the human body which are notified by the government. At present, the substances notified are mechanical contraceptives (eg. condoms, intra-uterine devices, tubal rings) and disinfectants.

c. Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;

d. Substances used for in vitro diagnosis (referred to in the 2017 Rules as "In Vitro Diagnostic Medical Device")

e. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. This is a catch-all category for substances;

The most important take-away from the definition of medical devices is that only the products that are covered by the definition of medical devices will be regulated by the 2017 Rules.

Unfortunately, since the Act, in which the definition of 'drug' includes all the medical devices identified above, remains unamended, the D&C Rules will continue to apply to all medical devices.

However, to avoid confusion, the 2017 Rules do clarify that in case of any contradiction between the provisions of 2017 Rules and the Drugs and Cosmetics Rules, 1945 (**"D&C Rules"**), the provisions of the 2017 Rules will have effect.[3]

1. Rule 1(2) of 2017 Rules.
2. Rule 3(zb) of 2017 Rules.
3. Rule 96 of 2017 Rules.

II. Introduction of risk based classifications system

In tune with the global practice, the 2017 Rules will introduce a risked based classification system for regulation of medical devices. The classification would be as follows:

a. Low (Class A)
b. Low Moderate (Class B)
c. Moderate High (Class C)
d. High (Class D)

The method of classification is described in detail in the first schedule of the 2017 Rules. It is important to note that unlike other countries which give liberty to manufacturers/importers to classify their product for the purpose of registration, the 2017 Rules do not provide this liberty and the manufacturers/importers will have to follow the classification decided by DCGI.[4] This classification will be made available on the official website of DCGI, i.e., www.cdsco.nic.in.[5] The classification once done, will unfortunately be non-appealable.

An example of the difference in regulation on the basis of risk-based classification is as follows:

The application for license to import Class A or Class B medical devices from Unregulated Jurisdictions (defined below) can be granted on the strength of a free sale certificate and either of published safety and performance data or clinical investigation in the country of origin. However, an application for import of Class C or Class D medical devices from Unregulated Jurisdictions can be granted only after its safety and effectiveness has been established through clinical investigation in India.

Unregulated Jurisdictions are jurisdictions other than Australia, Canada, Japan, European Union Countries, or the United States of America.

Similarly, for applications for grant of license to manufacture - Class A medical devices do not require prior audit by third party [6] or official inspection; Class B medical devices require prior audit by third party [7] but do not require official inspection, and; Class C or Class D medical devices require prior official inspection.[8]

The application for manufacture of Class A or Class B medical device will be assessed by the State licensing authority whereas the application for manufacture of Class C or Class D medical device will be assessed by DCGI.

III. Single window clearance

All applications for import, manufacture, sale or distribution and clinical investigation, whether to be assessed by the DCGI or State licensing authority, will have to be made through a single online portal of the central government. The details of the portal will be notified in the near future.

IV. Product standards for medical devices

All medical devices will be expected to conform to the following standards, in the same order of relevance [9]:

a. A standard notified by central government for the medical device specifically or which has been laid down by the Bureau of Indian Standards (**"BIS"**); or

4. Rule 4(3) of 2017 Rules.
5. Rule 4(4) of 2017 Rules.
6. Rule 20(4)(i).
7. Rule 20(5) r/w Rule 20(6)(iii)
8. Rule 21(1) of 2017 Rules.
9. Rule 7

b. Where (a) is absent, to a standard laid down by International Organisation for Standardisation (**"ISO"**) or the International Electro Technical Commission (**"IEC"**), or by any other pharmacopoeial standards; or

c. Where both (a) and (b) are absent, to the validated manufacturer's standards.

The clarity in products by 2017 Rules is a welcome step by the government. For much too long, the medical device manufacturers and importers suffered because of absence of clarity on product standards. The D&C Rules presently states that manufacturers or importers of notified medical devices are required to confirm to BIS standards or in absence of BIS standards, to international standards and such standards as may be specified.[10] There was always a question on which standards would have to be followed when the BIS standards were not available. However, the introduction of 2017 Rules is expected to resolve this issues.

V. Certainty and rationalization of timelines

The government has brought certainty of timelines and has rationalized the time required for obtaining licenses required to market medical devices. Under the 2017 Rules, an applicant can be certain of the time within which its application will be decided and can also plan the time within which it can expect an audit or inspection to happen because timelines have been assigned to each regulatory function. Further, unlike the D&C Rules, the 2017 Rules do not give any scope to the regulators to extend the time-line for coming to a decision for any reason whatsoever. For instance, in case of license to manufacture Class C or Class D medical device, the scrutiny of the application is required to submitted within forty five (45) days of the date of the application[11], the inspection of the manufacturing site is required to be completed before sixty (60) days from the date of the application[12], the report of the inspection has to be forwarded to the applicant[13], and the decision on the application has to be communicated within forty five (45) days from date of receipt of the inspection report.[14]

Similarly, a decision on application to import a medical device is required to be communicated within 9 months from the date of the application irrespective of whether the foreign manufacturing site is inspected or not.[15]

The 2017 Rules have also introduced the concept of deemed approval in event of non-communication of a decision in application for approval to undertake major change in licensed particulars (the subject of major change in licensed particulars is discussed later in detail). If the appropriate licensing authority i.e. the DCGI or the State licensing authority is unable to communicate its decision on the aforesaid application within the stipulated timeline, i.e., forty five (45) days for manufacture, sixty (60) days for import, then such approvals shall be deemed to have been granted.[16]

VI. Perpetual licenses

The licenses granted under the 2017 Rules are perpetual, meaning they will continue to be valid unless they are cancelled. In order to save a license from getting cancelled, the licensee is required to pay a prescribed license retention fee every five years. A delay of ninety (90) days past the five years is acceptable provided the licensee pays a prescribed late fee. However, if the licensee fails to deposit the license retention fee within the aforementioned time-limit, then the license is deemed to have been cancelled.

Once a license is cancelled, the licensee will have to apply afresh for the license.

10. Schedule R-1 of Rules.
11. Rule 21(4)
12. Rule 23(1)
13. Rule 24
14. Rule 25
15. Rule 36(1)
16. Rule 26(iii); Rule 38(vi)

Please note that while the license may be perpetual, if a licensed manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, it is obligated to inform the appropriate licensing authority.[17]

VII. Consolidation of registration certificate and import license into a single license

The 2017 Rules have done away with the requirement of a registration certificate for registration of the foreign manufacturer, its manufacturing site and the products. The only regulatory requirement to be able to import and market products in India is to appoint an authorized agent in India and apply for an import license through it. The immediate outcome of this change is that the hassle of making two separate applications (registration and import license) has vanished and the timeline for obtaining the import license (of nine months) has become certain.

Further, it will not be possible for two different importers to import different products manufactured at the same manufacturing site. Where an importer has been licensed to import certain products from a manufacturing site, all other products manufactured at the same site are mandatorily required to be licensed to the same importer.[18]

VIII. Certainty on consequence of change in licensed particulars

The 2017 Rules are clear about the consequences of change in licensed particulars. Any major change requires a prior approval from the appropriate licensing authority (either DCGI or State licensing authority, as the case may be).[19] Any minor change only requires written intimation to the appropriate licensing authority within a period of thirty days.[20]

What constitutes major change and minor change has also been specified.[21] For instance, the change in name or address of the manufacturer (whether domestic or foreign) or importer is a major change. A change in design which does not affect quality in respect of its specifications, indication for use, performance and stability of the medical device is a minor change.

This clarificatory inclusion in the 2017 Rules is greatly welcomed. At present, the D&C Rules do not specify what constitutes a major change or a minor change. That is not all. Whether a change in the manufacturing or in processing or in testing or in documentation is major or not is left to the discretion of the licensing authority and triggers the requirement to make a fresh application.[22] The challenges of making a fresh application are discussed later with the subject of change in constitution.

In fact, at present, it is known that the following changes will result in the requirement to obtain a fresh import license [23]:

a. Changes in name and/or address of Indian agent/ Importer or change in constitution after issue of Registration Certificate/ Import License
b. Change in the Indications and/ or Intended use
c. Change in constitution

17. Rule 26(xii)
18. Rule 34(4)(ii)
19. Rule 26(iii); Rule 38(vi)
20. Rule 26(iv); Rule 38(vii)
21. Sixth Schedule
22. Schedule D(I), Para 3.5 of Rules.
23. See Import and Registration of Medical Devices FAQs published by Central Drug Standards Control Organization.

Under the 2017 Rules, the above changes (excepting change in constitution) do not require fresh application. There is one more welcome change. Under the D&C Rules, it is prescribed that the application for registration certificate for import of notified medical devices will be decided within nine months[24] and for import license the application is customarily decided within three months after grant of registration certificate. Thus, on an average, a total time of around one year is spent in obtaining the import license. Since it is a considerably long span of time, it is possible that certain changes may occur in the details that were submitted to the licensing authority at the time of making of the application. For instance, it is possible for business reasons that a different manufacturing site is sought to be registered. Ideally, since the application has not been decided, it should be possible for the applicant to revise the application. However, the current practice is that in case of such a change, even if the application has not been decided, a fresh application has to be made.[25] Apart from loss of money and resources, this results in loss of valuable time and sometime delays imminent and time-sensitive launch of products. This serious shortcoming appears to have been rectified in the 2017 Rules. Such a change now is required to be informed in writing to the licensing authority.[26] Due to this explicit requirement, it should not trigger requirement to make a fresh application.

IX. Meaning of "change in constitution" finally explained and change in constitution rationalized

"Change in constitution" could easily be the most dreaded event under D&C Rules, even more than a "serious adverse event". This is because no one seems to have any idea about what it means. Having said that, the D&C Rules require that upon its occurrence the license remains valid for three months only. The licensing authority itself has issued several clarifications, FAQs and guidelines over past seventy two (72) years but has not clarified what it means.

But worry no more. The 2017 Rules state that change in constitution of a licensee in relation to[27]:

i. *a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;*
ii. *a company means-*
   a. *its conversion from a private to a public company, or from a public to a private company; or*
   b. *any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate;*

Therefore, it is now clear that at least after enforcement of 2017 Rules:

1. Change in directors will not result in change in constitution;
2. Change in shareholding by way of sale/investment will not result in change in constitution; and
3. Change of parent shareholder due to restructuring exercise will not result in change in constitution.

Whether or not the above events constitutes a change in constitution of the licensee remains an enigma under the Drugs and Cosmetic Rules, 1945.

24. Rule 27A(1) Proviso of D&C Rules.
25. FAQ No. 51 under Import and Registration of Medical Devices FAQs published by Central Drug Standards Control Organization.
26. Rule 34(2) Proviso.
27. Rule 3(j)

Let us understand what the practical challenge is if the license only remains valid for a period of three months due to change in constitution. It has already been discussed that it takes around a year to obtain an import license under the D&C Rules. It means that after change in constitution, an importer has only three months at present to import and stock products for domestic market to last for the time when it does not have an import license i.e. at least nine (9) months. This is almost impossible due to production, logistics, storage and commercial considerations. Thus, for many importers today, a change in constitution means halt of business for close to a year.

However, the government seems to have realized this pitfall and has made the process surrounding change in constitution a breeze under the 2017 Rules. Upon a change in constitution as defined before, a manufacturer licensee has forty five (45) days to inform the licensing authority and one hundred eighty (180) days to make a fresh application.[28] An importer does not even have to inform the licensing authority but simply make a fresh application in the same time-frame.[29] After making such an application, the existing license is deemed to be valid until the fresh application is decided by the licensing authority. Thus, there remains nothing to dread about change in constitution under the 2017 Rules.

X. License for sale of medical devices

The 2017 Rules do not have separate provisions for sale of medical devices. The provisions related to sale of drugs other than homeopathic medicines under the D&C Rules will apply to medical device as if inserted within the 2017 Rules.[30] All licenses for sale of drugs other than homeopathic medicines issued prior to commencement of 2017 Rules shall be deemed to be valid for sale of medical devices as well.[31]

The 2017 Rules do, however, address a practical difficulty faced by many distributors in India. Implantable medical devices cannot be self-administered and therefore are seldom bought at retail. They are stocked by hospitals for clinical use as and when required. The hospitals sell the medical device to the patient directly on a unit basis or as part of treatment package. However, considering the medical devices are expensive and its demand is difficult to predict, hospitals are hesitant to purchase medical devices in large quantities. At the same time, some of the medical devices are critical and may be required on short notice, therefore it is in hospital's and patients' interest that the hospital maintains a large stock of medical devices. As a solution to this dilemma, the distributors transfer a sizeable stock of the medical devices to the hospital through a stock transfer. A stock transfer is not a sale, it is merely transfer of stock. As and when the hospital requires a medical devices, it uses it from the stock. The distributor then charges the hospital on the basis of its use. All the unused stock is later re-transferred to the distributor. The proof of stock-transfer of medical devices by distributor to the hospital is a delivery note.

The D&C Rules requires that any sale or distribution should be recorded by the distributor. A stock transfer is not a sale or distribution, therefore it is not recorded by the distributor. However, the presence of stock at the hospital may be interpreted as an act of distribution. This can lead to unnecessary investigation against the distributors by the licensing authority. In order to resolve this complication, the 2017 Rules have permitted supply of implantable medical devices against a delivery note (challan).[32]

XI. Mandatory recalls on knowledge of risk to safety

The 2017 Rules make it mandatory[33] for manufacturers and importers to immediately initiate recall in case it has reasons to believe that a medical device is likely to pose risk to the health of a user or patient during its use and therefore may be unsafe. The recall should aim to withdraw the medical device in question from both the market as well as patients, indicating reasons for its withdrawal. The manufacturer and importer initiating recall is required to inform the licensing authority about the details of the recall.

28. Rule 27.
29. Rule 39.
30. Rule 87(1).
31. Rule 87(2).
32. Rule 88(1).
33. Rule 89(1).

In contrast, the D&C Rules do not obligate the manufacturer or importer to recall medical devices upon knowledge of risk to user or patients.[34] There is also no explicit requirement to report the facts leading to a recall, unless the medical device is "new" and is required to submit periodic safety update reports and have a system of pharmacovigilance in place.[35]

XII. New thresholds for residual shelf life of imported products

The D&C Rules prescribe that all imported products should have a minimum residual shelf life of sixty (60) percent on the date of import unless specific permission is obtained to the contrary.[36] This becomes an issue for importers of medical devices which have a short claimed shelf life.

The 2017 Rules have addressed the issue by relaxing the residual shelf life requirement for medical devices with short shelf life.[37] Any medical device, whose total shelf life claim is

a. less than ninety (90) days, will be allowed to be imported if it has more than forty (40) per cent residual shelf-life on the date of import

b. between ninety (90) days and one (1) year, will be allowed to be imported if it has it has more than fifty (50) per cent residual shelf-life on the date of import

c. is more than one (1) year, will be allowed to be imported by the licensing authority if it has more than sixty (60) per cent residual shelf-life on the date of import.

XIII. New regulatory framework for clinical investigation of medical device

The 2017 Rules will introduce a new regulatory framework for clinical investigation of medical devices. Some of the interesting provisions of this framework are:

a. A fixed timeline of ninety (90) days has been prescribed for the licensing authority to arrive at a decision on application for permission to conduct clinical trial;

b. After obtaining permission to conduct clinical trial, the first subject is required to be enrolled within one year;

c. New concepts of Pilot Study (i.e. exploratory study) and Pivotal Study (i.e. confirmatory study) have been introduced with respect to approval of investigation medical device;

d. New concept of "substantial equivalence" to predicate devices has been introduced with respect to approval of medical devices other than investigational medical devices;

e. The clinical performance evaluation of In Vitro Diagnostic Devices is now part of the regulatory framework;

34. Rule 26(v); Rule 74(j); Rule 78(i) of D&C Rules
35. Schedule Y, Para 3(4)
36. Rule 31 Proviso of D&C Rules.
37. Rule 47

f. Any institute, organization, hospital run or funded by the Central Government or the State Government is exempted from payment of fees for conduct of clinical investigation; and

g. g)Academic clinical trials do not require prior approval of the licensing authority for its initiation if the data generated during the study will not be used for obtaining manufacturing or import license.

XIV. Debarment on account of supply of misleading information

The 2017 Rules frown upon submission of misleading information along with an application for grant of any license. It prescribes that any applicant found guilty of submitting misleading, or fake, or fabricated documents, may be debarred by the appropriate licensing authority for such period as it may deem fit.[38] In other words, if any misleading or false information is found to have been submitted to the licensing authority, then it can debar the applicant from doing business in India.

The provision appears to be based on the jurisprudence of strict liability. It does not matter whether the applicant knew or intended to submit misleading or false information. This should act as a wake-up call to importers, manufacturers, distributors and researchers to ensure that all information that is finally submitted by it (or on its behalf) is verified prior to submission.

XV. Medical Devices Rules, 2017 to be placed before Parliament

The Medical Device Rules, 2017 will be issued under the Act. The Act requires that every rule made under it is laid down before each House of Parliament, for a total period of thirty days. If both Houses agree to make any modification in the rules or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified from or be of no effect, as the case may be.

Thus, the 2017 Rules will soon be placed before the Indian Parliament. It will be interesting to see whether the Indian Parliament effects any modification to the 2017 Rules or rejects it completely. However, given the political and economic scenario, either event seems unlikely.

XVI. Next steps for existing importers, manufacturers and distributors

After the commencement of 2017 Rules, all licenses and registrations for medical devices issued under the D&C Rules that are valid on the date of commencement, shall be valid at least until July 31, 2018 or until the expiry date of the license or registration, whichever is later (**"Grace Period"**). Upon expiry of the Grace Period, all existing licensees will require a license issued under the 2017 Rules. Therefore, there is no need to rush to adopt to the 2017 Rules. However, it is important to start preparing for the new regulatory regime under 2017 Rules.

It is not clear whether existing licensees could voluntarily surrender their license before expiry of the Grace Period in order to obtain a license under the 2017 Rules. However, such a step is not advisable. This is because the license fees paid to obtain the license under Rules is far cheaper than the license fees prescribed in 2017 Rules. By opting to surrender the license, the licensee would effectively end up forfeiting the license fees already paid and incur expense of higher license fees. In case the decision to surrender is being contemplated for taking benefit of the beneficial provisions of 2017 Rules (eg. change in constitution), then such rationale needs to be re-evaluated because the 2017 Rules clarify that the existing license under

38. Rule 93(1).

the Grace Period shall be deemed to be valid under the corresponding provision of 2017 Rules. Therefore, all existing licensees should be able to derive the benefit of 2017 Rules during the Grace Period despite transacting on a license issued under the Rules.

XVII. An opportunity lost

Though the 2017 Rules have introduced a number of business friendly provisions, one cannot help but regret that it was an opportunity lost to bring more change. The fact of the matter is that even after commencement of the 2017 Rules, medical devices will continue to be deemed to be drugs, since the definition of medical devices is tied to the definition of drugs under Act. This has repercussions under other laws, most important of which is the price control legislation – the Drugs (Price Control) Order, 2013 issued under the Essential Commodities Act, 1955. The Essential Commodity Act, 1955 has notified drugs as defined under Act as essential commodity. Due to the reference to this definition, medical devices which are deemed to be drugs, are also currently subject to limited price control. Had the government separated the definition of medical devices form the definition of drug, the tragedy that inadvertent and unintended price control of medical devices is today would have been avoided.

Having said that, there is no doubt that the fact of notification of the 2017 Rules and the very real possibility of it coming into effect in 2018 should be celebrated!

About NDA

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

As a firm of specialists, we work with select clients in select verticals on very complex and innovative transactions and disputes.

Our forte includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Aviation, Artificial Intelligence, Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech, Ed-Tech and Medical Devices and Nanotechnology.

We specialize in Globalization, International Tax, Fund Formation, Corporate & M&A, Private Equity & Venture Capital, Intellectual Property, International Litigation and Dispute Resolution; Employment and HR, Intellectual Property, International Commercial Law and Private Client. Our industry expertise spans Automobile, Funds, Financial Services, IT and Telecom, Pharma and Healthcare, Media and Entertainment, Real Estate, Infrastructure and Education. Our key clientele comprise marquee Fortune 500 corporations.

Our ability to innovate is endorsed through the numerous accolades gained over the years and we are also commended by industry peers for our inventive excellence that inspires others.

NDA was ranked the 'Most Innovative Asia Pacific Law Firm in 2016' by the *Financial Times - RSG Consulting Group* in its prestigious FT Innovative Lawyers Asia-Pacific 2016 Awards. While this recognition marks NDA's ingress as an innovator among the globe's best law firms, NDA has previously won the award for the 'Most Innovative Indian Law Firm' for two consecutive years in 2014 and 2015.

As a research-centric firm, we strongly believe in constant knowledge expansion enabled through our dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs. Our constant output through Webinars, Nishith.TV and 'Hotlines' also serves as effective platforms for cross pollination of ideas and latest trends.

Our trust-based, non-hierarchical, democratically managed organization that leverages research and knowledge to deliver premium services, high value, and a unique employer proposition has been developed into a global case study and published by John Wiley & Sons, USA in a feature titled 'Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage' in the September 2009 issue of Global Business and Organizational Excellence (GBOE).

A brief below chronicles our firm's global acclaim for its achievements and prowess through the years.

- IDEX Legal Awards: In 2015, NDA won the "M&A Deal of the year", "Best Dispute Management lawyer", "Best Use of Innovation and Technology in a law firm" and "Best Dispute Management Firm<http://idexlegalawards.in/ArticlePage.aspx?aid=6>". Nishith Desai was also recognized as the 'Managing Partner of the Year' in 2014.
- Merger Market: has recognized NDA as the fastest growing M&A law firm in India for the year 2015.
- Legal 500 has ranked us in tier 1 for Investment Funds, Tax and Technology-Media-Telecom (TMT) practices (2011, 2012, 2013, 2014, 2017)

- International Financial Law Review (a Euromoney publication) in its IFLR1000 has placed Nishith Desai Associates in Tier 1 for Private Equity (2014, 2017). For three consecutive years, IFLR recognized us as the Indian "Firm of the Year" (2010-2013) for our Technology - Media - Telecom (TMT) practice.
- Chambers and Partners has ranked us # 1 for Tax and Technology-Media-Telecom (2014, 2015, 2017); #1 in Employment Law (2015 & 2017); # 1 in Tax, TMT and Private Equity (2013, 2017); and # 1 for Tax, TMT and Real Estate – FDI (2011).
- India Business Law Journal (IBLJ) has awarded Nishith Desai Associates for Private Equity, Structured Finance & Securitization, TMT, and Taxation in 2015 & 2014; for Employment Law in 2015
- Legal Era recognized Nishith Desai Associates as the Best Tax Law Firm of the Year (2013).

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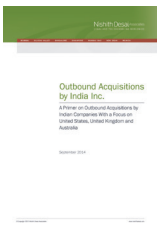

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Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "Hotlines". These Hotlines provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our NDA Insights dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction.

We regularly write extensive research papers and disseminate them through our website. Although we invest heavily in terms of associates' time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our ThinkTank discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports.

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