ECONOMIC LAWS PRACTICE
ADVOCATES & SOLICITORS

ELP Pharma Track

1st Quarter 2017

Table of Contents

Preface

Pharma Industry is the art of making billions from milligrams

~Gerhard Kocher

Dear Reader,

The First Quarter of 2017 saw several announcements, policy statements and regulatory actions affecting the Pharma & Life Sciences Industry. While some immediate effects were seen as in the price regulation of Stents, the lasting effect of these changes will be seen in the coming months.

The Medical Devices Industry is a key focus area in the National Health Policy, 2017 as well as in Government action in the First Quarter. India, which presently imports more than 70% of medical devices sold in the country, is expected to become a manufacturing hub of medical devices. The Medical devices Industry has been invited to participate in the Government's "Make in India" initiative.

For the rest of the industry, Government Policy indicates further preferential purchase by the Government, further changes in the Drugs and Cosmetics Rules to promote the use of generic drugs, and changes in the clinical trial guidelines to promote transparent polices regarding patient compensation and an innovative research environment.

It will be seen in the coming months how the Government maintains the balance between policies promoting the affordability of medicines and industry's need for returns on investments. While increased access of people to healthcare is an imperative, increased price control will prove counterproductive for innovation, which will ultimately be to the detriment of patients in India. Knee jerk actions like enforcing regulations on doctors to prescribe drugs by their generic names may pose serious challenges. NPPA's actions fixing the price of various drugs have faced review actions and innovator companies have considered withdrawing their products.

The First Quarter also saw efforts by the Government to digitise its systems to promote "ease of doing business".

The judiciary in the meanwhile has been busy deciding the battles between the multinational innovator companies seeking protection of their Intellectual Property Rights on the one hand, and refusing to interfere with the approval granted by the Regulator for manufacture of a biosimilar drug, on the other. The Judiciary has by far been able to set a well-reasoned standard, as well as maintain equilibrium of obligations under the TRIPS, Patents Act and the social interest of the country.Through this update, Economic Laws Practice ("ELP") brings to you a summary of some noteworthy developments during January to April 2017. We hope you find this update useful.

Warm Regards,

Pharma & Life Sciences Team

ECONOMIC LAWS PRACTICE
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I. Government Policy and Legislation

There are few things wholly evil or wholly good. Almost everything, especially of government policy, is inseparable compound of the two, so that our best judgment of the preponderance between them is continually demanded.

~ Abraham Lincoln

1. Budget 2017 and the Pharma & Life Sciences Sector

On February 1, 2017, the Finance Minister announced the Union Budget for 2017-2018 which received a mixed reaction from the Pharma & Life Sciences Sector. Expectations of the Sector were based on the Government's stated vision of making India one of the top three pharmaceutical markets by 2020.

Judging from this perspective, the Budget did not promise major financial incentives for the pharma sector. However, welcome announcements were made nevertheless.

Promising to alleviate poverty, the Finance Minister in his speech, recognised that poverty, amongst other causes, is usually associated with poor health. He also announced that the Government has prepared an action plan to eliminate Kala-Azar and Filariasis by 2017, Leprosy by 2018 and Measles by 2020. Elimination of Tuberculosis by 2025 is also targeted.

It was also announced that amendments to the Drugs and Cosmetics Rules would be made, to ensure the availability of drugs at reasonable prices, and to promote the use of generic medicines. New rules for regulating medical devices were also stated to be in the pipeline.

It was further announced that the Foreign Investment Promotion Board ("FIPB"), having completed the tasks set out for it, was ready to be phased out.

2. Notification of the Medical Devices Rules, 2017

The Medical Devices Rules, 2017[1] were notified on January 31, 2017, almost at the same time as the Union Budget was announced.

The much awaited Medical Devices Rules are to come into force with effect from January 1, 2018 and have set a framework for separate regulation for sale and distribution of medical devices in India.

The Rules have largely borrowed from the now defunct Global Harmonization Task Force Framework, thereby aligning manufacturing practices of medical devices sold in India with international standards. While this would ensure availability of high quality devices in India, it would also make the Indian medical devices industry more competitive in the world market.

[1] Available at http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

The Rules have departed from the four-phase clinical trial process designed for drugs and have streamlined the pathway for the clinical investigation of medical devices.

For the Rules to actually take effect from January 1, 2018, however, the Central Licensing Authority must first publish the class-wise list of medical devices under Rule 4(4) as unless such classification is published, the documents to be submitted along with the application for licenses cannot be ascertained.

Once the regime is rolled out, manufacturers, wholesalers and importers would find that the new regulations have considerably streamlined the procedure. Fresh applications for licenses would not be necessary after every 3 years thus reducing paperwork considerably. The standards of quality check would also be raised under the new regime, which would ensure a level playing field for quality products.

However, while the notification of the Rules is a step in the right direction, it may take some time before all medical devices sold in India come under the regulations. The sale and distribution of medical devices that are not mentioned in the definition of Medical Device in the Rules, or notified by the Central Government as on date, would remain unregulated.

*(For a brief view of the Medical Devices Rules, 2017 please see **Annexure A** at p.31)*

3. National Health Policy, 2017

Soon after the budget, the much awaited National Health Policy 2017[2] ("the Policy") was announced in March 2017. As per the Policy, the Indian context has changed in the following four major ways in the 14 years since the last National Health Policy of 2002:

Firstly, health priorities are changing and there is a growing burden on account of communicable diseases and some infectious diseases.

Secondly, there is an emergence of a robust healthcare industry estimated to be growing at double digits.

Thirdly, there is a growing incidence of catastrophic expenditure due to healthcare costs, which is presently estimated to be one of the major contributors to poverty.

And **fourthly**, rising economic growth enables enhanced fiscal capacity.

Some of the Goals, Principles, Objectives and Programmes set out by the Policy, which may be of interest to the Pharma & Life Sciences Sector, are as under:

- **Affordability:** Affordability is listed as one of the Key Policy Principles and it states that catastrophic household healthcare expenditure defined as health expenditure exceeding 10% of a household's total monthly consumption expenditure or 40% of its monthly non-food consumption expenditure, are unacceptable (Para 2.2 III).

[2] http://www.mohfw.nic.in/showfile.php?lid=4275

- **Health Finance:** The Policy envisages increased government spending under Specific Quantitative Goals and Objectives as under;
  - Increased health expenditure by Government as a percentage of the GDP from the existing 1.15% to 2.5% by 2025;
  - Increased State Sector health spending to more than 8% of their budget by 2020;
  - Decrease in proportion of households facing catastrophic household health expenditure from the current levels by 25% by 2025. (Para 2.4.3)

- **"Make in India" initiative:** The Policy lists the Government's "Make in India" initiative as one of the ways of engagement with the private sector. The Policy states that towards furthering "Make in India", the **private domestic manufacturing industry could be engaged to provide customised indigenous medical devices to the health sector** and in the creation of forward and backward linkages for medical device production. The policy also assures **purchase by Government health facilities from domestic manufacturers,** subject to quality standards being met. (Para 13.11)

- **Private Sector Incentive:** The Policy further goes on to state that to incentivise the Private Sector, the policy envisages, inter-alia**, preferential purchase by Government health facilities** from domestic manufacturers, subject to quality standards being met. (Para 13.13)

- **Changes in Regulatory Framework:** The policy recognises that the **regulatory role of the Ministry of Health and Family Welfare needs urgent and concrete steps towards reform** and states that this would entail moving towards a more effective, rational, transparent and consistent regime. (Para 14)

- **Drug Regulation:** Apart from regulation of the prices of drugs, the Policy recommends the following further actions in the area of drug regulation:
  - **Streamlining of the system of procurement of drugs;**
  - Facilitating spread of low-cost pharmacy chains such as Jan Aushadhi stores linked with ensuring prescription of generic medicines;
  - Educating the public with regard to branded and non-branded generic drugs;
  - **Setting up of a common infrastructure for development of the pharmaceutical industry;**
  - Strengthening and rationalising the drug regulatory system, **promotion of research and development in the pharmaceutical sector and building synergy and evolving a convergent approach with related sectors.** (Para 14.4)

- **Medical Device Regulation:** The Policy recommends strengthening the regulation of medical devices and **establishing a regulatory body for medical devices to** unleash innovation and the entrepreneurial spirit for manufacture of medical devices in India. (Para 14.5)

- **Clinical Trial Regulation:** The Policy further recommends that clear and transparent guidelines, with independent monitoring mechanisms, are the ways forward to foster a progressive and innovative research environment, while safeguarding the rights and health of the trial participants. (Para 14.6)

- **Pricing – Drugs, Medical Devices and Equipment:** The Policy recognises that the regulatory environment around pricing requires a **balance between patients' concern for affordability and industry's concern for adequate returns on investment for growth and sustainability**. It recommends:

  - Timely revision of the National List of Essential Medicines along with adequate price control mechanisms for generic drugs as a key strategy for decreasing the cost of care for all those patients seeking care in the private sector.

  - An approach on the same lines but suited to specific requirements of the sector would be considered for price control with regard to a list of essential diagnostics and equipment.
  (Para 14.7)

- **Medical Technologies:** The Policy **recognises** that even though India is known as the pharmacy of the world, **its role in new drug discovery and drug innovations including bio-pharmaceuticals and bio-similars for its own health priorities is limited and needs to be addressed** in the progress towards universal healthcare. It further goes on to add that:

  - Making available **good quality, free essential and generic drugs and** diagnostics at public health care facilities is the most effective way of achieving the goal;

  - The free drugs and diagnostics basket would include all that is needed for comprehensive care, including care for chronic illnesses, in the assured set of services;

  - At the **tertiary care** level too, at least for in-patients and out-patients in geriatric and chronic care systems, **most drugs and diagnostics should be free or subsidised** with fair price selling mechanisms for most and some co-payments for the "well-to-do".
  (Para 16)

- **Availability of Drugs and Medical Devices:** In this area, the Policy recommends the following:
  - Special focus on production of Active Pharmaceutical Ingredient (API) which is the back-bone of the generic formulations industry.

- Recognizing that over **70% of the medical devices and equipment are imported in India**, the policy advocates the need to **incentivize local manufacturing** to provide customized indigenous products for the Indian population in the long run. (Para 18)

- **Aligning other policies for medical devices and equipment with public health goals:** The Policy recommends and prioritises establishing sufficient labelling and packaging requirements, adequate medical devices testing facility and effective port-clearance mechanisms for medical products. (Para 19)

- **Improving Public Sector Capacity for Manufacturing Essential Drugs and Vaccines:** The Policy recognises that public sector capacity for the manufacture of certain essential drugs and vaccines is also essential in the long term for the health security of the country and to address some needs which are not attractive commercial propositions. These public institutions need more investment, appropriate HR policies and governance initiatives to enable them to become comparable with their benchmarks in the developed world. (Para 20)

- **Drug Innovation & Discovery:** The Policy recognises the key role that health research plays in the development of a nation's health and states that Government Policy would be to both **stimulate innovation and new drug discovery as required**, to meet health needs as well as to ensure that new drugs discovered and brought into the market are affordable to those who need them most. The Policy further states that **public procurement policies** and **public investment in priority research areas** with **greater coordination and convergence between drug research institutions, drug manufacturers and premier medical institutions** must also be aligned to drug discovery. (Para 25.2)

II. Regulatory Updates – Drugs

A lot of people think that regulations bring higher costs, but regulation is also about making sure that someone doesn't get to beat out the competition because they are dumping filth in the river or spewing poisons in the air

~Elizabeth Warren

1. Central Government sets up forum for Appeal against decisions of SECs

By a notice dated February 2, 2017[3], the CDSCO has laid down the procedure for appeal against decisions of the Subject Experts Committees ("SECs") that are set up to evaluate various categories of applications for clinical trials, new drugs and new medical devices. Appeals shall be heard by a Committee under the chairmanship of the concerned JDC (I), which shall give its recommendation within 7 days.

So far, in cases where the applicant was not satisfied with the recommendations of the SEC, the applicant had to approach various authorities for redressal of grievances against the SEC's decision.

2. Steps initiated to facilitate Ease of Doing Business for export of drugs

In keeping with the existing focus of the Central Government on taking relevant steps to facilitate the ease of doing business, the CDSCO, by a notice dated February 6, 2017[4], has proposed to make the following services available online through the SUGAM portal w.e.f. March 1, 2017:

- Seeking written confirmation issued by CDSCO for export of API to European Union (350 nos.) and
- Certificate of Pharmaceutical Products (COPP) issued jointly by State and CDSCO (1550 nos. approx)

The CDSCO has further announced that Risk Based Inspections would be carried out by the Centre and State with definite tools as reflected in the Risk Based Document prepared by the CDSCO. However, the applicant would mandatorily submit the details of observations made during self-inspections and follow any other overseas regulatory bodies or as decided by the Centre and State regulator from time-to-time.

It has been further provided that wherever extra inspections are required, the reasons for doing the same will have to be stated to the satisfaction of the higher ups of the concerned Central or State Regulator.

3. Online Application for Human Vaccines

In furtherance of its ease of doing business initiative, by a further notice dated February 6, 2017[5], CDSCO has announced that the applications for the following permissions are to be filed online through the SUGAM portal:

[3] The copy of the notice is availablewww.cdsco.nic.in/writereaddata/Publice%20Griveancejan2017.pdf
[4] The copy of the notice is available at: http://www.cdsco.nic.in/writereaddata/notice6_2_2017.pdf
[5] The copy of the notice is available at: http://www.cdsco.nic.in/writereaddata/Noticesugambio6_2_2017.pdf

- Clinical Trial applications for Human Vaccines.
- Marketing Authorization application for Human Vaccines.
- Registration Certificate for Human Vaccines.
- Import License for Human Vaccines.

4. NOC in respect of FDCs declared rational by Kokate Committee

In the year 2014, the Central Government had set up an Expert Committee under Prof. C.K Kokate ("Kokate Committee"), to examine the safety and efficacy of certain Fixed Dose Combination drugs ("FDCs") which were being sold in the market. The said Committee had declared certain FDCs as rational. Some manufacturers had been selling some of the FDCs declared as 'rational' by the Kokate Committee, under manufacturing licenses granted by the State Licensing Authorities, but without NOCs having been granted by the Central Licensing Authority. By a notice dated March 16, 2017[6], the DCG (I) has notified the following pathway for clearance of subsequent applications for permission to manufacture such FDCs:

1. The applicants will apply in Form 44 along-with a fee of Rs. 15000/- to the CLA through TR (6) challan, specifying, whether he is already holding product permission from SLA indicating date of permission or intends to obtain fresh permission.
2. The period of 4 years is to be reckoned from the date of approval of the Kokate Committee recommendation by the Central Government in respect of particular FDC.
3. The NOC from the Central Licensing Authority under Rule 21(b), as per the drugs and Cosmetic Rules, shall be issued within 30 working days, failing which, it would be deemed to have been approved.
4. The State Licensing Authority shall permit the manufacture of such FDCs if other conditions of license under the Drugs & Cosmetics Rules, which need to be verified by SLA, are found to have been fulfilled. The SLA shall verify the quality of such FDCs of each applicant/manufacturer, before grant of license as per the Drugs and Cosmetics Rules, 1945; and
5. Every manufacturer permitted to manufacture the FDCs shall send the Periodic Safety Update Report (PSURs) as per Schedule Y of the Drugs and Cosmetic Rules to the Licensing Authority under Rule 21(b) i.e. DGC(I). Failure to submit the PSURs shall be deemed as contravention of these Rules.

5. E-Enabled structure for regulating the sale of medicines in India

The Ministry of Health and Family Welfare (MoHFW), by a Public Notice dated March 16, 2017[7] has invited comments from stakeholders and the public at large, on the proposal for regulation of sale of drugs in the country through an e-enabled structure.

It has proposed the development of an electronic platform to be maintained by an autonomous body under MoHFW where all manufacturers, stockists/wholesalers or other distributors and also pharmacies located in rural and other remote areas, would be required to register themselves and enter data relating to the sale of

[6] The copy of the notice is available at: http://www.cdsco.nic.in/writereaddata/Noticesugambio6_2_2017.pdf
[7] The copy of the public notice is available at: http://www.cdsco.nic.in/writereaddata/public%20notice16march.pdf

drugs by them. The details of medicines dispensed will be entered in the e-platform and bills would be generated through the system. Such details would include the prescribing doctor's registration number, name of the chemist dispensing and the quantity supplied.

6. Creation of Database for drugs and medicines on SUGAM-Portal

By a notice dated April 3, 2017[8], the DGC (I) has requested all pharma drug companies, not yet registered in SUGAM, to register themselves.

After such registration, the companies are required to upload the databases of their drug manufacturing facilities and approved drug formulations, which shall be authenticated by the concerned State Drug Controllers. The existing users of SUGAM can fill their manufacturing facility details from their user profile.

CDSCO has launched the SUGAM platform as part of its comprehensive e-governance program for filing, tracking and processing applications for various services rendered by CDSCO.

7. Committee for improving the availability, affordability and accessibility of drugs to domestic patients

The Department of Pharmaceuticals has issued a public notice dated April 6, 2017[9], announcing the constitution of a committee to recommend to the government further steps to improve the availability, accessibility and affordability of drugs to domestic patients. Suggestions/comments have been requested to be submitted by May 1, 2017.

[8] The copy of the notice is available at: www.cdsco.nic.in/writereaddata/notice3_4_2017.pdf
[9] The copy of the public notice is available at: http://www.cdsco.nic.in/writereaddata/publicnotice6_2017.pdf

III. Regulatory Updates - Devices

Medicine is a science of uncertainty and an art of probability

~William Osler

1. Online portal for registration of Notified Bodies under Rule 13

By a notice dated April 7, 2017[10], the Central Licensing Authority announced the setting up of the online portal for the registration of notified bodies envisaged under the Medical Devices Rules and invited interested organisations etc. to a meeting convened on April 17, 2017 to test the alpha version of the online portal.

It is relevant to mention that under Rule 13 (5), w.e.f. July 1, 2017, duly accredited Notified Bodies interested in auditing manufacturing sites of Class A or Class B medical devices, can apply for registration with the Central Licensing Authority through the online portal.

*(For a list of the Relevant Rules Regarding Notified Bodies, please see **Annexure B** p.34)*

[10] Available at http://www.cdsco.nic.in/writereaddata/notified%20body%20notice.pdf

IV. Regulatory Updates – Drug Pricing

There's no need for fiction in medicine, for the facts will always beat anything you fancy

~Sir Arthur Canon Doyle

1. Notice for completion of compliance under "IPDMS"

By a notice dated January 12, 2017[11], the National Pharmaceutical Pricing Authority ("NPPA") requested Pharmaceutical manufacturers' associations to ensure Integrated Pharmaceutical DataBase Management System ("IPDMS") compliances by all companies. IPDMS compliance is mandatory under the Drugs Price Control Order 2013 ("DPCO 2013").

The list of companies which were not present in IPDMS and a list of companies which had not responded to Show Cause Notices for non-compliance were also annexed with the notice.

2. Revised guidelines for discontinuation of Scheduled Formulations

On January 23, 2017, the NPPA issued the following revised Guidelines[12] for discontinuation of Scheduled Formulations under para 21(2) of the DPCO 2013.

- **Where MAT of the formulation is less than 10% of the total MAT value of the formulation:** 'No objection' may be granted by NPPA without reference of case to the Chairman for gradual discontinuation. Applicant will be advised within 60 days of receipt of Form IV, to continue to manufacture/import and sell for a minimum period of 6 months from intended date of discontinuation. The company should not reduce production by more than 25% of previous year's production in each quarter during such period. Company shall follow ceiling price as may be fixed by NPPA. The company shall also issue a public notice in the prescribed format in at least 2 national newspapers (one in English and one in Hindi).

- **Where MAT of the formulation is 10% or more but less than 25% of the total MAT value of the formulation:** 'No Objection' may be granted by NPPA with the approval of the Chairman for gradual discontinuation. Applicant will be advised within 60 days of receipt of Form IV to continue to manufacture/import and sell for a minimum period of 9 months from intended date of discontinuation. Rest of the conditions remain the same as above

- **Where MAT volume of the formulation intended for discontinuation is 25% or more:** Such cases shall be put up for decision of the Authority. 'No Objection' may be granted by the Authority for gradual discontinuation after ascertaining availability. Applicant may be advised within 60 days of receipt of

[11] Available at: http://www.nppaindia.nic.in/order/NoticeUnderIPDMS_13-01-2017.pdf
[12] Available at: http://nppaindia.nic.in/order/GuidlinesForDiscontinuation31012017.pdf

Form IV to continue to manufacture/import and sell for a maximum period of 12 months from intended date of discontinuation. The company should not reduce production by more than 25% of previous year's production in each quarter during such period. The manufacturer will also follow other conditions as may be prescribed.

- **Exceptional cases where formulation has more than 25% share and proposed discontinuation may cause short supply and public inconvenience:** Such cases will be decided on merit and will be subject to approval of the Authority. NPPA will explore alternatives for bridging the production gap by approaching other manufacturers of the same formulation and also to DoP for a direction to Government PSUs under para 3 of DPCO 2013 to produce the formulation if possible. **NPPA may also consider an upward price revision under Para 19 if the formulation is proposed to be discontinued on account of non-remunerative pricing, a ground which needs to be established by the manufacturers.** The no-objection for discontinuation in such cases will either be deferred till alternative arrangements are ensured, or the Authority may allow partial discontinuation on a case-to-case basis.

3. Fresh notice for IPDMS compliance by companies

On account of continued physical filing of mandatory forms under the DPCO by some companies, by an Office Memorandum dated February 1, 2017[13], the NPPA informed all manufacturers' associations that henceforth only forms (Form II, III, V) filed through IPDMS would be considered as compliance and in case such forms were filed in the physical format, such filing would not be considered.

The NPPA also informed that it would not consider certain applications filed by companies unless their IPDMS compliances were complete.

4. DoP notifies formalities and documents for retail price fixation of new drugs

By an Office Memorandum dated February 7, 2017[14], the Department of Pharmaceuticals requested manufacturers and/or marketing companies to comply with formalities and furnish documents as set out in the Office Memorandum, along with Form I, for retail price fixation of a new drug.

5. NPPA makes IPDMS submissions compulsory for filing review

By an Office Memorandum dated February 16, 2017[15] the NPPA informed all Pharmaceutical Manufacturers' Associations that companies challenging PTR considered by NPPA, in review cases, are required to submit copies of supporting IPDMS submissions. A certificate to the effect that all requisite forms for all formulations have been filed through IPDMS is also required to be submitted.

[13] Available at: http://www.nppaindia.nic.in/order/NoticeDated01022017.pdf
[14] Available at: http://www.nppaindia.nic.in/order/officememorandamon07022017_02.pdf
[15] Available athttp://nppaindia.nic.in/order/IPDMSCompliance16022017.pdf

6. Revised guidelines for representations and review cases

By an Office Memorandum dated March 28, 2017, the NPPA issued revised Guidelines[16] making it mandatory for companies filing representations prior to price notification as well as in review cases, to submit (a) original samples indicating compliance with ceiling price notification against which review is filed, (b) another sample in support of the PTR claimed by the company for August 2015. Further, where data furnished relates to third companies, the onus of proving such data lies with the applicant.

7. DoP invites suggestions on improvements in the provisions of DPCO, 2013

By a Public Notice dated April 6, 2017[17] the Department of Pharmaceuticals informed that the Government had constituted a Group to recommend suggestions on improvements in the provisions of the DPCO 2013 to improve the availability, affordability and accessibility of drugs, and invited comments from all stakeholders in this regard, latest by May 1, 2017.

8. Further Guidelines and Standard Operating Procedure for Review Cases

By an Office Memorandum dated April 13, 2017, the NPPA issued Guidelines[18] and Standard Operating Procedure for Review Cases, fixing timelines for compliances by companies required to submit supporting documents after issuance of review orders relating to 'reconsideration of documents submitted by the companies'.

[16] Available at: http://nppaindia.nic.in/order/overcharging28032017_28.pdf
[17] Available at: http://nppaindia.nic.in/order/publicnotice0704201.pdf
[18] Available at: http://nppaindia.nic.in/order/gsopdr13042017.pdf

V. Regulatory Updates – Medical Devices Pricing

The doctor of the future will give no medicine but will interest her or his patients in the care of the human frame, in a proper diet, and in the cause and prevention of disease

~Thomas Edison

Coronary Stents

1. NPPA notifies options for fixing ceiling price

By an Office Memorandum dated January 4, 2017[19], the NPPA invited representations by stakeholders on the manner of calculation of ceiling price for coronary stents, since unlike other Schedule Formulations, Price to Retailers ("PTR") of stents are not captured by Pharmatrac. This difficulty arises as hospitals and/or nursing homes are the de facto retailers of stents. Representations were invited within 10 working days of such Office Memorandum.

2. Data requested from manufacturers for price notification

By a further Office Memorandum on the same date, i.e. January 4, 2017[20] the NPPA requested manufacturers/marketers/importers of coronary stents to submit data regarding Price to Retailer, Price to Stockist, Price to Distributor, Price to Hospitals, MAT and MRP for the months of May, July and November 2016 for all types and/or categories of coronary stents, latest by January 9, 2017.

3. NPPA invites comments on draft Calculations Sheets

Thereafter, by an Office Memorandum dated January 12, 2017[21] and Clarifications dated January 13, 2017[22] and January 16, 2017[23] the NPPA requested comments from stakeholders on draft calculation sheets for fixing ceiling price for coronary stents.

4. Ceiling Price of Coronary Stents fixed

By a lengthy order dated February 13, 2017[24] the NPPA fixed the ceiling price of bare metal stents at **INR 7,260/-** per unit; and of Drug Eluting Stents and Bioresorbable Vascular Scaffold/Biodegradable Stents at **INR 29,600/-** per unit.

[19] Available at: http://www.nppaindia.nic.in/order/CeilingPriceFixationOfCoronaryStent_04-01-2017.pdf
[20] Available at: http://nppaindia.nic.in/order/CeilingPriceFixationOfCoronaryStent_04-01-2017.pdf
[21] Available at: http://nppaindia.nic.in/order/CoronaryStents_12-01-2017.pdf
[22] Available at: http://nppaindia.nic.in/order/ClarificationRegCoronary%20Stents_13-01-2017.pdf
[23] Available at: http://nppaindia.nic.in/order/ClarificationRegCoronary%20Stents_16-01-2017.pdf
[24] Available at: http://nppaindia.nic.in/ceiling/press13Feb2017/so412e-13-02-17.pdf

5. NPPA threatens action for creating artificial shortage

By Office Memoranda dated February 16, 2017[25] and February 17, 2017[26] the NPPA informed stakeholders of manner of immediate compliance of price fixation notification for coronary stents including filing of Form II and Form V under DPCO 2013, and warned those trying to create artificial shortage, of strict action under Para 30 of DPCO 2013 (Power of entry, search and seizure).

6. Clarifications on trade margins in respect of price notification

By an Office Memorandum dated February 20, 2017[27] the NPPA clarified that the notified price for coronary stents was inclusive of an 8% trade margin, which would cover margins across the trade channels and also cover hospital handling charges. The NPPA further clarified that no additional charge whatsoever, over and above the ceiling price, would be charged from the consumer, except local sales tax/VAT, if paid in actual. The NPPA noted that Hospitals and/or Doctors would be expected to follow ethical standards and applicable regulatory provisions.

7. NPPA threatens action against those not complying with price notification

By Office Memoranda dated February 21, 2017[28] and February 23, 2017[29], the NPPA warned manufacturers/importers/hospitals of action under para 21 of DPCO 2013 (Monitoring the availability of Scheduled Formulations) including prosecution, in cases where revised price list had not been communicated to retailers and where such lists had not been displayed in conspicuous areas in hospitals where they were easily accessible to patients. "The NPPA further reminded manufacturers/importers of their obligation to maintain smooth supply of coronary stents in the same manner as before the price notification and warned of action if any complaints of withdrawal were received". "It further warned that complaints had been received that some hospitals had refused to make the "best stents" available on the ground that companies had told them to "hold" these stents. The NPPA warned that this was a clear violation of para 28 of the DPCO 2013 (Manufacturer, distributor or dealer not to refuse sale of drug)". It further clarified that the effective date for implementation of price cap was the date of billing and not the date of angioplasty and accordingly if a patient had angioplasty before February 14, 2017 but was billed after, such patient would mandatorily get the benefit of price fixation and hospitals are under obligation to refund the extra charges. The NPPA invited complaints from patients in case of grievances.

[25] Available at: http://nppaindia.nic.in/order/CoronaryStentsPriceFixed16022017.pdf
[26] Available at: http://nppaindia.nic.in/order/ComplianceOfPriceFixation17022017New.pdf
[27] Available at http://nppaindia.nic.in/order/CoronaryStents20022017.pdf
[28] Available athttp://nppaindia.nic.in/order/CoronaryStentsceilingpricesfixed21022017.pdf
[29] Available at http://nppaindia.nic.in/order/coronarystentpricecap23022017.pdf

8. NPPA continues to monitor the implementation of price notification

By an Office Memorandum dated February 28, 2017[30] the NPPA issued further instructions for compliance of price notification for coronary stents, viz:

i. All manufacturers/marketers/importers of coronary stents must display the MRP of different brands of the coronary stents of the company on the home page of their website within 3 working days;
ii. All hospitals/nursing homes/clinics/cardiac centres must display the MRP or price at which they are charging/billing patients for coronary stents, along with brand names, specifications and names of manufacturing/marketing companies, on the home page of their website within 3 working days.

Other Medical Devices

9. Instructions issued for mandatory printing of MRP on notified medical devices

By an Office Memorandum dated March 10, 2017[31] the NPPA advised manufacturers of non-scheduled medical devices notified as 'drugs' under the Drugs and Cosmetics Act and Rules, to ensure compliance of the provisions of the DPCO, 2013, to avoid action against them.

The following medical devices are presently notified as 'drugs':

1. Disposable Hypodermic Syringes
2. Disposable Hypodermic Needles
3. Disposable Perfusion Sets
4. In vitro Diagnostic Devices of HIV, HBsAg and HCV
5. Catheters
6. Intra Ocular Lenses
7. I.V. Cannulae
8. Bone Cements
9. Heart Valves
10. Scalp Vein Set
11. Orthopedic Implants
12. Internal Prosthetic replacements
13. Blood Grouping Sera
14. Ligatures, Sutures and Staplers
15. Tubal Rings
16. Surgical Dressings
17. Umbilical Tapes
18. Blood/Blood Component Bags
19. Drug Eluting Stent

[30] Available at http://nppaindia.nic.in/order/PriceFixationofCoronaryStents28022017.pdf
[31] Available at http://nppaindia.nic.in/order/officememorandomprinting10032017.pdf

20. Cardiac Stents (BMS)
21. Condoms
22. Intra Uterus Devices

Of the above, the devices under Sr. Nos. 19 – 22 are 'Scheduled Formulations' under the DPCO 2013 and are under price control of NPPA.

As regards the remaining, which are 'Non-Scheduled Formulations', **Para 25(1)** of the DPCO 2013, casts an obligation on every manufacturer to display the MRP of such formulations and the words 'inclusive of all taxes' after such MRP, on the label of the container thereof and the minimum pack thereof. **Para 25(2)** requires every manufacturer of such formulations to issue price lists thereof in Form V to dealers, State Drug Controllers and the Government indicating changes from time to time. **Para 25(3)** requires every retailer and dealer to display such price list at a conspicuous part of the premises where he carries out business.

Para 26 prohibits any person from selling any formulation at a price exceeding the price specified in the current price list or printed on the label of the container or pack, whichever is less.

Under **Para 20(1)** a manufacturer of a 'Non-Scheduled Formulations' cannot increase the MRP of such formulation by more than 10% of the MRP of such formulation during the preceding 12 months.

10.Draft format issued for collecting price data of medical devices, heart valves

On April 13, 2017[32] the NPPA issued a draft format for collection of price data for Heart Valves prepared in consultation with manufacturers and/or importers of Heart Valves, and invited comments within seven days of issue of such draft.

[32] Available at http://nppaindia.nic.in/order/medicaldevice13042017.pdf

VI. Court Updates – Important Orders and Judgments

Always laugh when you can. It is cheap medicine

~Lord Byron

1. Transfer of FDC matters pending across India to the Hon'ble Supreme Court

By an order dated March 31, 2017, the Hon'ble Supreme Court, hearing a transfer petition filed by the Union of India[33], directed that all matters pending before various High Courts, against the Government's notifications dated March 10, 2016 prohibiting manufacture for sale and distribution of 344 fixed-dose-combination ("FDC") drugs, be transferred to the Hon'ble Supreme Court for final adjudication.

Such matters will now be heard along with the Special Leave Petition[34] filed by the Union of India against the judgment and final order dated December 01, 2016 passed by the Hon'ble High Court of Delhi quashing all 344 notifications.

The Hon'ble Supreme Court further directed that till such time that the matters are heard, proceedings before various High Courts shall remain stayed. The matters have been directed to be listed in the month of July 2017.

ELP Delhi advises leading associations of the Pharmaceutical Industry viz., Federation of Pharma Entrepreneurs ("FOPE") and the Indian Drug Manufacturers Association ("IDMA"), who had challenged all 344 notifications before the Hon'ble Delhi High Court, on the ground inter alia, that the notifications which banned all 344 FDCs citing identical reasons, had been issued without the due process of law. The Hon'ble Delhi High Court has set aside all the 344 notifications hearing the petition filed by FOPE and IDMA.

2. Division Bench grants Biocon-Mylan permission to market new Bio-similar for additional indications without restrictions

By an order dated March 3, 2017[35] the Hon'ble Division Bench of the Delhi High Court, hearing appeals filed by Biocon and Mylan[36] against order dated April 25, 2016 passed by Hon'ble Mr. Justice Manmohan Singh, permitted Biocon and Mylan to manufacture and sell their biosimilar Trastuzumab without any restrictions, for all three indications, viz, Her2 Metastatic Breast Cancer ("MBC"), Early Breast Cancer ("EBC") and Metastatic Gastric Cancer ("MGC").

[33] Union of India v. Anglo French Drug & Ors. bearing T.P (C) No. 1729-1732/2016.
[34] UOI & Anr. v. Pfizer Ltd and Anr. bearing No. S.L.P.(C) 7061 /17
[35] Order available at http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=50677&yr=2017
[36] Biocon Ltd. V. Roche Products India Pvt. Ltd. and Ors. FAO(OS)132/2016 & Mylan INC v. Roche Products India Pvt. Ltd. and Ors. FAO(OS)133/2016

The Division Bench passed such an order in view of marketing approvals having been granted by the Drugs Controller General of India to Biocon and Mylan. The Single Judge's order, whereby certain restrictions on the sale of their biosimilar drugs CANMAB and HERTRAZ were imposed on both these companies, was also stayed.

Roche has filed a Civil Suit[37] alleging that Biocon's CANMAB and Mylan's Hertraz are not biosimilars of Trastuzumab since all requisite tests had not been carried out and the approvals granted by the Drug Controller General were issued wrongly. By his interim order dated April 25, 2016, the Hon'ble Single Judge had imposed restrictions on Biocon and Mylan with respect to the packaging and labelling of their drugs.

ELP Delhi is representing a Hyderabad-based pharmaceutical company against which Roche has filed a similar petition with respect to another biologic drug, Bevacizumab, used to treat cancer, alleging "passing off", misappropriation of Roche's data and non-completion of clinical trials.

3. *Division Bench refuses to grant relief to Sun Pharma in a trademark infringement case against Mylan Laboratories*

By an order dated March 24, 2017[38], the Division Bench of the Delhi High Court refused to interfere with an order dated February 10, 2017 passed by the Single Judge in a Civil Suit filed by Sun Pharma against Mylan Laboratories[39], alleging trademark infringement of cancer drug Oxaliplatin.

Sun Pharma had alleged that the trademark of Mylan's drug, SOXPLAT, was phonetically similar to OXIPLAT that is, the trademark under which its own drug is sold.

The Hon'ble Single Judge had dismissed Sun Pharma's application for interim injunction under Order 39 Rule 1 and 2 of the Code of Civil Procedure, holding that the words 'SOX' and 'OXI' used by the two companies (as prefixes) in their respective names for the medication, were distinctly different in nature.

4. *CCI DIRECTS INVESTIGATION AGAINST F. HOFFMAN LA ROCHE AG*

Vide an order dated April, 21, 2017[40], the Competition Commission of India ('CCI') has directed investigation against F. Hoffman La Roche AG, Genentech Inc., and Roche Products (India) Private Limited (collectively 'Roche') on allegations of abuse of dominant position.[41]

CCI rejected the preliminary objection of Roche to the maintainability of the Information. Roche had argued that since issues raised in the Information were pending before the Delhi High Court in the Civil Suit, the Information was not maintainable. Rejecting the same, the CCI noted that the issue of abuse of dominant position by Roche could only be adjudicated upon by the CCI in view of Section 61 of the Act. Placing reliance on the decision of the Delhi High Court in Telefonaktiebolaget LM Ericsson (Publ) v. CCI & Anr, the CCI concluded

[37] Roche Product India Pvt. Ltd. and Ors. v. Drug Controller General of India CS(0S) No. 355 of 2014
[38] Order available at http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=59353&yr=2017
[39] Sun Pharma Laboratories Ltd. V. Mylan Laboratories Limited and Anr. CS(OS) 1098/2016 ANDI.A. No. 21119/2014
[40] Case No. 68 of 2016
[41] http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf

that the pendency of the Civil Suit would in no way place an embargo on the power of the CCI to adjudicate on alleged violations of the Act.[42]

The observations of CCI with respect to Mylan-Biocon's submissions are summarised as follows:

- Denial of market access by filing vexatious suits to stall approval and launch of biosimilar products: While recognising that in certain circumstances filing of suits can be considered as abusive and anticompetitive, on account of the duration for which the Civil Suit has been pending and the order dated April 25, 2016 the CCI was "reluctant" to hold the Civil Suit as baseless and hence found no prima facie case in this regard.[43]

- Denial of market access by influencing regulatory standards, tender conditions and denigrating biosimilars: The CCI noted that misrepresentations made by Roche regarding the implications of the Civil Suit, the representations made to stall regulatory approval, the attempts to influence tender conditions and the attempts made to denigrate and disparage biosimilars would "have a cumulative effect of foreclosing the market for biosimilars.[44]"

- Imposing unfair conditions in purchase of biosimilars: Roche's failure to provide 150 mg vials despite having approval for the same was considered by the CCI to be a prudent business strategy and hence the CCI found no prima facie contravention of Section 4(2)(a)(i) of the Act.[45]

[42] *Biocon Limited and Mylan Pharmaceutical Private Limited* v. *Hoffman La Roche AG & Ors,* Case No. 68 of 2016, order dated 21 April 2017 at para 38-42.
[43] at Para 65 of the Order
[44] at Para 76 of the Order
[45] at Para 80 of the Order

VII. Directors' Liability and Key Compliances

Those who build great companies understand that the ultimate throttle on growth for any great company is not markets, or technology, or competition, or product. It is one thing above all others; the ability to get and keep enough of the right people

~James C Collins

Directors' Liability in the Pharma & Life Sciences sector is dealt with under **Section 34** of the Drugs and Cosmetics Act 1940 ("D & C Act") and **Section 10** of the Essential Commodities Act, 1955 ("ECA").

The said provisions affix liability in case of offences by companies[46] in two ways:

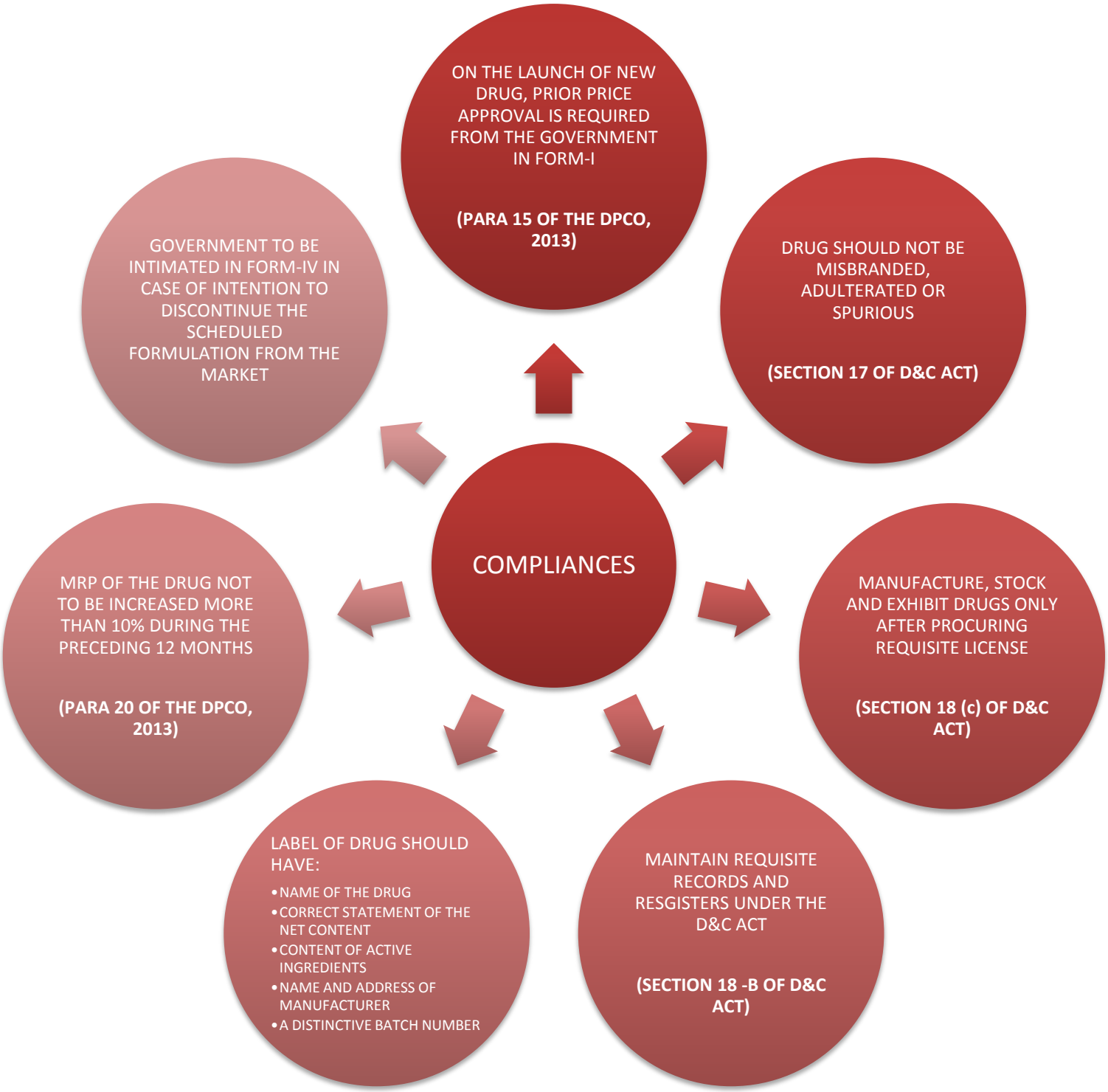
- Firstly, they affix liability on ***every person*** who was ***in charge of*** and was ***responsible to the company for the conduct of the business of the company***. **[See section 34 (1) D & C Act and Section 10 (1) ECA]**
  - Such persons would, however, not be liable for the contravention if they can prove that the contravention took place ***without their knowledge*** or that they ***exercised due diligence to prevent*** such contravention. **[See Proviso to Section 34 (1) D & C Act and Section 10 (1) ECA]**

- Secondly, a ***director***, manager, secretary or other officer of the company is specifically made ***liable*** if it is proved that the offence was committed with the ***consent*** or ***connivance*** of or was ***attributable to any neglect*** on their part. **[See section 34 (2) D & C Act and Section 10 (2) ECA]**

The provisions mentioned above embody the general principle of Vicarious Liability in the law of tort, that a person, including a director, may be imposed with liability for the offences committed by another, (in this case a company), if it is proved that (1) a tortious act or omission by another has taken place, (2) there is some relation between the wrongdoer and the defendant whom it is sought to make liable, and (3) there is some connection between the tortious act or omission, and that relationship.[47]

In order to hold a director liable for the contraventions of the company under the abovementioned provisions, the prosecution must establish that at the material time he was in charge of and was also responsible to the company for the conduct of its business[48] and the contravention took place with his knowledge/consent/connivance or due to his neglect. In his defence, it would be open to the director to show that he had nothing to do with the acts resulting in the contravention[49], or that he exercised all due diligence in preventing the contravention.

[46] The definition of a "company" for the purposes of these sections includes a firm or other association of individuals and a "director" in relation to a firm means a partner in the firm.
[47] Vicarious Responsibility in law of Torts, P.S Atiyah (London Butterworths, 1967)
[48] State of Haryana vs Brij Lal Mittal & Ors; (1998) 5 SCC 343
[49] Dinesh B. Patel and Ors. vs. State of Gujarat & Anr; (2010) 11 SCC 125



VIII. Impact of Gst on Pharma Companies

GST means 'Great Step towards transformation', 'Great Step towards transparency' in India

~P.M. Narendra Modi

INTRODUCTION:

The Pharma and Life Sciences sector is one of the major contributors to GDP, as well as one of the fastest growing sectors in the country. Goods and Service tax (GST) which is expected to replace the complex current indirect tax regime is a regime that will obliterate multiplicity of taxes, will divide powers between the central and state governments, will create a distinction between goods and service, the concept of tax cascading and onerous compliance obligations. GST is therefore bound to impact the sector significantly.

GST was originally expected to peg India as one seamless market for businesses such that state barriers do not place a hurdle on trade in any manner. While baby steps have been taken in the right direction, the overall ambition may take some time, given the shape and form of the laws and other drafts made public.

The following table illustrates the differences between the present tax regime and the new regime under the GST, in the standard business model followed by the Pharma industry:[50]

Activity/Business Process	Present Tax Regime	GST Regime
Manufacturing of pharmaceutical products at Company's factory	- Liable to Excise duty at time of removal of goods from its depot. - 'Retail sale price' (less 35% abatement as given under Abatement Notification) will be considered for the purposes of discharging excise duty.	No GST will be levied at the manufacturing stage

[50] Currently, the pharmaceutical sector in India faces a multistage taxation system. Different taxes—such as import customs duty, central excise duty on manufacture, CST/VAT on sale, and service tax on provision of services—greatly add burden to operating margins of the pharma industry.

GST implementation will lead to re-distribution of taxes across different business functions, thereby, leading to low taxation cost for drug makers. The most direct impact is likely to come from elimination of CST which will inevitably lead to a reduction in transaction cost.

Transfer of Goods from Company's factory to its depot	Not liable to VAT/ CST (stock transfer against Form F)	- IGST[51] will be levied on transfer of goods from factory to depot provided both are located in different states (no tax in case of supply of goods within the same state provided no separate registration is taken for factory and depot both located in same state). Credit of the IGST shall be available to depot. - Value of supply will be determined as per Rule 2 of draft Valuation Rules i.e. value declared in the invoice (in case depot is eligible for full input tax credit) *or* 'open market value' (in any other case).
Sale of Goods from Company's depot to specific buyers	Sale of goods is liable to VAT/CST	- Supply of goods shall be liable to CGST[52]+SGST[53]/UGST[54] or IGST. - Value of supply will be '**transaction value**' i.e. price actually paid *or* payable for the supply of goods. - Export of goods will be 'zero rated supplies' i.e. no GST will be payable.
Sale of Goods by Company to Stockist on principal to principal basis	Sale of goods is liable to VAT/CST	- Supply of goods shall be liable to CGST+SGST/UGST or IGST. - Value of supply will be '**transaction value**' i.e. price actually paid *or* payable for the supply of goods.
Sale of Goods by Company to final consumer *via* CNF Agent	- Transfer to goods from Company to CNF Agent is not liable to tax against Form-F. - Sales made by CNF on behalf of Company is subject to VAT/CST and Company will be liable to	- Transfer to goods from Company to CNF Agent will be liable to CGST+SGST/UGST or IGST. - Value of supply will be determined as per Rule 3 of the draft Valuation Rules i.e. '**open market value'** *or* **90% of the price charged for supply of goods** of like kind and quantity by the recipient (i.e. agent) to Central Goods and Service Tax the

[51] Integrated Goods and Service Tax
[52] Central Goods and Service Tax
[53] State Goods and Service Tax
[54] Union Territory Goods and Service Tax

	pay VAT/CST. - Commission paid by Company to CNF is liable to Service tax in the hands of CNF	customer not being a related person.

IMPACT AREAS

As in other sectors, the impact of GST on 'ease of doing business', supply chain efficiencies, warehousing and logistics efficiency is also expected to be felt in the Pharma Sector. The time horizon however, is medium to long term, as re-augmentation cannot happen either before the GST start date or instantly thereafter. Hence, these opportunities must be carefully planned and dealt with.

For a deeper understanding of the impact of GST on the pharma sector, it is pertinent to note the following peculiarities of the pharma sector:

- Highly regulated sector on the counts of quality as well as pricing;
- Pre-fixed margins in the distribution chain (i.e. for wholesalers as well as retailers);
- Price efficiency of generic products;
- Special transportation and storage conditions;
- Most active job-work scenarios including tax free zones;
- Standard sales promotion strategy but huge cost – physician samples and gifts and volume-linked value incentives;
- Non-process loss to arrive at marketable production (quantity applied for batch and quality testing as required under regulations);
- Low rate scenarios in the current regime;
- Prolonged litigation of place of provision of testing services and eventual unfavorable tax consequence;
- Bucketing each matter in the list of favourable impact or otherwise is difficult since the opportunities and risks vis-à-vis each co-exists.

Some matters have been detailed below:

THE DISADVANTAGE OF BEING REGULATED

The prices of most products are covered by the Drug Price Control Order and for the remainder; restrictions apply on both the timing and quantum of price alteration. With the altered rate structure (i.e. to fit within the prescribed GST rate slab) and trade not willing to lose the absolute margin currently enjoyed, the manufacturer or the marketer will have to take a hit on their margins since the prices can't be increased easily.

THE RATE ANATOMY

With several exemptions and low-rate taxation models prevalent for drugs and pharma products, fitment into rate slabs would not be straightforward. The issue is even more complex as manufacturers currently opt for a lower rate of excise duty on production by forgoing tax credit on procurement. Affordable healthcare may, therefore, need a new strategy.

PHYSICIAN SAMPLES UNFIT FOR INPUT TAX CREDIT

Is it worthy of a debate to ascertain whether a genuine age-old established practice of distributing pharma samples is nothing but well-recognized marketing expenditure? While sales promotion expenditure is eligible for input tax credit, pharma samples find place in the effective negative list for input tax credit.

BUSINESS PRESENCE CONSOLIDATION

While the tax hurdle goes away, the need for special transportation and storage facilities for drugs and medicines never let businesses follow an ideal structure of warehousing and logistics planning. GST may enable unlocking of the profit-and-loss potential of such drugs and medicines.

THE SEASONAL IMPACT

The trade generally understands that the transition inventory, which would have suffered current taxes, may have the inability to present a business case for ramping up the stocks on the GST cut-off date. Several trade associations have also recommended a minimum or no stock approach to its constituents such that the uncertainty of GST does not impact them. What can the manufacturers do in the following business and/or practical scenarios?

- July onwards, a 4 to 6 month period is effectively a season for the pharma industry with the monsoon kicking in and the approach of winter.

- Inventories cannot be lowered or up scaled drastically due to production and storage capacities (assuming the distribution chain is not storing anything on the cut-off date).
- Production plan, even if altered, needs 2 to 3 months of implementation, since the raw materials and logistics are all aligned to the plan, and volume commitments may have already been made.

Therefore with a lack of clarity on the start date, on the rate of applicable tax, as well as on transitional credits, the pharma industry is finding it increasingly difficult to strategize, as different cut-off dates and production-distribution lead time keep its hands locked for any creativity.

MISCELLANEOUS

The industry is also working overtime to find answers as to how to handle promotional schemes where heavy lifting leads to lowering of per unit prices. There is also an ongoing debate on the place of supply of testing services, where one counter party is outside India. Therefore, several other such matters need resolve.

Experts opine that companies must make timely preparation for GST. Experts also fear that failing to do so would result in prospective business risks and reputational and compliance threats. It is important to note that while the sector prepares for GST, that GST transition is not just a transition of tax; it impacts every aspect of the business operations and therefore it requires a 'whole of business' approach to ensure a smooth transition.

Annexure A

A Brief View of the Medical Devices Rules, 2017

The Central Government has notified the Medical Devices Rules, 2017 (hereinafter "the Rules"), setting the stage for bringing Medical Devices under a new regime of regulation.

Some key features of the Rules are as under:

1. **"Medical Device"** has been defined under **Rule 3 (zb)** as:
   i. Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant,
   ii. Substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under Section 3(b)(ii) of the D & C Act, and
   iii. Devices notified from time to time under Section 3(b) (iv) of the D & C Act.

2. **Under Rule 4**, Medical devices have been **classified into four categories based on their risk factor** viz., **Class A, Class B, Class C and Class D**, where Class A comprises of low risk devices, Class B of low moderate risk devices, Class C of moderate high risk devices and Class D of high risk devices.

3. Based on such classification, a class-wise list of medical devices shall be published on the website of the Central Drug Standards Control Organization. **(Rule 4 (4)).**

4. The Rules further provide for grant of **separate licenses for the manufacture and import** of medical devices and impose separate conditions to be fulfilled for obtaining these licenses.

5. Licenses for manufacture for sale or for distribution for devices falling under **Classes A and B** shall be granted by the **State Licensing Authority (Rule 8 (2)),** whereas, licenses for manufacture for sale or for distribution for devices falling under Classes B and C shall be granted by the **Central Licensing Authority. (Rule 8 (1)).**

6. **Import** of all medical devices will continue to be regulated by the **Central Government (Rule 34).** The manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.

7. An **authorised agent** having a license to manufacture for sale or distribution or a wholesale license for sale or distribution under the Rules, may apply to the Central Licensing Authority **for grant of import license** for medical devices. **(Rule 34 (1).**

8. **Clinical Investigation for the grant of Import License is not required in case a free sale certificate** has been issued in respect of a medical device, by the national regulatory authority of Australia, Canada, Japan, EU or USA **(Rule 36).**

9. Where the medical device is imported from countries other than those specified, Import License in case of **Class C and Class D** devices may be granted after their **safety and effectiveness** has been established through **clinical investigation in India. (Rule 36 (4)).**

10. Where the medical device is imported from countries other than those specified, Import License in case of **Class A and Class B** devices may be granted after their **safety and performance** has been established through **published safety and performance data** or **through clinical investigation in the country of origin** and **a free sale certificate from the country of origin (Rule 36 (5)).**

11. No permission to import any class of investigational medical device or new in vitro diagnostic medical device shall be granted without prior permission of the Central Licensing Authority. **(Rule 36 (6)).**

12. Medical devices are required to conform to the standards laid down by the **Bureau of Indian Standards** or any other standard as may be notified by the Ministry from time to time. In the absence of any relevant standard, they are required to conform to the standard laid down by the **International Organization for Standardization (ISO)** or the **International Electro Technical Commission (IEC)** or any other pharmacopoeial standard. **(Rule 7).**

13. A network of **'Notified Bodies'** accredited by the National Accreditation Body to be set up under the Rules and registered with the Central Licensing Authority, would be empowered to carry out an audit of manufacturing sites. Whereas audit by a Notified Body is mandatory for Class A and Class B devices, the Central Government may avail the services of a Notified Body if necessary, for Class C and Class D devices. **(Rules 11 and 13).**

14. The Rules also prescribe requirements for **labeling** of medical devices. **(Rule 44).**

15. Every medical device will be required to bear a **Unique Device Identification** w.e.f. January 1, 2022. **(Rule 46).**

16. The **term of licenses** for manufacturer or import would be in **perpetuity** until they are surrendered or cancelled, subject to payment of license retention fee before completion of five years from the date of issue. **(Rules 29 and 37).**

17. The **shelf life** of a medical device shall ordinarily **not exceed 60 months** from the date of manufacture unless a justification to the contrary is presented by the manufacturer to the Central Licensing Authority. The restrictions on the shelf-life of imported medical devices would vary depending on the percentage of residual shelf-life as on the date of import. **(Rule 47).**

18. Separate provisions for regulation of **Clinical Investigation** of investigational medical devices have also been made at par with international practices and regulated by the Central Licensing Authority. The Rules also provide for the payment of **compensation to a subject of clinical investigation** who has been adversely impacted by such investigation. **(Rule 55).**

(ELP is tracking any new developments in this area and will update as soon as any fresh steps are taken for implementation of the Rules.)

Annexure B

Relevant Medical Devices Rules regarding Notified Bodies

- Under **Rule 13 (1),** any institute, organisation or body corporate may seek accreditation, after notification of the Medical Devices Rules, as a "Notified Body" by applying to the National Accreditation Body set up under Rule 11.

- **Rule 13 (2)** provides that Notified Bodies duly accredited under Rule 13 (1) shall be competent to audit manufacturing sites of Class A or Class B medical devices to verify conformance with the Quality Management System as specified in the Fifth Schedule to the Rules, and other applicable standards as specified under the Rules in respect of medical devices, as and when so advised by the State Licensing Authority.

- **Rule 13 (3)** provides that any duly accredited Notified Body, interested in carrying out an audit of manufacturing sites of Class A or Class B medical devices are required to register with the Central Licensing Authority.

- **Rule 13 (4)** provides that any duly accredited Notified Body, with an experience of at least 2 years, may apply to the Central Licensing Authority for registration as a Notified Body for carrying out an audit of Class C or Class D medical devices provided it has personnel with requisite qualifications and experience.

- **Rule 13 (5)** provides that with effect from July 1, 2017, the duly accredited Notified Body interested in auditing manufacturing sites of Class A or Class B medical devices, may apply to the Central Licensing Authority for registration in Form MD-1 through an online portal.

- **Rule 13 (6)** provides that the Central Licensing Authority shall register the Notified Body and issue Registration Certificate in Form MD-2 on being satisfied.

- **Rule 13 (7)** provides that such Registration Certificate shall remain valid in perpetuity, unless suspended or cancelled on deposit of registration retention fee as specified, every five years.

Glossary

Term	Meaning
API	Active Pharmaceutical Ingredients
BIS	Bureau of Indian Standards
CDSCO	Central Drug Standard Control Organization
CLA	Central Licensing Authority
COPP	Certificate of Pharmaceutical Products
DCI	Drug Controller of India
DDCI	Deputy Drug Controller India
DCGI	Drug Controller General of India
DoP	Department of Pharmaceuticals
D&C Act	Drugs and Cosmetic Act
D&C Rules	Drugs and Cosmetic Rules
IEC	International Electro Technical Commission
IPA	Indian Pharmaceutical Alliance
IPDMS	Integrated Pharmaceutical Data Management System
ISO	International Organization for Standardization
JDC	Joint Drug Controller
MAT	Moving Annual Turnover
MCI	Medical Council of India
MoHFW	Ministry of Health and Family Welfare
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
PSUR	Periodic Safety Update Report
PTR	Price to Retailer
SDC	State Drug Controllers
SECs	Subject Expert Committees
SLA	State Licensing Authority
US FDA	United States Food and Drug Administration

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Ashish has immense experience in handling commercial litigation and IP issues. Having started his career with Lall & Sethi Advocates in 2003, he has advised and strategized IP enforcement actions, involving Trademarks, Copyrights, Designs, Patents, Domain Names, Confidential information, Trade secret, Comparative advertising, Counterfeiting, Ambush Marketing and executed Anti-piracy operations in India and the South Asia Subcontinent, before foraying into commercial/regulatory litigation, arbitration and dispute resolution practice.

Ashish is adept in providing legal solutions in conflict situations - involving contractual disputes, government actions, regulatory changes, and statutory violations. He regularly undertakes risk analysis and advises clients on key legal issues involved in commercial transactions with a keen eye on resolution of (potential) conflict situations. Ashish has handled some major issues in sectors including Food & Drugs, Telecom, Infrastructure, Pharmaceutical, Information Technology, Media, Television and Broadcast, Foreign Investments and Defense amongst many others. He continues to advise a wide range of industries on the protection of their Intellectual Property Rights ("IPR").

He regularly advises on Food & Drug Laws and assists in compliance with regulations under the FSSA, 2006 and D&C Act. Ashish has played a key role in defending first approval for a *biosimilar* cancer drug in India, and has strategized a timely launch of their drug. He has successfully led the challenge to the ban on FDC before the Delhi High Court and the issue of product approval in regard to proprietary food on behalf of industry associations and leading Pharma/Food companies.

Ashish has represented clients before the Arbitral tribunal(s) – both domestic as well as international. He has been involved in advising and representing clients before DRT, NGT, NCLT, District Courts, High Courts and the Supreme Court of India ("SC").

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