

## **CUTS' NOTE FOR THE FINANCE MINISTER: PRE-BUDGET CONSULTATION – JANUARY 03, 2013**

We would like to begin with appreciating the Government for taking some praiseworthy steps such as the Cash Transfer Scheme and foreign direct investment (FDI) in multi brand retail.

At the same time it is worthwhile to take note of an article on the Planning Commission's website which suggests that our democratic system is likely to yield a better economic performance if it relies on an economy with greater reliance on market forces, rather than one subject to constant political interference and, therefore, the instruments of planning must be very different in a market economy that is increasingly integrated with the world.

Growth is often hampered by leakages, corruption, crony capitalism even in the face of the fact that growth is needed for eradication of poverty. Proper planning is necessary to achieve distributional objectives and to achieve a high growth rate. Bringing the states on board in a proactive manner, even in seemingly unconnected spheres such as road safety, is desirable.

In the light of the above, we take this opportunity to draw the attention of the Finance Minister on five critical policy issues:

1. National Competition Policy;
2. Investment Policy;
3. Trade Policy;
4. Public Procurement Policy; and
5. Allocation of Natural Resources Policy.

### **1. National Competition Policy**

While a legal framework (competition law) exists in India, there is no documented policy on competition principles necessary to build a better competition culture across the country. Looking at our dismal economic scenario, one of the contemporary and important policy prescriptions by the government is to adopt competition reforms through a National Competition Policy (NCP). The Ministry of Corporate Affairs has scripted such a policy after a long-drawn consultative process with policymakers, state governments, experts, CSOs, media and business. The NCP, when implemented, will usher in the second big wave of economic reforms after 1991, as mentioned by Former Union Minister of Corporate Affairs M Veerappa Moily.

In this exercise of drafting of the NCP, India, among other countries, was inspired by Australia that adopted a national competition policy in 1995, a good 14 years after it has been operating a competition law. Interestingly, a study undertaken by Australian Productivity Commission on expected benefits of competition reforms revealed that the annual gain in real GDP was 5.5 percent and consumer gains by A\$9bn due to competition reforms in the nation.

The relevance of a strong NCP for India cannot be overstressed. This is especially so because of the presence of various policies followed by different states of the country. There is need for effective implementation of NCP in India since anticompetitive forces cause hurdles to growth and it is an essential element to create a conducive business environment in the country.

We enclose (annexure 1), as an example, analysis undertaken in the Pharmaceutical sector through the lens of Competition Policy, for your kind perusal.

**Action desired:** Strong support of the Finance Ministry for effective adoption and implementation of the National Competition Policy

## 2. Investment Policy

FDI undoubtedly is the most influential channel through which foreign capital comes into a country. In India FDI is being allowed in different sectors of the economy in different percentage/ratios through either the government or the automatic route. An enabling environment for FDI would entail the creation of a sound policy and regulatory framework and supporting institutions to enforce the relevant laws and regulations. In an openly competitive market, the test of attractive investment climate would include how an investor is received, how many administrative and regulatory obstacles an investor has to overcome to enter and operate, and how commercial disputes are handled through the judicial system, etc. The maze of such barriers needs an institutional Aftercare Services for investors which should include an Ombudsman to assist the investors.

The food retail in the multi brand retail sector is the most unorganised in structure where the supply chain consisting poor farmers on one side and consumers on the other. Literature reveals existing structure is suffering with high operational inefficiency which leads to remunerative prices to the farmers/producers but consumers are ending up with high prices. Thus without a strong regulatory and institutional support for the retail it will be tough to reap the benefits of the expecting FDI at its desired level.

**Action desired:** Need for retail regulation: A model retail regulatory law can be designed covering issues mainly in terms of location of the large scale stores so as to assuage the fears of small retailers, suppliers and farmers which are very critical and vocal.

## 3. Trade Policy

The National Foreign Trade Policy of India, 2009-2014 is expected to achieve its objectives of doubling our exports by 2015 and creating one million new employment. Studies have shown that various schemes designed to boost our exports are showing good results.

However and lately, our exports are falling, mainly as a result of reduced demand from traditional markets. It is good to note that the government is exploring new market access opportunities. While exports are expected to increase, our study has argued that benefits from this increase are not necessarily percolating to small producers.

On the other hand, there should be more emphasis on import policy, within the overall rubric of trade policy, so as to balance producer interest with that of consumers. The next Foreign Trade Policy, expected to be announced in May 2014, should focus on, among others: a) market access opportunities in non-traditional markets and products, b) benefit sharing mechanism between large and small producers/exporters, and c) balancing producer interest with consumer interest.

**Action desired:** The benefits of increased exports should percolate to small producers. Further, the next Foreign Trade Policy should focus on market access in non-traditional

markets/products, benefit sharing between large and small producers/exporters and balancing producer-consumer interest.

#### **4. Public Procurement Policy**

Public procurement accounts for almost 30 per cent of our gross domestic product and is, therefore, one of the most important sources of our growth. We congratulate the government for bringing a modern public procurement bill, focusing on the principles of transparency and coherence. This Bill should be enacted at the earliest so as to inter alia enhance efficiency in our public procurement system and also to help Indian companies to better access procurement markets in other countries.

We have analysed this Bill and submitted a set of suggestions (annexure 2) to the government and the Parliamentary Standing Committee on Finance, which is enclosed. For effective implementation of this Bill, we urge the government to prepare a Public Procurement Policy of India, making it compatible with other important macroeconomic policies including growth- and employment-oriented policies such as national manufacturing policy, public-private partnership policy.

**Action desired:** The proposed Bill on public procurement should be enacted at the earliest and a Public Procurement Policy prepared that is compatible with other macro-economic policies.

#### **5. Allocation of Natural Resources Policy**

The Ashok Chawla Committee on allocation of natural resources submitted its report in May 2011. It was expected to suggest allocation of natural resources in a more transparent, efficient and sustainable manner. The report and accepted recommendations should be placed in the public domain to enable all stakeholders to benefit from such a seminal work on the subject and a more informed decision-making is facilitated so that the intent of the Government to curb corruption is converted into reality.

The common thread across the recommendations pertains to the merits of transparency, public disclosure, consultation, capacity building, competitive bidding and expeditious clearances. Clearly, the recommendations favour the markets-based solutions. For this, it would be prudent for each relevant Ministry to frame a dynamic policy on allocation of the resource.

**Action desired:** The Report and the recommendations should be placed in the public domain and concerned Ministries advised to frame/update the relevant policies that should be dynamic and market-sensitive.

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Annexure: As above

## The Pharma Sector through the lenses of Competition Policy Principles

### 1. Introduction

- 1.1 Health is a crucial socio-economic asset. Considerable improvement in health outcomes are a prerequisite for a developing country like India to break out of the clutches of the vicious circle of poverty. Good health contributes to development in a number of ways such as higher productivity, improved human capital, higher rates of national savings etc. Hence, it is right to assert that investment in health is imperative to economic development. Indian pharmaceutical industry in turn plays a vital role in providing health care to billions of population in India and abroad. In India, the cost of medicines is around 72 percent of the health care costs, which is considerably high especially for the poor.
- 1.2 Over a period of thirty years, the Indian pharmaceutical industry has evolved from almost nonexistent to a world leader in the production of high quality generic drugs. Growing at about 8 to 9 percent annually, ranking the third largest in the world in terms of volume and 14<sup>th</sup> in terms of value<sup>1</sup>, and upholding varied capabilities in the complex field of drug manufacture and technology, the Indian pharmaceutical industry currently is the frontrunner amongst India's science-based industries.
- 1.3 The "organized" sector of India's pharmaceutical industry consists of about 250 to 300 companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent.<sup>2</sup> However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. There are about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units)<sup>3</sup>.
- 1.4 When India joined the WTO in 1995, its pharmaceutical exports were valued at less than \$600 million. By 2005, its exports had grown to \$3.7 billion and accounted for more than 61 percent of industry turnover<sup>4</sup>. The Indian Pharmaceutical Industry is among top five producers of bulk drugs in the world. Pharmaceuticals market can be roughly classified into Bulk drugs (20 percent of the market) registering growth rates of 20 percent and formulations (80 percent of the market) with an annual growth rate of 15 percent<sup>5</sup>.

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<sup>1</sup> A BRIEF REPORT PHARMACEUTICAL INDUSTRY IN INDIA. January, 2011. Electronically accessed on: 5, July, 2011, available at: [www.cci.in/pdf/surveys\\_reports/indian-pharmaceuticals-industry.pdf](http://www.cci.in/pdf/surveys_reports/indian-pharmaceuticals-industry.pdf)

<sup>2</sup> Indian Pharmaceutical Industry: Collaboration for Growth, KPMG Pharmaceutical Practice. Electronically accessed on 15, July, 2011, available at: <http://www.in.kpmg.com/pdf/Indian%20pharma%20outlook.pdf>

<sup>3</sup> Report India's Pharmaceuticals Industry. Electronically accessed on, 7, July, 2011, available at: [http://www.cci.in/pdf/surveys\\_reports/indias\\_pharmaceutical\\_industry.pdf](http://www.cci.in/pdf/surveys_reports/indias_pharmaceutical_industry.pdf)

<sup>4</sup> G. William, "The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market", OFFICE OF ECONOMICS WORKING PAPER, U.S. INTERNATIONAL TRADE COMMISSION

<sup>5</sup> Dr. Geeta Gouri, "Competition Issues in the Generic Pharmaceuticals Industry in India". Electronically accessed on 01, August, 2011, available at: [http://www.cci.gov.in/images/media/presentations/ComIssGenPharmIndusIndia\\_20100401142346.pdf](http://www.cci.gov.in/images/media/presentations/ComIssGenPharmIndusIndia_20100401142346.pdf)

1.5 However, a number of activities and issues may adversely impact industry's competitiveness. For instance, medicines are promoted by all means, fair and foul. Misleading information, incentives and unethical trade practices are reported<sup>6</sup> to be widespread to increase the sale of prescription drugs. The malpractice of cartel formation accompanied by collusive bidding and bid rigging has evidently<sup>7</sup> been a serious public procurement problem in India. In between, corrupt practices in drug and medical supplies have been found<sup>8</sup> to emanate due to misuse of procuring power that rests with the authorised agencies.

1.6 Certain government policies, even though unintentionally, may turn out to be counterproductive. Policies like price controls<sup>9</sup> and tax concessions<sup>10</sup> undertaken from

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<sup>6</sup> K.Anita, Libby Levison, "Price components and access to medicines in Delhi, India" available at:

<http://www.scribd.com/doc/35879219/Price-Component-Report-Delhi-India-MeTA>. The study reports that: A survey conducted in Delhi revealed that 4 of 8 medicines sold to retailers take the form of "buy 10 get 1 free" (9.09% discount) or "buy 7 get 3 free" (30% discount). R. Nobhojit, Neha Madhiwalla, Sanjay A Pai, "Drug promotional practices in Mumbai: a qualitative study", available at: <http://www.issuesinmedicalethics.org/152oa57.html>. The study reports that: A survey which was conducted in Mumbai revealed that medical representatives offered various gifts to doctors which served as inducements and hence, persuaded them to prescribe the related company's drugs.

<sup>7</sup> S. Ramesh, "Haryana govt ignores DoP advisory on turnover criterion for participating in tenders", Mumbai, Saturday, 7 May, 2011, available at: <http://www.pharmabiz.com/PrintArticle.aspx?aid=62762&sid=1>. The pharma portal reports: Haryana government's eligibility criteria for participating in drug purchase tenders for pharma companies has been fixed at annual turnover of Rs.35 crore as against Rs.3 crore earlier, rendering SMEs ineligible to participate in the tendering process.

<sup>8</sup> "Karnataka Lokayukta exposes Rs 100-cr drug racket", available at: <http://indiatoday.intoday.in/site/story/karnataka-lokayukta-exposes-rs-100-cr-drug-racket/1/132474.html>. The article reports that: The Karnataka Lokayukta exposed a racket worth Rs 100 crore in the supply of drugs to government hospitals in the state. The report highlighted nexus between pharmaceutical companies and government agencies, the Karnataka State Drug Logistics and Warehousing Society and the Karnataka Antibiotics and Pharmaceutical Limited, which bought medicines at exorbitant rates. An IV fluid, which costs Rupees 9.00 per sachet, was procured at Rupees 43.00 per sachet. Another drug, equine rabies immunoglobulin, which costs Rupees 300.00 per vial, was purchased for Rupees 5000.00 per vial.

<sup>9</sup> Joe C Mathew, "Shift from medicines to food supplements under NPPA scanner", Business Standard, July 1, 2011, available at: <http://www.business-standard.com/india/news/shiftmedicines-to-food-supplements-under-nppa-scanner/441141/>. The article reported: In lieu of the price controls, there has been an increasing trend among pharmaceutical companies to shift their products from the drug category to the dietary supplement. Companies such as Ranbaxy, Merck, Trikho and Indochem, etc has shifted some of the products from the medicine category and got manufacturing licences under Prevention of Food Adulteration Act. While National Pharmaceutical Pricing Authority (NPPA) fix and monitor the prices of all medicines that contain at least one of the 74 drug ingredients mentioned in the scheduled list of drugs notified under Drugs Price Control Order (DPCO), it cannot take any action if the same medicine gets re-launched as food supplement.

<sup>10</sup> NEW INDUSTRIAL POLICY AND OTHER CONCESSIONS FOR HIMACHAL PRADESH, available at: <http://himachal.nic.in/industry/Packages%20for%20HP.htm>. It stated that: With an objective to develop backward and hilly areas like Himachal Pradesh, Uttarakhand and Jammu and Kashmir, the central government announced tax holiday for pharmaceutical companies in the year 2003. The major attraction for investors included 100 per cent outright excise duty exemption for a period of ten years from the date of commencement of commercial production, 100 per cent income tax exemption for an initial period of five years and thereafter 30 per cent for companies for a further period of five years. Sushmi Dey, "Excise or no excise?". Electronically accessed on: 27, July, 2011, available at: <http://www.cipi.in/news240807epo.htm>. It stated that: The Central Government in early 2005 came up with a new excise structure, thereby increasing the disparity between excise free and non-excise free zones. According to the new excise structure, companies had to pay a 16% excise duty on the MRP instead of earlier 16% excise duty on the ex-factory price of allopathic drugs. Consequently, from 2005 onwards, a big stream of pharmaceutical units from different parts of the country like Gujarat, Maharashtra, Punjab and Delhi, changed course and flowed into these designated excise free zones.

A. Joseph, "Clash if interests reaches a flash point", Thursday, March 25, 2010. Electronically accessed on 11 July, 2011, available at: <http://safron.pharmabiz.com/article/detnews.asp?articleid=54695&sectionid=50>. The pharma portal reported that: Punjab was one of the worst hit states as a large number of industrial units shifted base to the neighbouring Himachal Pradesh. Its position in the industry graph slipped sharply to 15<sup>th</sup> from the 2<sup>nd</sup> position at one time. Almost 75 per cent of the small scale units moved to comparatively safer havens of excise free zones. Of

the point of view of consumer welfare and development of backward areas respectively have been found to hamper competition in the pharmaceutical industry. Likewise, The Government of India has proposed a cap on the FDI in pharmaceutical industry by bringing it down from 100 percent to 49 percent in wake of acquisitions that have taken place at an unprecedented rate in the recent past. Even though there are a large number of companies competing in this area, a fear still exists, that large scale acquisitions may drive away the domestic companies, reducing the availability of generic drugs and focus on patented drugs, thus leading to rise in the prices of lower cost drugs. However, even after 2 years of acquisition of Ranbaxy by Daiichi Sankyo, it was found<sup>11</sup> that Ranbaxy had a price growth of 0.4 percent in 2010 as opposed to an industry figure of 1.0 percent. It can also be recalled that the twin objectives for 100 percent FDI in pharma sector was to ensure transfer of technology and permit an easy access to long-term foreign funds for industrial sector. Also, on the face of it, this cap of 49 percent may create barriers to entry in Indian pharmaceutical sector.

1.7 Hence, it is highly essential to tap the expertise of competition authorities to assess whether a government policy or regulation is compatible with stimulating competition or not. On these lines, principles of competition policy vis-à-vis pharmaceutical sector in India have been discussed as follows:

## 2. Application of Competition Principles vis-à-vis pharmaceutical sector in India

### 2.1 Principle: Fostering Competitive Neutrality

*Application:* Competitive neutrality not only means that public sector should not be unduly favoured but also that it should not be discriminated against. There are glaring instances of distortion of a level playing field in favour of private sector (reverse competitive neutrality) in the pharmaceutical sector. For example, three large vaccine manufacturing PSUs (Central Research Institute at Kasauli, the Pasteur Institute of India at Coonoor and the BCG Vaccine Laboratory at Chennai) were closed down in January 2008 on grounds of non-compliance of Good Manufacturing Practices even though the vaccines produced did comply with standards of safety.

*The government has, since the closure, been procuring vaccines required for the country's national immunization programme from the private vaccine companies at high prices thereby leading to a substantial increase in the expenditure on the universal immunisation programme. Evidence has shown that private players offered vaccines at competitive prices prior to closing down of the three PSUs after which the government has been seen to steadily pay higher prices for procuring vaccines from them to this day. This is because the closure has stifled competition in the pharmaceutical sector with only private vaccine manufacturers*

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300 small pharma units in Haryana only 50-60 were left by 2010, 30-40 units in Delhi and 50 out of 500 left in Punjab.

<sup>11</sup>H. Kewal, "Should FDI in pharma be regulated?", 08 April 2011, available at: <http://news.in.msn.com/business/article.aspx?cp-documentid=5106351>

operating in the market and has seen a resulting increase in the price of vaccines by upto 75 percent.

## **2.2 Principle: Procedures should be rule bound, transparent, fair and non-discriminatory**

**Application:** Under the Drug and Cosmetics Act, the regulation of manufacture, sale and distribution of drugs is primarily the concern of the State authorities while the Central Authorities are responsible for approval of new drugs, clinical trials in the country, laying down the quality standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organisations and providing expert advice with a view of bringing about uniformity in the enforcement of the Drugs and Cosmetics Act. It is essential that the Drugs Controller General, the State Drugs Controllers and the various drugs inspectors and other officers carry out these tasks as per the laws, rules and regulations laid down in a transparent and non-discriminatory manner.

Quite often it has been seen that rules are not applied in a transparent or a fair manner. Authorities also use circulars etc to define their own interpretation of the laws and policies without proper consultation with the affected parties. In *Sagar Medical Hall vs. State of Bihar*<sup>12</sup>, a petition was filed against the order of State Government restraining the regional licensing authorities from issuing or renewing licence for the wholesale and retail sale of drugs. Rule 64 provides for conditions subject to which a licence shall be granted or renewed. The State Government's justification for its policy decision was that the ban on the issuance of wholesale and retail drug licences was a temporary measure to prevent the spurt of spurious drugs. The State Government said that there were adequate drug stores to meet public need. The High Court held that the grant and renewal of drug licence is governed by statutory rules and nowhere do such rules provide that the license can be declined or renewal refused on the ground that the State Government reckons that the number of shops are sufficient to meet demand of public. Thus, executive decisions of the State cannot override the statutory provisions. This case shows how sometimes rules are misinterpreted by the authorities in a manner, which can be, detrimental to competition.

In *Bharat Biotech International Ltd. vs. A.P. Health and Medical Housing and Infrastructure Development Corporation*<sup>13</sup>, eligibility criterion for the tender for supply of Hepatitis-B drugs required WHO pre-qualification. This was challenged as arbitrary and with the intent to exclude competition in favour of one manufacturer. The high court evaluated the provisions of Drugs and Cosmetics Act. The court concluded that the State had failed to establish that WHO adopts standards that are higher than the standards adopted under the Indian law for assessing the quality of the product. It held that the Indian laws were stringent in ensuring a high standard of drugs but has been futile because of laxity on part of State in enforcing the law. Instead of rectifying the implementation of the Act, the State cannot seek shelter in such a manner. Accordingly, such a prequalification was set aside.

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<sup>12</sup> (CWJC) Patna HC dt. 7/12 /01, extracted from "Health Care Case Law in India", Centre for Enquiry into Health and Allied Themes (CEHAT) and India Centre for Human Rights & Law (ICHRL), at pg.97 available at: <http://www.cehat.org/humanrights/caselaws.pdf>

<sup>13</sup> "Health Care Case Law in India", Centre for Enquiry into Health and Allied Themes (CEHAT) and India Centre for Human Rights & Law (ICHRL), available at: <http://www.cehat.org/humanrights/caselaws.pdf>

### **2.3 Principle: Third party access to essential facilities on reasonable fair terms will ensure effective competition and therefore, should be provided in law.**

**Application:** TRIPs allows for certain flexibilities in its clauses to protect public health. It is correct to assert that all forms of IPRs have the potential to stifle competition since they provide exclusive rights to the person who has claimed the same for an invention etc. as the case may be. With regard to the pharmaceutical market, patents confer monopoly status to pharmaceutical companies as patent-holder are granted exclusive rights to make, use or sell a product for a specified period. Access to affordable medicines can seriously be impacted in case such patented drugs are priced to extract monopoly profits.

In India, with product patent regime in place from 2005, any patented products entering the market will essentially be marketed by a monopolist or its licensees. Unlike a competitive producer, a monopolist produces in small quantity and sells it at high rates. Thus, it is highly likely that patented drugs will be greatly overpriced, depriving underprivileged people from the benefits of these drugs. At this juncture it is imperative to illustrate the manner in which Novartis exercised its exclusive marketing rights (EMR) granted in India with respect to what might be expected in the new patent regime. Novartis' Glivec is used for treatment of Chronic Myeloid Leukaemia ('CML'). There was an increase in the price of the drug from \$90 to \$2610 after the grant of EMR, which put the drug out of reach of approximately 24,000 patients in India who suffer from CML<sup>14</sup>.

The abuse of monopoly power bestowed upon by the patent system on the patentee could be remedied by granting compulsory licence or through parallel imports. This in turn can be achieved by issuing compulsory licenses to generic producers in the pharmaceutical sector. generic substitutes enhance competition in the market and automatically check the price rise, the market would be more competitive and see a fall in prices. While these measures are necessary they are not sufficient because the purchasing power of the people remains low highlighting the need to expand the list of essential drugs under price control. To make essential medicines accessible to the masses, manufacturers and retail pharmacy stores may be provided with a variety of incentives such as lower duty, subsidy etc., to supply essential drugs.

### **2.4 Principle: Ensure free and fair market process**

**Application:** Many procurement policies of the government are seen to introduce entry barriers in the manner tenders/bids are drafted. For example, in a tender call for Ayurvedic medicines, the Directorate of Ayurveda in Government of Rajasthan, Ajmer was seen to bend the rules governing the procurement of medicines by adding conditions that manufacturers must have minimum five years of experience, a condition that did not figure in the original call for tenders. On the other hand, the purchase committee had decided to invite public sector undertakings and cooperatives, with GMP compliance for the purchase bid without the five year clause. Later, in its advertisement, it inserted a condition that the manufacturer must have a minimum five-year experience. Of the existing PSUs and co-ops that manufacture Ayurvedic medicines, only eight had an experience of five years and more. Unless an experience of minimum of five years was necessary to ensure the level of quality sought which the purchase committee failed to adequately demonstrate, such a rider acted as a deterrent for entry of new players which also stifles innovation. It is to be noted that

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<sup>14</sup> Archa Saran, "India: A Changing Regime - India's Tryst with January 1, 2005", 15 November 2004, available at: <http://www.mondaq.in/article.asp?articleid=29573>

*government policies should not interfere with the free and fair market process by restricting market access to players.*

*The above referred Bharat Biotech case referred to in Para: 2.2 is another illustration of procurement policy practice distortions.*

## **2.5 Principle: Notification and Public Justification of Deviations from Principles of Competition Policy**

**Application:** *Intervention in market process to achieve social, environmental and other goals may be entirely appropriate. One such goal may be to ensure affordability of medicines. In September 2010, the Parliamentary Standing Committee on Health & Family Welfare, in its report, suggested a series of measures like increasing the number of drugs under price control, a blanket cap on profit margins of all medicines and promoting the use of generic drugs to make it more affordable and accessible to the common man.*

*Dr. Reddy's Laboratories opposed the Parliamentary Standing Committee recommendations on increasing the number of drugs under price control and cap on profit margins of all medicines. Such a move by the government has ostensibly been propelled by the public interest argument. The Indian pharmaceutical industry needs huge investments in research and development. Unfortunately, capping the prices of drugs will cut down profits and thereby reduce availability of finance and discourage investment in research. Such issues are delicate as they require more research so as to assess the net benefit of fixing the prices of medicines, by weighing its negative effects on competition against the benefits of ensuring easy affordability and consumer welfare. Regardless, it is necessary that such deviations are publicly notified, justified and implemented in a transparent manner and not just presumed in the interest of meeting national priorities.*

## **2.6 Principle: Effective control of anticompetitive conduct through competition rules**

**Application:** *Several anticompetitive practices occur in this sector, which can be categorised into primarily three classes: intellectual property rights related breaches, potential abuse of competition norms arising from mergers & acquisitions and collusive and other anti-competitive practices. Anti-competitive practices in the healthcare delivery system range from receiving kickbacks by doctors from pharmaceutical companies for influencing drug sales, to tied sales. With specific reference to doctors, suggesting more tests than necessary and accepting commission for referrals are practices, which may have anticompetitive implications. With particular reference to pharmacists, the anticompetitive practices most commonly engaged in are reflective of collusion. In a CUTS study, the majority of pharmaceutical companies surveyed claimed awareness with respect to the existence of collusive practices in the pharmaceutical industry and a high 32.3 per cent of respondents asserted that such practices prevail in the industry to a great extent.*

*The pharma trade too engages in anticompetitive practices by demanding higher margins from manufacturers with the threat of boycott, which result in higher prices. For instance, the pharmacists, organised under the All India Organisation of Chemists and Druggists, and some of their state bodies collectively boycotted pharma companies in order to pressurise them for higher margins in 1980s. When faced with action under the MRTP Act, they cleverly changed their course of action ranging from calling for 'non-cooperation' to negotiating an MOU with particular companies on margins.*

*The pharmaceutical industry has witnessed increased consolidation lately. Matrix lab was acquired by US based Mylan Inc in August 2006, Dabur Pharma acquired by Singapore based Fresenius Kabi in April 2008, Ranbaxy Laboratories Limited acquired by Japan based Daiichi Sankyo in July 2009, Shantha Biotech by France based Sanofi Aventis in July 2009, Orchid Chemicals (injectible business) by US based Hospira in December 2009, Piramal Healthcare (domestic formulation) acquired by US based Abbott Laboratories in May 2010<sup>15</sup>. As a natural consequence of M&As, there is bound to be an increase in scale and scope of enterprise activities and reduction in the costs of the firms merged. However, given the fact<sup>16</sup> that companies like GSK and Abbott Labs have resorted to anti competitive practices overseas in the past, the potential of such consolidation to throttle competition and subject consumers to increase in price of medicines in India cannot be ignored.*

*There are multiple legal and policy options, which may be utilised to deal with anticompetitive practices in the pharmaceutical sector and the healthcare delivery system. Using competition law and compulsory licencing under the IPR law are the obvious choices of legal remedy to deal with anti-competitive practices in the pharmaceutical industry and healthcare delivery system resulting from IPRs.*

## **2.7 Principle: Where a separate regulatory arrangement is set up the functioning of the regulator should be consistent with the principles of competition as far as possible**

**Application:** *Department of Pharmaceuticals, established under the Ministry of Chemicals and Fertilizers, has been entrusted with the responsibility of policy, planning, development and regulation of pharmaceutical industries. Agencies like National Pharmaceutical Pricing Authority (NPPA), National Institute of Pharmaceutical Education Research (NIPER), and all five pharma PSUs (IDPL, HAL, RDPL, KAPL, and BCPL) are now under its control.*

*Competition issues are complex and matters having a substantive competition content, even if comes under the jurisdiction of the Department of Pharmaceuticals, should be referred to the Competition Authority whose decision or opinion on competition related issues, for instance say excessive pricing due to abuse of monopoly by the patent holder, may be held binding.*

## **2.8 Principle: Respect for International Obligations**

**Application:** *Essential medicines can be classified as those medicines which cater to the priority health care needs of a population and hence should be made available in health systems round the clock in adequate amounts, in appropriate dosage forms, with assured quality, and at affordable prices. Poor medicine supply, insufficient health facilities and staff, low investment in health and the high cost of medicines are a few factors which adversely affect the availability of medicines in developing countries. The WHO Model List of Essential Medicines is a list of over 350 medicines, selected on the basis of disease prevalence, evidence of safety and efficacy, and comparative cost-effectiveness and includes treatment options for priority conditions such as malaria, HIV/AIDS, tuberculosis, reproductive health and also chronic diseases, such as cancer and diabetes, based on evaluation of the best available evidence. This list can be used by India as a guide for the development of our own*

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<sup>15</sup> Competition Law and Indian Pharmaceutical Industry, *available at:*  
<http://www.cci.gov.in/images/media/completed/PharmInd230611.pdf>

<sup>16</sup> Mehta, Pradeep S., "Overseeing pharma mergers through competition lens?", The Financial Express, June 20, 2010

*national essential medicines list which in turn can help prioritize the purchasing and distribution of medicines, thereby reducing costs to the health system.*

*All Member countries of the WTO have adopted IP protections in line with the TRIPs Agreement which aims at striking a balance between the need to provide incentives for innovation and the obligation to the public of ensuring access to the benefits of the invention (in this case, of medicines). Further, the Doha Declaration on the TRIPs Agreement and Public Health (2001), aimed at improving access to medicines, especially for HIV/AIDS, malaria and tuberculosis in developing and least developed countries. It underscores the ability to use flexibilities that are built under the TRIPs Agreement, in particular compulsory licensing and parallel import.*

*The waiver in August 2003 allowed members to waive the requirement under Art 31(f) of TRIPS to provide for compulsory licensing (CL) only if the medicine is predominantly for domestic use. It further allowed members of Regional Trade Agreements (RTAs) to export within the region despite the territoriality principle applicable to patents. The step may have generated hope that there would be some reduction in the cost of medicines. However, majority of developing countries (DCs) have not been able to utilise the flexibility of CL under the Agreement effectively due various reasons such as lack of local industry; small markets – weak economies and economy of scale; lack of supportive laws etc. Furthermore, there is lack of awareness of their rights within the regulators, judges and enforcement agencies. Thus the unfavorable legal, economic and institutional framework makes it difficult for DCs to utilise the existing TRIPs flexibilities.*

*Nonetheless, it is considered vital to supplement and possibly substitute imported medicines with locally obtained products. Such an effort calls for building and strengthening the capacity to manufacture affordable, high-quality generic essential medicines within the region, which can significantly contribute in achieving public health objectives in these countries. This in turn requires a concrete policy measures backed by legislations that support the manufacturing of essential quality medicines at an affordable price and also the import of generic medicines. Thus incorporating TRIPs flexibilities in framing and implementation of supporting legal and policy measures, such as those concerning local innovation and production of pharmaceuticals is vital.*

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## **CUTS Suggestions for Strengthening the Public Procurement Bill, 2012**

### **1. Grievance redressal mechanism**

- 1.1 The jewel-in-the-crown of any system of rules is its ability to address perceived transgressions. That is where it is tested whether the rules have ‘bite’ i.e. enforceability, or are simply “best endeavour” clauses. It is in this critical area that the bill falters. The Bill sets up an independent grievance redressal mechanism, in the form of Procurement Redressal Committees to be set up by the Central Government (vide the provisions of section 40 of the Bill), but their powers are restricted to making recommendations to the procuring entity and hence fall short of what is needed to ensure fair play.
- 1.2 The procuring entity may reject the recommendation under sub section 15 of Section 41 of the Bill, the only saving grace being that reasons for non -acceptance would have to be communicated. Since the procurement entity is itself a party to the dispute, its objectivity and willingness to accept the recommendations of the Tribunal are debatable. Moreover, under the grievance redressal mechanism, it has already once reviewed the grievance of the supplier and it is only in case of failure to dispose of the grievance within the specified period/ the bidder remaining aggrieved by the procurement entity’s decision in review that the bidder has gained the right to address its grievance to the Procurement Redressal Committee. Thus, expecting the procurement entity to reverse its own earlier decision at this stage on the recommendation of the Procurement Redressal Committee is unrealistic.
- 1.3 In contrast, other international enactments on public procurement, like the UNCITRAL model law on public procurement, under its Chapter VIII dealing with 'Challenge Proceedings' also provides for an independent review body, whose decisions are binding. This model law has been the inspiration for the public procurement laws of many countries.
- 1.4 Furthermore, there is no provision for judicial review from the decisions of this tribunal, although a two-tier redressal mechanism has been recommended in the Report of the Expert Committee on Government Procurement set up by the Government, on whose recommendations the Bill is to some extent based. Having sequential appeal mechanism is no doubt cost and time consuming and delays in execution of the contract impact on public interest, which is of paramount importance in public procurement.
- 1.5 On the other hand, it ensures ‘due process’. A golden mean would be to provide for reference to a higher body only in cases where the procurement contract is above a very high threshold level. Thus, the grievance redressal mechanism is still weak in the PPB and would need further strengthening to ensure fair play for bidders.

### **2. Electronic reverse auction**

- 2.1 The online real-time purchasing technique utilized by a procuring entity to select the successful bid, which involves presentation by bidders of successively lowered bids, during a scheduled period of time and the automatic evaluation of bids, which is termed

as 'Electronic Reverse Auction', has been introduced as a mode of procurement under Section 34 of the proposed Bill. It is an accepted mode of procurement, used mainly for procuring standard items and finds reflection in Section 53 of the UNCITRAL Model Law on procurement, too.

2.2 Reverse auctions, depending on the situation, can also reduce the human risk. Corruption is known to be highest in situations where there is a lot of face-to-face contact between government officials and private sector bidders. ICT tools can reduce the need for this type of interaction, thereby reducing opportunities.

2.3 However, world experience is gradually showing that the tool needs to be used with adequate safeguards. Studies by the World Bank show that in Eastern Europe, where the tool is widely being used in public procurement, a lion's share of the contracts are going to a few bidders, possibly because the specifications of the subject matter of procurement are tilted to qualify only these few bidders.

2.4 Experience in Brazil<sup>17</sup> and also in the former CIS<sup>18</sup> countries throws up concerns including the following:

- Very low prices: it is not uncommon that a supplier wins a session with a much lower price than the market, but fails to honour the contract. This occurs either through inexperience of the bidder or by the climate of fierce competition in the bidding phase. There are also situations in which the competitor deliberately, aware of the fragility of the contract management system in government, intentionally wins a bid with a very low price. Its goal is requesting for increase in the contract price soon after work starts or simply to deliver a product or service below the specifications of the bidding. It is not uncommon that the citing of lower than market prices causes bankruptcy of the winning company, with consequences for its employees and for the government, which may have to conduct a new bidding process.
- E-reverse auction put to procuring inappropriate items: Approximately 57.5 per cent of purchasers of the Brazilian federal government are purchased through e-reverse auction, covering a wide range of products and services. It is not known whether all these purchasers are really standard product and services items, or the public buyers are, on account of the advantage of bidding, especially for its simplicity and speed, using e-reverse auction in an inappropriate manner. In the light of this, the modalities regarding e-reverse auction in the Indian Bill need to be accompanied by sufficient safeguards.

2.5 Section 34 of the Bill states that the procuring entity shall solicit e-reverse auction bids in accordance with the provisions of sub Section 5 of Section 30 or sub Section 2 of Section 31 and the invitation to bid shall contain information as specified in Section 15 along with some additionalities as required under the electronic mode. But these

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<sup>17</sup> Alexandre Motta, 'E-Reverse Auction in Brazil Federal Government: A Critical View', [www.nottingham.ac.uk/pprg/documentarchive/phdconference2009](http://www.nottingham.ac.uk/pprg/documentarchive/phdconference2009)

<sup>18</sup> Expert Group Meeting on Transparency, Competition and Objectivity in Public Procurement, UNODC/IACA, 24-26 Sept., 2012, Laxenburg, Austria, Report thereof & World Bank, 'Procurement Challenges in Europe & Central Asia Client Countries of World Bank', 8th Regional Public Procurement Forum, Tirana, Albania, May 22-25, 2012, [siterources.worldbank.org/INTECA.../WB-Devesh-pp-Eng.pptx](http://siterources.worldbank.org/INTECA.../WB-Devesh-pp-Eng.pptx)

provisions would not serve to cover the main problems with the system as shown through world experience.

2.5.1 It is, therefore, felt that the existing safeguards be supplemented with provisions to the effect that the description of the subject matter of procurement shall be set out in a manner prescribed in Section 9 of the Bill, i.e. objective specifications, wherever possible based on national/international standards; there shall be automatic evaluation of all bids in accordance with the criteria, procedure and formula provided to suppliers or contractors.

2.6 If the e-reverse auction leads to a result where the winning bid is seen to be abnormally below the market price, the same remedial process as laid out in Article 20 of the UNICTRAL Model Law on 'Rejection of abnormally low submissions' may be followed. There can also be technology-related weaknesses in e-procurement systems. Some red flags are chat facilities where bidders can chat directly with procurement officers during an e-auction and issues of ensuring authenticity of bids via digital certificates, i.e. cases of identity theft, password leaks etc.

2.7 Certain safeguards may be built in to guard against these malpractices, including Safeguards as provided under Article 56 of the UNICTRAL Model Law, such as the prohibition of communication between the procuring entity and bidders during the e-reverse auction process except to the extent that each bidder receives instantaneously and on a continuous basis, during the auction, sufficient information allowing it to determine the standing of its bid vis-a-vis other bids.

2.8 In the light of world experience to show that mere introduction of e-reverse auctions have not led to competition, transparency and value for money, it is important that in India we introduce this technology-driven procurement mode with adequate safeguards, which include those mentioned above.

### **3. Abnormally low bid prices**

3.1 In all forms of procurement, if the price quoted by the L-1 supplier is abnormally low in relation to the subject matter of the procurement it raises concerns as to the ability of the supplier to perform the procurement contract. No mechanism appears to be there in the Bill to guard against this phenomenon. The mechanism to deal with this phenomenon - rejection of the abnormally low bid in case the explanation of the supplier is not found satisfactory, as provided for in Article 20 of the UNICTRAL Model Law - may be considered for adoption.

### **4. Communication of reasons for rejection of bids**

4.1 Section 38 (under the Chapter 'Transparency Mechanism') provides that details of successful bids, list of bidders excluded with reasons, particulars of debarred bidders and the cause of debarment action are communicated through the Central Procurement Portal. However, there is a need to further strengthen transparency provisions by providing, on request, to an unsuccessful tenderer, the reasons why his tender was not selected, and the characteristics and relative advantages of the selected tender. Similarly, it should be considered to provide a supplier on request why her/his application to be considered as a registered bidder under Section 14 or a pre-qualified bidder under Section

13 was rejected. This is likely to inspire greater public confidence in the procurement process and lessen unnecessary challenges to the bid process.

## **5. Upholding quality norms even in preferential procurement**

5.1 Section 6 of the Public Procurement Bill, 2012 provides well considered grounds (like promotion of domestic industry, considerations of public interest and other socio-economic considerations) on which the central government may base its preference policy, it is felt that even in this context the quality criteria should be in-built. The selected bidders in this category should possess the capacity to supply as per minimum specified standards/building codes, etc. This will ensure that proper quality in public procurement is met and that the categories of entities which are the subject matter of preference are encouraged to be competitive.

## **6. Developing standard bidding documents**

6.1 The Committee on Public Procurement appointed by Government, in its report submitted in 2010, inter alia mentioned as one of the reasons for the confusion faced by bidders in public procurement, leading to limited participation/restricted competition was the plethora of bidding documents used by different government departments, even for the same item of procurement. India has as early as in the 1990s successfully prepared standard bidding documents for procurement in World Bank aided projects. Through the Bill, the mandate for preparation of such standard bidding documents for major items of common use may be considered.

## **7. Emphasis on offences by officials and experts only**

7.1 Section 44 of the Bill provides that ‘Whoever, being a public servant acting in connection with any procurement process, accepts or agrees to accept or obtains or attempts to obtain from any person, for himself or for any other person, any gratification ... shall be punishable with imprisonment and shall also be liable to fine’. The term ‘public servant’ is not defined in the Section nor in Section 2, the definition's Section of the Bill. But later on, Section 51 provides that ‘Every official of a procuring entity or any member of a committee constituted under this Act, acting under or in pursuance of the provisions of this Act or rules, orders or notifications made thereunder, shall be deemed to be a public servant within the meaning of Section 21 of the Indian Penal Code’.

7.2 Both these provisions read singly or together along with the absence of the term ‘public servant’ in the Definitions Section of the Bill, appear to indicate that only officials or experts who are members of a committee connected with public procurement may be held liable for offences under the Act. In reality, especially in big ticket procurement, such as public private partnership procurement, the persons responsible for a decision against the public interest are not the officials or the experts, but their political masters. World experience as reflected in the literature shows that in many cases the very decision taken at the political level for entering into public-private partnership for execution of a particular project and its concomitant procurement process is suspect/ not in the public interest.

- 7.3 The two major Indian legislations dealing with corruption and criminality, the Indian Penal Code, 1860 and the Prevention of Corruption Act, 1988, both clearly indicate that liability for malpractices include even politicians in their scope.
- 7.4 Section 21 of the IPC, sub section 12 (a) thereof, covers in its definition of the term ‘public servant’: ‘Every person in the service or pay of the Government or remunerated by fees or commission for the performance of any public duty by the Government’ and in its sub section 12 (b) ‘Every person in the service or pay of a local authority...’. Similarly, Section 2 (c) (i) of the P.C. Act inter alia defines the term ‘public servant’ as ‘Any person in the service or pay of the Government or remunerated by the Government by fees or commission for the performance of any public duty’ and Section 2 (c) (vii) as ‘Any person who holds an office by virtue of which he is authorised or required to perform any public duty’.
- 7.5 The connotation of public servant to imply just officials and members of committees connected with procurement in Section 51 of the Act and the absence in Section 44 (dealing with Offences, Penalties and Debarment) of the definition of the term ‘public servant acting in connection with any procurement process’ to carry the same connotation as in Section 21 of the IPC and Section 2 (c) of the P.C. Act are lacunae in the Public Procurement Bill, 2012. The definition Section of the Bill, i.e. Section 2, should incorporate that the definition of the term ‘public servant’, wherever it occurs in this legislation, would carry the same meaning as under Section 21 of the IPC and Section 2 (c) of the P.C. Act, so as not to exclude any person deliberately responsible for taking decisions against the public interest for personal gain or influence.

## **8. Post-award management of contracts**

- 8.1 Many of the issues in public procurement are said to crop up at the post-award stage, as there is likelihood of the contract not being implemented properly. It may, therefore, be beneficial if the Bill provides that through the Rules thereto, whether for procurement of goods, services or works, there will be provision for post-award contract management, as in the PPP draft Rules, which have recently been put up on the Finance Ministry’s website for comments. Such a contract management mechanism should inter alia provide for:
- A Dispute Settlement Mechanism, as disputes between the procuring entity and the supplier are frequent at the implementation stage and the present system of going in arbitration or to the courts is costly and time consuming;
  - A Contract Management Team to be set up by the contracting authority to monitor the supplier and ensure adherence to performance standards, delivery timelines, reporting procedures etc.;
  - An Empowered Review Cell to be set up in the relevant Department of the Government, headed by a sufficiently senior officer, to issue instructions to the contracting authority for rectifying defaults/lapses, regarding grievances of users and manner and extent of their redressal, getting independent evaluation done of the implementation, especially in the case of procurement of works and services etc.

## 9. What the Bill must retain

- 9.1 Current economic policy in India, reflected, *inter alia*, through the National Manufacturing Policy, 2011, leverages public procurement to stimulate manufacturing in India. Also, the international practice is to limit participation in Government procurement to domestic players, except to the extent necessitated by force of bilateral/plurilateral agreements.
- 9.2 In the face of the current economic recession, this protectionist tendency is being strengthened by further policy instruments, such as the U.S. mandate, as part of its Federal stimulus funding package, that all steel and cement to be used in public works would have to be US manufactured. A criticism of the Public Procurement Bill, 2012 is that in unconditionally providing national treatment to foreign bidders, through its Section 11, it flies in the face of both current economic strategy in India, as also goes counter to the international practice in this regard.
- 9.3 It takes away the negotiating space necessary for a government to cater to its domestic preferences freely, without taking recourse to exceptions under the law. It may also be not left with any leverage with which to squeeze out concessions from its trading partners in exchange for providing reciprocal market access, in case accession to GPA is contemplated.

There are two arguments against this approach.

- 9.3.1 First, the concern for India is not merely one of securing protection for its domestic industry. It is also that of securing best quality at best price for its domestic consumers, who are to a large extent dependent on publically procured goods and services. Fostering open competition in the Indian market, including from foreign players, is important for this purpose. A totally protected market in government procurement, as in the pre-liberalized era of the Indian economy, will have its dangers of regression for the entire economy, given the considerable size of the Indian GP market.
- 9.3.2 Secondly, the Bill provides the necessary flexibility to safeguard domestic preference in the sectors in which there is a perceived need. The Bill empowers the Central Government to provide by notification for 'mandatory procurement of any subject of procurement from any category of bidders or purchase preference in procurement from any category of bidders' on the ground of (a) promotion of domestic industry, (b) socio-economic policy of the Central Government and (c) 'any other consideration in public interest in furtherance of a duly notified policy of the Central Government' (sub section 2 of Section 11 of the draft Bill). The further deepening of the special preference accorded to the MSE sector by reserving 20 per cent of all Central procurement for this sector with effect from April 1, 2012 (vide Central Government notification dated March 23,2012) is one example of the Government's ability to prioritise domestic preference as and when needed, utilizing the flexibilities within the procurement system.