Pharma & Healthcare Update

October 23, 2012

PHARMA UPDATE - II

This is the second part of the Pharma Update series which we started last month. The first part can be found here.

GoM finalizes pharma pricing policy - market based pricing model proposed by industry adopted, covers all essential medicines under NLEM 2011

On September 11, 2012, the Supreme Court had directed the Government to decide the pharma pricing policy by September 27, 2012.[1] Acting on this direction, the Group of Ministers ("**GoM**") has approved the proposal to bring all of the essential medicines specified under National List of Essential Medicines, 2011 ("**NLEM**")[2] under price control, as was proposed in the Draft Pharmaceuticals Pricing Policy, 2011 ("**Draft Policy**")[3], released by Department of Pharmaceuticals. However, the GoM has drifted from the Draft Policy by proposing to price these medicines as per the weighted average of market price of the all brands which hold more than one (1) percent market share by volume. The proposal has been forwarded to the Cabinet for the final approval. It has been reported that the Cabinet will finalize the policy by end of November, 2012, and the Department of Pharmaceuticals will notify the new Drug Price Control Order based on this policy within a week of the Cabinet's approval.[4]

The Drug Price Control Order, 1995 (DPCO) gives power to the National Pharma Pricing Authority ("**NPPA**") to regulate price of drugs included in the Schedule of the DPCO. As per the old pharma pricing policy, seventy four (74) Bulk Drugs and their Formulations were brought under the DPCO and their price was fixed with reference to the cost of manufacture of those drugs ("**Cost- based pricing model**"). The Draft Policy had proposed to bring all of 348 (three hundred and forty eight) essential medicines specified under the NLEM as well as various other formulations and combinations of drugs, which were not listed under the NLEM under price control. It is notable that GoM decision covers only essential medicines covered under NLEM, and does not extend to other formulations and combinations which are hitherto covered by the Draft Policy.[5]

t has been predicted that the proposed new Pharma Pricing Policy as suggested by GOM is likely to impact the industry as essential medicines cover about thirty (30) percent of pharmaceutical market[6] in India, while on the other hand it will benefit the consumers as the new pricing policy will certainly bring down prices of essential drugs. It has been reported that Indian subsidiaries of multi-national pharma companies will be worst hit as all their profits are derived from sale of medicines in India.[7] Indian Companies may not be hurt as much as they derive their profits from export market.[8] The impact of the new drug policy on other countries which use prices of drugs in India as a reference to fix prices will be felt after the policy has been finalized.

CDSCO to take action on Adverse Drug Reactions (ADRs) submitted under Pharmacovigilance Program of India (PvPI) soon

Continuing its emphasis on collection of data on ADRs to ensure patient safety, the Central Drugs Standard Control Organisation (CDSCO), which is the apex drugs regulator in the Country, may soon start initiating regulatory action based on ADRs which are collected by Drug Monitoring and Reporting Centers (DMRCs) under PvPI. [*Readers may note that in our previous update, we had mentioned that the Drugs Controller General of India, which is the executive wing of CDSCO, had issued a directive to manufacturers of new drugs to submit all pending Periodic Safety Update Reports (PSURs) within a prescribed deadline or face penalty. The PSURs contain information, inter alia, about all adverse drug reaction which have come to the notice of the manufacturer.*]

The PvPI was initiated in 2010 by the Health Ministry of India to prepare drug safety profiles for drugs marketed in India. Such a program is necessary since pre- marketing clinical trials of new drugs may not be sufficient to guarantee patient safety in the long run, as they cater to a limited population and some adverse effects may take time to come to notice of the investigators. Under the Program, various

Proud Moments

Legal500 Asia-Pacific: Tier 1 for Tax, Investment Funds, Labour & Employment and TMT
2020, 2019, 2018, 2017, 2016, 2015, 2014, 2013, 2012

Chambers and Partners Asia Pacific: Band 1 for Employment, Lifesciences, Tax and TMT
2020, 2019, 2018, 2017, 2016, 2015

IFLR1000: Tier 1 for Private Equity and Project Development: Telecommunications Networks.
2020, 2019, 2018, 2017, 2014

AsiaLaw Asia-Pacific Guide 2020: Tier 1 (Outstanding) for TMT, Labour & Employment, Private Equity, Regulatory and Tax

FT Innovative Lawyers Asia Pacific 2019 Awards: NDA ranked 2nd in the Most Innovative Law Firm category (Asia-Pacific Headquartered)

RSG-Financial Times: India's Most Innovative Law Firm
2019, 2017, 2016, 2015, 2014

Benchmark Litigation Asia-Pacific: Tier 1 for Government & Regulatory and Tax
2019, 2018

Research Papers

3D Printing: Ctrl + P the Future
April 02, 2020

Dispute Resolution in India: An Introduction
April 02, 2020

Impact of Covid-19 on Contracts
March 31, 2020

Research Articles

Chambers Global Practice Guide: Gaming Laws
December 19, 2019

The Tips and Traps to Avoid When Investing in India
December 31, 2018

Evolving HR Law: Giving GCs Sleepless Nights?

some adverse effects may take time to come to notice of the investigators. Under the Program, various Medical Colleges and Hospitals throughout the country have been named as DMRCs and have been made responsible to collect ADRs and report them. The CSDCO may take regulatory action if a drug is found to be unsafe based on its safety profile.

Though the PvPI is planned to be executed in a phased manner between years 2010- 2015[9], it has been reported that the CDSCO will start taking cognizance as soon as credible data is available with it under the Program.[10]

This move may be seen as an indication of CDSCO's intention to treat the issue of patient safety with high priority and seriousness.

Audio- video recording of informed consent of clinical trial subjects to be made mandatory soon; Subject to be informed about possibility of failure of intended therapeutic effect of the administered dose

The Drugs Technical Advisory Board ("**DTAB**"), the highest technical advisory body under the Drugs and Cosmetics Act, 1940 ('**DCA**'), has accepted the suggestion of the Drugs Controller General of India ("**DCGI**") to make audio- video recording of procedure to obtain informed consent of subjects of clinical trial in India and maintain it.[11] According to DCGI, such a step will authenticate that at the time of enrollment proper care was taken to inform the subject about the pros and cons of the clinical trial and his participation was voluntary.[12] The DTAB has also accepted DCGI's proposal to make it mandatory for the investigator of a clinical trial to inform the trial subject about the possibility of failure of investigational product to provide intended therapeutic effect and in the case of placebo- controlled trial, to inform that the placebo administered would not have therapeutic effect.[13] The reason behind this proposal is obvious and does not require mention.

The proposed changes will be reflected in law as an amendment to the Schedule Y of Drugs and Cosmetics Rules, 1945 ('**DCR**') and Appendix V thereunder.

The Clinical Trial Industry, which is already encumbered with approval delays and continuing regulatory uncertainty surrounding compensation in case of trial related injury or death, may find this amendment to be burdensome as recording of informed consent procedure and maintenance of such recording will require a lot of resources and specialty with the investigator who is engaging the trial subjects.

Medical Devices sector may be further regulated by amendment of Drugs and Cosmetics Rules

The Drugs Technical Advisory Board ("**DTAB**"), the highest technical advisory body under the Drugs and Cosmetics Act, 1940 ("**DCA**"), has approved certain proposals made by an expert committee to further regulate the Medical Devices sector.[14] The Committee comprised of experts from the medical industry, regulatory authorities and clinicians who use such devices.[15] As a result of the approval, the Medical Devices sector may face more regulations by amendment in the Drugs and Cosmetics Rules, 1945 ("**Draft Regulations**").[16]

Readers may note that the Ministry of Health and Family Welfare had constituted six medical advisory committees to advise the Central Drugs and Standards Control Organisation ("**CDSCO**") on matters related to review and regulatory approval of new medical devices and clinical trials in India.[17] It seems like certain recommendations in form of amendments to the Drugs and Cosmetics Rules, 1945 ("**DCR**") have flowed from the recommendations of these Committees. The proposed amendments cover several aspects of import / manufacture / marketing of medical devices in India such as labeling, shelf life, standards on quality management systems and exemptions for custom made devices for their import.[18]

Only limited number of Medical Devices are currently regulated under the DCR, where they are classified as drugs. Unfortunately, there are numerous lacunae in the regulation surrounding medical devices sector. To address these lacunae, the Department of Science and Technology had prepared a comprehensive Bill to regulate medical devices sector in India. However, the Bill is pending legislative approval since 2006. Sensing that the Bill may not become an Act soon, the DCGI may have proposed these amendments to the Drugs and Cosmetics Rules, which may not require parliamentary assent.

It seems unlikely that Draft Regulations will be published and enforced immediately. The CDSCO will first prepare a draft and notify it, and publish it for public comment.[19]

Express permission required to manufacture, sale and distribute drugs for non- medicinal use -likely to impact multi- vitamin manufacturers

The Drug Technical Advisory Board ("**DTAB**"), the highest technical advisory committee under the Drugs and Cosmetics Act, 1940 ("**DCA**"), has approved a proposal to amend the item 1 of Schedule K[20]

of the Drugs and Cosmetics Rules, 1945 ("DCR") in such a way that all Persons who manufacture, sale or distribute drugs for non- medicinal use will have to take permissions / no- objection certificate

from relevant licensing authority to undertake any of those activities.21

This is similar to an older amendment to Schedule D recommended by DTAB. Under Schedule D, Item 1, an imported drug would be exempted from Part III of the DCA (covering import of drugs), if the label of the drug describes that it is intended to be used for non- medicinal purpose or any purpose other than medicinal purpose. The previous amendment proposed that in addition to the labeling requirement, a no- objection certificate or permission must be taken from the relevant drug authority.

Like Schedule D, Rule 123 of the DCR provides that items specified under Schedule K of the DCR will be exempted from Part IV (Manufacture, Sale and Distribution of Drugs) and Rules thereunder. The item 1 of Schedule K covers 'drugs not intended for medicinal use.' Thus, a drug not intended for medicinal use is exempted from application of Part IV of the DCA and supplementary rules in DCR. Many vitamins and multi- vitamins manufacturer had hitherto availed the exemption under Rule 123 by declaring their product as 'not for medicinal use' and applied for a license under Food Standards and Safety Act, 2006 ('FSSA') to manufacture and market vitamins as a 'food'.[22]

This practice, however, is considered illegal as it leads to violation of Drugs Price Control Order, 1995 ("**DPCO**").[23]

Over the years, the Department of Pharmaceuticals ("DOP") has notified many vitamins as controlled drugs. Since the DPCO also applies to formulations prepared form controlled drugs, any vitamin preparation containing controlled vitamins is also brought under price control. This affects products containing multi- vitamins.

In a case where a controlled vitamin or multi- vitamin is registered as 'food', it is difficult to enforce the DPCO and control price of the drug. It had been brought to the attention of the DCGI that many vitamin manufacturers were evading price control by registering vitamins as food under the FSSA.[24] The proposed amendment sought will fill this regulatory gap by requiring the vitamins manufacturers to register with the Drug Authorities too, making enforcement of DPCO easier.

On a different note, a Scientific Panel on Nutraceuticals has been set up to make recommendations for comprehensive regulations to govern manufacture, sale and distribution of Vitamins and Vitamin Compounds which do not exceed the Recommended Daily Allowance for Indians.

Schedule H1 in relation to prescription drugs receives DTAB approval, to be introduced soon

The Health Ministry had notified a draft amendment to the Drugs and Cosmetics Rules, 1945 ("**DCR**") in March this year that would result in creation of Schedule H1 to the DCR.[25] The draft amendment proposed that drugs which are included in the new Schedule H1 in addition of warning to retailers that the drugs should be sold only on prescription of a registered medical practitioner, would also have a warning for the consumers that there may be some harm associated with the consumption of the drug if not take in accordance with medical advice. The proposed label below is reproduced for information purposes.

Schedule H1 drug - warning:

-It is dangerous to take this preparation except in accordance with the medical advice

-Not to be sold by retail swithout the prescription of a Registered Medical Practitioner

The intention behind introduction of this new schedule to the DCR was to check the continuing practice of indiscriminate use of antibiotics in India.[26] This practice is resulting in development of anti-microbial resistance, that is, the pathogens are getting resistant to existing form and dosage of antibiotics. Increased anti- microbial resistance is resulting in requirement to prescribe new forms / higher dosage of antibiotics.

The draft amendment proposed to include these antibiotics and few habit- forming and anti- TB drugs which are abused, under Schedule H1 (total of 91 medicines), so that they will be sold with additional warning. It is hoped that the additional warning will make many indiscriminate users of these antibiotics refrain from using them without medical advice.

The aforementioned amendment was notified in March, 2012 without consultation with DTAB. It was eventually referred to DTAB for consultation, and the DTAB has now concurred for its validity.[27] Post the concurrence of DTAB, a final amendment may be notified anytime soon.

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

[1] 'NGO set to challenge market-linked drug pricing formula in Supreme Court', The Economic Times, September 29, 2012 (last accessed October 9, 2012).

[2] Available at http://cdsco.nic.in/National%20List%20of%20Essential%20Medicine-%20final%20copy.pdf (last accessed October 9, 2012).

[3] Available at http://pharmaceuticals.gov.in/mshT2810/FTY2.pdf (last accessed October 9, 2012).

[4] 'Change of drug pricing policy must not hurt common man: Supreme Court', The Times of India, October 12, 2012 available at http://articles.timesofindia.indiatimes.com/2012-10-12/india/34412079_1_dpco-essential-medicines-rise-in-drug-prices (last accessed October 12, 2012).

[5] Id.

[6] Quote by Ranjit Shahani, President, Organisation of Pharmaceutical Producers of India (OPPI) in Times of India, September 27 , 2012 available at http://timesofindia.indiatimes.com/business/india-business/Regulating-drug-prices-Group-of-Ministers-clears-pharma-policy/articleshow/16579986.cms (last accessed October 9, 2012)

[7] 'What is new drug pricing policy?', Moneycontrol.com, October 01, 2012 available at www.moneycontrol.com/smementor/mentorade/policy/what-isnew-drug-pricing-policy-763346.html (last accessed October 9, 2012).

[8] Id.

[9] 'Introduction to Pharmacovigilance Programme of India (PvPI) for Assuring Drug Safety', Central Drugs Standard Control Organisation, available at http://cdsco.nic.in/pharmacovigilance_intro.htm (last accessed October 8, 2012).

[10] CDSCO to begin regulatory action on ADRs reported under PvPI soonâ€, Pharmaiz.com, September 21, 2012 available at http://pharmabiz.com/NewsDetails.aspx?aid=71264&sid=1 (last accessed October 8, 2012).

[11] See Agenda No. 3 in DTAB Meeting Minuetes, available at http://cdsco.nic.in/dtab%20dcc%20ind/Minutes%20of%20DTAB/Minutes%20of%2061st%20DTAB%2024.07.2012.pdf (last checked October 8, 2012).

[12] Id.

[13] Supra note 11.

[14] See Agenda No. S- 3 in DTAB Minutes. Available at http://cdsco.nic.in/dtab%20dcc%20ind/Minutes%20of%20DTAB/Minutes%20of%2061st%20DTAB%2024.07.2012.pdf (last accessed October 8, 2012).

[15] Id.

[16] Supra note 14.

[17] Press Information Bureau, August 12, 2012 available at http://pib.nic.in/newsite/erelease.aspx?relid=86110 (last accessed October 8, 2012).

[18] Supra note 14.

[19] Supra note 14.

[20] Available at http://www.mogsonline.org/pdfs/shedule_k.pdf (last accessed October 8, 2012).

[21] See Agenda 7 in DTAB Meeting Minutes. Available at http://cdsco.nic.in/dtab%20dcc%20ind/Minutes%20of%20DTAB/Minutes%20of%2061st%20DTAB%2024.07.2012.pdf (last accessed October 8, 2012).

[22] The Chairman, National Pharmaceutical Pricing Authority has written to the office of DCG(I) that vitamin tablets and capsules are being marketed in the country as dietary / food supplement to circumvent the Drugs Price Control Order. Id.

[23] Supra note 21.

[24] Supra note 21.

[25] Gazette Notification GSR 228(E) dated 20th March, 2012 published by Ministry of Health and Family Welfare.

[26] See Agenda No. 2 in DTAB Meeting Minutes available at http://cdsco.nic.in/dtab%20dcc%20ind/Minutes%20of%20DTAB/Minutes%20of%2061st%20DTAB%2024.07.2012.pdf

(last accessed October 8, 2012).

[27] Id.

– Shreya Rao & Abhinav Harlalka
You can direct your queries or comments to the authors
