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Refresh

Changing Regulatory Landscape

Newsletter
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Sectoral regulations

Pharmaceuticals

Drug (Price Control) Order (DPCO) 2013

The Department of Pharmaceuticals has issued the Drug (Price Control) Order (DPCO) 2013, authorising the NPPA to regulate prices of drugs on India's NLEM 2011, using new market-based rules. The new policy will control around 30% of the domestic pharmaceutical market.

Under the 1995 order, drug prices were determined on a cost plus basis, which was further changed to the simple average of current prices, in which manufacturers were given a margin. To safeguard the manufacturer from the fluctuating prices of ingredients and other input costs, the policy provides to increase prices every year, according to the wholesale price index. A 10 % increase will be allowed on non-essential medicines.

To ensure the regular supply of medicines, the government has the authority to allow manufacturers to continue production for a period of one year. Manufacturers also need to inform the government six months prior to cessation of production.

Provisions set out in the order will not be applicable on the following manufacturers:

- A manufacturer producing a new drug patented under the Indian Patent Act 1970 and not produced elsewhere



- A manufacturer producing a new drug in the country by a new process, developed through indigenous R&D and patented under the Indian Patent Act 1970
- A manufacturer producing a new drug involving a new delivery system, developed through indigenous research and development, for a period of five years from the date of its marketing approval in India

Aerospace and defence

DIPP notifies the list of defence products requiring industrial licence

Following the amendments approved by the Defence Acquisition Council on 20 April 2013, the DIPP, Ministry of Commerce and Industry has recently released the list of defence products that will require an industrial licence.

The list is based on the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Goods Technologies. However, the clauses on technology and software have been removed from the list. This confirms that defence software and technology will not require an industrial licence. We have been earlier stressing on the need for clarity on the definition of the term 'defence equipment'. This clarification will facilitate investments into the sector.

Broadcasting

Consultation paper on DTH tariff regulations

A consultation paper has been issued by the TRAI on the obligation for a DTH operator to provide a compulsory offer to its subscribers, a standard tariff package for customer premises

equipment. A DTH operator shall give customers an option to acquire a customer premises equipment either through an outright purchase, a hire purchase or on a rental basis.

Currently, operators offer to their subscribers various types of CPEs with different features and capabilities such as a 'recording facility', internet or broadband compatibility, high definition or 3D reception capability etc, in addition to basic functionalities. These wide variations in terms of features and costs, oblige the customer to purchase specific CPE without understanding its requirements. Therefore, a standard tariff package is provided only for the basic or vanilla CPEs, meant for the reception of an SDTV, conforming to the relevant standards set by the Bureau of Indian Standards.

Food

Guidelines for obtaining an approval for a food product

The Indian food regulator, FSSAI in May 2013 announced a set of new guidelines to be followed for product approvals, applicable to operators in the food business. Although advisories for this have been issued in the past, given the complexities involved in the food sector and the timelines for obtaining product approval, the regulator has issued these new guidelines, which supersede earlier advisories, especially for food products for which standards are not specified in the FSS Act.

We have provided below a summary of the procedures laid down in the new guidelines:

S no	Nature of the food product	Prescribed guidelines
1.	<p>Food products having following attributes:</p> <p>a. Safety of ingredients is known and permitted under the FSS regulation, 2011/Codex and by other global regulatory bodies like the EU,/FSANZ and USFDA etc.</p> <p>b. The food product does not contain plants or botanicals or substances of animal origin.</p>	<ul style="list-style-type: none"> • Application in form 1(a) to be made by a FBO along with an affidavit and a list of documents as prescribed (refer to the annexure below) • The product approval division of the FSSAI will grant product approval on satisfactory submission and scrutiny of documentation.
2	<p>Food products having the following attributes:</p> <p>a. Safety of ingredients is known and permitted under the FSS regulation, 2011/Codex and by other global regulatory bodies like the European Union, Food Standards Australia New Zealand and the United States Food and Drug Administration etc.</p> <p>b. The food product contains ingredients including plants or botanicals or substances of animal origin.</p>	<ul style="list-style-type: none"> • These food products shall be considered for either a product approval or a NoC. • Application in Form 1(b) to be made by a FBO along with an affidavit and a list of documents as prescribed (refer to the annexure below) • Product approval will be granted after a safety assessment has been completed. • A NoC will be granted to food products in market, after a license has already been granted under a previous order or Acts.
3	<p>Food products similar to the food products mentioned in point two , that is, these contain ingredients, including plants or botanicals or substances of animal origin, except that the safety of the ingredients is insufficient to make a safety determination.</p>	<ul style="list-style-type: none"> • To be referred to the respective scientific panels. • Application in Form 1(c) to be made by a FBO along with an affidavit and a list of documents as prescribed (refer to the annexure below) • Product approval will be granted or denied, based on the risk assessment carried out by scientific panels.
4	<p>Food items where the safety of its ingredients and their conditions of use are published by the FSSAI or products whose ingredients are standardised or permitted under FSSR 2011.</p>	<ul style="list-style-type: none"> • Application in Form 1(d) to be made by a FBO along with an affidavit and a list of documents as prescribed (refer to the annexure below). • Such food products will not require any safety assessment except for authorisation of the ingredients contained.

General considerations

- Safety data wherever required needs to be provided for all the ingredients
- Use of minerals, vitamins, proteins, metals and amino acids as well as their compounds will not exceed the prescribed recommended daily allowances for Indians. In this regard, a FBO will need to follow the guidelines issued by the Indian Council of Medical Research or the NIN/WHO/ or the FAO.
- The above procedure, for obtaining a product approval will not be applicable if the food products or ingredients are either prohibited or banned.
- The procedure will equally apply to goods imported into India.
- In case of rejection of the application under the approval procedure, the products will be recalled as per the provisions laid down in the FSS (licensing and registration of food businesses).
- Complete list of ingredients specifying the level of use
- Copy of the label for products available in the market or proposed to be placed in the market
- Category number of the product as applicable under the Indian food category code
- Copy of the product approval or the NoC issued by the FSSAI (applicable only to food products whose ingredients are standardised or permitted under FSSR 2011)

Annexure

Documents required for product approval

The application for obtaining a product approval (in all the above cases) will require submission of the following documents:

- Respective application form along with the prescribed fee
- Affidavit in a prescribed form

Corporate regulations

Export of goods and software: Realisation and repatriation of export proceeds

The RBI has in consultation with the government of India, reduced the period for the realisation and repatriation to India, of the amount representing the full value of goods or software exported from 12 to 09 months from the date of export, with immediate effect. The reduced period is valid till 30 September 2013.

The provisions in this regard for a unit situated in a SEZ, where no time limit for the realisation and repatriation to India is specified, as well as exports made to warehouses established outside India (specified period of realisation is 15 months from the date of export, shall remain unchanged.

A.P(DIR series) circular no 105 dated 20 May 2013

Trade credits for imports into India:- Review of all-in-cost ceiling

The existing all-in-cost ceiling of 350 basis points over six months LIBOR will continue to be applicable till 30 June 2013.

A.P. (DIR series) circular no 98 dated 9 April 2013



Overseas direct investments:Clarification

The RBI has clarified that any overseas entity having an equity participation directly or indirectly of Indian parties shall not offer financial products linked to the Indian rupee (for eg non-deliverable trades involving foreign currency, rupee exchange rates, stock indices linked to Indian market, etc.) without its specific approval. This is to avoid any adverse implications these products can have for the exchange rate management of the country given that currently the Indian rupee is not fully convertible.

A.P. (DIR series) circular no 100 dated 25 April 2013

FDI in India:- Issue of equity shares under the FDI scheme allowed under the government route against pre-operative/pre-incorporation expenses

The RBI has issued a notification amending the condition specified in para 3(II)(c) of its circular, permitting the issue of equity or preference shares to foreign investors against pre-operative or pre-incorporation expenses under the government approval route. The amended condition is in line with the consolidated FDI Policy issued by the DIPP.

Existing condition: *‘Payments should be made directly by the foreign investor to the company. Payments made through third-parties citing the absence of a bank account or similar such reasons will not be eligible for issuance of shares towards FDI’.*

Amended condition: *‘Payments should be made by the foreign investor to the company directly or through the bank account opened by the foreign investor as provided under FEMA Regulations’*

A.P. (DIR series) circular no 104 dated 17 May 2013

Perspective

Bringing about a change through corporate social responsibility

An evolving concept, in the last two decades, Corporate Social Responsibility (CSR) has transformed from conventional philanthropy to a formally recognised social responsibility. The term clearly lays down the principle that the corporate needs to engage in activities and spend a portion of its profits and earnings towards social objectives. From business to business and social entrepreneurs, effective business models are harnessed to achieve both the economic and social objectives of the nation.

Till recently, the concept was voluntary as specified under the Indian corporate law framework, but now it has been made mandatory. The MCA has released Voluntary Guidelines on CSR in 2009, which were revised in 2011. The Companies Bill, 2012 (the Bill) has brought in mandatory provisions for corporates to adhere to the principle of social responsibility, by bringing in reporting and disclosure requirements. The intention behind this change is to strategise CSR initiatives in such a manner that the social development is integrated with economic development.

The vision of the lawmaker is to monetise social benefits along with business benefits. The aim of the CSR initiatives is to create value for all stakeholders as well as society at large. Under the new provisions, corporates are free to strategise and plan in order to fulfil the objectives of the policy within the framework of law. The corporate can thus align its business objectives with social causes and multiply the benefits. As commonly misunderstood, CSR is



not another tax in India. The intention of the policy is to capitalise on the core competencies of the corporate to work towards achieving social development.

Implementation

Applicability

Under clause 135(1) of the Bill, every company with a net worth of 500 crore INR or more, or with a turnover of 1,000 crore INR or more, or a net profit of 5 crore INR or more, during any financial year shall constitute a Corporate Social Responsibility Committee of the board consisting of three or more directors, out of which at least one director shall be an independent director.

Disclosures

Under Clause 135 (2) of the Bill, the composition of the Corporate Social Responsibility Committee must be disclosed in the report of the board of directors.

Under Clause 135 (5) of the Bill, the responsibility has been given to the board to ensure that the company spends in every financial year, at least 2% of its average net profits of the three immediately preceding financial years, as per the policy of the company. If the company fails to spend this amount, the board shall specify the reasons for not spending the amount.

Under Clause 134(3) (o), the report of the board of directors shall include the details of the policy developed and implemented by the company, and initiatives taken during the year.

The report of the board of directors also needs to reflect the areas in which activities are proposed to be undertaken, salient features of

the programmes proposed to be undertaken during the year, allocation of the amounts to specific areas and amount spent during the year, comments and observations of the CSR committee members and reasons for deviations from the proposed action plan.

Schedule VII of the Bill lays down the activities which may be included in the CSR policies. These include eradication of poverty, promotion of education, promoting gender equality, environment sustainability, contribution to national relief funds, combating diseases and epidemics and other matters as may be prescribed.

Based on our discussions with MCA officials, we understand that expenditure towards CSR initiatives in India will be counted for the purpose of compliance under the proposed Bill. The salaries and perks of employees engaged exclusively in CSR activities and corporate training with respect to the implementation of the policy may be included while calculating the total amount spent on the CSR activities during the year. On combined reading of all the above clauses, it may be concluded that reporting of CSR initiatives undertaken by the company is mandatory while spending is not mandatory.

On the anvil

The MCA is soon expected to come up with the draft of its CSR rules which will talk of the manner in which the CSR policy needs to be formulated. Based on informal discussions with MCA officials, we understand that the draft rules will bring in clarity on the following aspects being debated across the corporate world:

- Mapping of the existing CSR policy in the light of the new provisions and customisation with the new policy.

- Monitoring mechanism by the company, employee participation in CSR programmes, joint and collaborative efforts for implementation of the policy, etc.
- Contribution by the company towards a trust, another section 8 company (companies with charitable objects), society, etc. setup by the company itself or otherwise. The eligibility criteria will be laid down for contribution to the entities which have not been set up by the company.
- Pooling of resources by different corporates towards fulfilling of CSR activities, thus ensuring compliance,

- Contributions by foreign subsidiary companies, whether considered a donation or a grant from foreign sources and any registrations or approvals if required.

We can expect more clarity on the CSR policy to be formulated by the corporate and the manner in which contributions can be made once the draft rules have been framed. However, the intent is to encourage corporates to imbibe the culture of social development and aim to develop long-term strategies in order to achieve social objectives by integrating them with their core businesses.

- Vidhi Malhotra (manager, Regulatory services)

Glossary

CPE	Customer premises equipment
CSR	Corporate social responsibility
DGCA	Directorate General of Civil Aviation
DIPP	Department of Industrial Policy and Promotion
DoC	Department of Commerce
DTH	Direct to home
FDI	Foreign direct investment
FEMA	Foreign Exchange Management Act
FIPB	Foreign Investment Promotion Board
FSS Act	Food Safety and Standards Act, 2006
FSSAI	Food Safety and Standards Authority of India
FY	Financial year
INR	Indian rupee
IT	Information technology
LIBOR	London Inter-Bank Offer Rate
LoA	Letter of approval
MCA	Ministry of Corporate Affairs
MoD	Ministry of Defence
NIN	National Institute of Nutrition
NLEM	National List of Essential Medicines
NPPA	National Pharmaceutical Pricing Authority
PIB	Press Information Bureau
R&D	Research and development
RBI	Reserve Bank of India
SDTV	Standard definition TV signals
SEZ	Special economic zone
TRAI	Telecom Regulatory Authority of India
USD	United States dollar
WHO	World Health Organisation
WOS	Wholly owned subsidiary

Contacts

Ahmedabad

President Plaza, 1st Floor Plot No 36
Opp Muktidham Derasar
Thaltej Cross Road, SG Highway
Ahmedabad, Gujarat 380054
Phone +91-79 3091 7000

Bangalore

6th Floor, Millenia Tower 'D'
1 & 2, Murphy Road, Ulsoor,
Bangalore 560 008
Phone +91-80 4079 7000

Chennai

8th Floor, Prestige Palladium Bayan
129-140 Grems Road,
Chennai 600 006
Phone +91 44 4228 5000

Hyderabad

#8-2-293/82/A/113A Road no. 36,
Jubilee Hills, Hyderabad 500 034,
Andhra Pradesh
Phone +91-40 6624 6600

Kolkata

56 & 57, Block DN.
Ground Floor, A- Wing
Sector - V, Salt Lake.
Kolkata - 700 091, West Bengal, India
Phone +(91) 033 - 2357 9101 / 4400 1111

Mumbai

PwC House, Plot No. 18A,
Guru Nanak Road - (Station Road),
Bandra (West), Mumbai - 400 050
Phone +91-22 6689 1000

Gurgaon

Building No. 10, Tower - C
17th & 18th Floor,
DLF Cyber City, Gurgaon
Haryana -122002
Phone : +91-124 3306 6000

Pune

GF-02, Tower C,
Panchshil Tech Park,
Don Bosco School Road,
Yerwada, Pune - 411 006
Phone +91-20 4100 4444

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