No. 31026/91/2015-PI-II
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
******

New Delhi, the 03rd June, 2015

To

1. IPA
2. IDMA
3. Association of Indian Medical Devices Industry (AIMED)
4. Federation of Indian Chamber of Commerce and Industry (FICCI)
5. CII
6. PHD Chamber of Commerce
7. ASSOCHAM
8. OPPI
9. AMCHAM

Subject: Draft National Medical Device Policy-2015 reg.
****

Sir,

I am directed to enclose a copy of draft National Medical Device Policy-2015 and to request you to furnish your comments/suggestions on the same urgently and latest by six weeks of the date of this letter.

Yours faithfully,

Encl: as above

(Raj Kumar)
Under Secretary to the Govt. of India
Tele: 23071162
Telefax: 23385765

Copy to:

Shri V.K. Tyagi, Consultant with the request to kindly upload the same on the Department's website.

National Medical Device Policy-2015

1. Preamble and Background

1.1 Medical devices industry is a multi-product industry, producing wide range of products. Manufacturing and trade in medical devices is also growing quite steadily. Double digit growth rates indicate its importance in health care. Medical devices industry mostly depends on imports. Most hi-tech innovative products and technology originate from a well-developed eco-system and innovative cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

1.2 It is estimated that the global market for medical devices is over US$ 220 billion. United States of America, with about 45% market share is the dominant market for medical devices in the world followed by European market with a share of 30% and Japan with a share of 10%. Medical devices sector in India is relatively small as compared to the rest of the manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is the 4th largest market in Asia after Japan, China and South Korea. Although accurate data is not available, an educated guess would place the sector at about Rs. 30,900 Crores in production terms. The medical devices industry can be broadly classified as consisting of (a) medical disposables and consumables(31.3%); (b) medical electronics, hospital equipments, surgical instruments (53.7%); (c) Implants (7.1%); and (d) Diagnostic Reagents(7.9%). Medical devices Industry in India is predominantly import driven accounting for over 65% of the total market and approximately 80% of import in categories (b), (c) and (d).

1.3 At present, the Indian medical devices industry is fragmented into small and medium enterprise category and is primarily manufacturing products such as disposables/medical supplies. Requirement for high end medical equipments are met by multinational companies. It is estimated that there are about 800 manufacturers in the country and based on their turnover, the industry profile of these manufacturers is as given in the table below.

Industry Profile	
Turnover	% Distribution
0-10 Cr	65
10-50 Cr	25
50-100 Cr	5
100-500 Cr	3
500+ Cr	2
Source : AIMED	

1.4 Various sources expect the Medical Electronics industry to reach around USD 2+ Billion in 2015 growing at a CAGR of 17% for the last five years from a size of USD 850+ Million in 2009. It is believed that the growth will not only sustain but may increase beyond 17%.

1.5 Large multinational corporations (MNC) controlling the global industry backed by multiple approvals, certification of accredited organizations and capacity to produce verified clinical trial record are able to control the major share compared to the home grown devices which lacked standardization, certification or seal of quality approval even from local authority. Lack of national regulation helped the foreign multinational corporations in doing business in this sector. The Drugs and Cosmetics (Amendment) Bill, 2015 for providing a separate chapter for regulation of the complete range of medical devices is now under legislative process.

1.6 Besides, the others issues facing the Indian medical device industry include training and capacity building programme, interaction with medical device regulators, policy to promote local manufacture of medical devices, granting subsidies and incentives and promoting higher education relevant to medical devices industry to bring fresh talent and techniques into research and development. There does not exist a single nodal authority for medical device industry.

1.7 Recognizing this policy deficit, the Government constituted a Task Force under the chairmanship of the Secretary, Department of Pharmaceuticals (DoP) to

address issues relating to the promotion of domestic production of high end medical devices and pharmaceutical manufacturing equipment in the country. The Task Force in its report released by Honourable Minister of Chemicals and Fertilizers on 08.04.2015 had made a set of recommendations for the promotion of the medical device industry.

2. Objective:

The National Medical Device Policy-2015 has the objective of strengthening the Make in India drive in medical device sector by reducing the dependence on imports and setting up a strong base for medical devices especially those having critical implications in terms of affordability and availability for patients.

3. Salient Features:

(i) An autonomous body "**National Medical Device Authority"(NMDA)** to be created under the Department of Pharmaceuticals, which may be headed by an officer of the rank of Additional Secretary/ Joint Secretary to the Government of India. The Authority shall have a Member Secretary of the rank of Joint Secretary/ Director; two eminent medical practitioners; two eminent medical device technologists or scientists; and Secretary General of Quality Council of India (exofficio). The Authority shall

a. Provide a single window mechanism to the industry with an objective of promotion of the medical device industry to make the country not only self reliant but also a global hub of production and innovation in medical devices.
b. Be responsible for setting up and managing, through appropriate corporate body/ SPV, Medical Devices Mega Parks of approximately 500 hectares and above, of various specialisations in the vicinity of Centres of Excellence.
c. Create benchmarks as per international best practices and update all the stakeholders on global development.
d. Develop knowledge networks with partners from industry.

e. Identify and prevent creation of unnecessary and unjustified technical barriers to trade especially by new or changing technical regulations.
f. Support and prepare indigenous businesses to face competition, access foreign markets, and find new business partners abroad.
g. Search, collect, collate and analyse relevant data.
h. Promote, co-ordinate and issue guidelines for the development of risk assessment methodologies and monitor, conduct and forward messages on the risks associated with medical devices to the Central Government, State Governments and other enforcement agencies.
i. Promote networking of national and international organizations within and outside India with the aim of facilitating scientific co-operation, co-ordination of activities, exchange of information, implementation of joint projects and exchange of expertise.
j. Take all such steps to ensure that the public, medical professionals and interested parties receive rapid, reliable, objective and comprehensive information through appropriate methods and means.
k. Promote general awareness as to medical device safety and medical device standards.
l. Undertake any other task assigned to it by the Central Government.

(ii) The Government on the recommendations of NMDA, subject to availability of Budgetary resources, may consider all or an appropriate mix of the following incentives for both Greenfield and Brownfield units:

a. Preference in government procurement may be considered for medical devices which are being manufactured in India with an additional preference for medical devices manufactured under MSME sector.
b. R&D by agencies like ICMR, DBT, CSIR, DIETY & DoP should be supported/ coordinated through the single window facilitating body.
c. Low cost funding like interest subsidy to MSME
d. Concessional power tariff for up to 5-10 years

e. Provide seed capital, viability gap funding and co-fund start-up projects
f. Support commercialization of innovations
g. Provide longer term view (10 years window) for 200% weighted tax deduction on approved expenditure on R&D as the gestation period in high in this industry.
h. Tax/ duty structure to be designed to promote local manufacturing of quality medical devices and diagnostic equipment
i. Minimum/ zero duty on the import of raw materials and manufacturing equipments for production of medical devices.
j. Restrictions on import of second hand diagnostic equipment/ tools
k. Higher taxes after 5-7 years of usage for imported second hand devices
l. Incentivize and promote exports in the medical devices sector.

(iii) Institutional framework:

- Medical device testing centres to be set up preferably in the PPP mode- Common medical device testing facilities can be set up by government in major medical device manufacturing hubs to facilitate testing/ evaluation of medical devices. Recurring expense can be borne by the industry.
- Designate "Centers of Excellence" (CoE) for supporting product development and validation- The centers having existing requisite facilities and expertise for different categories of medical devices (Example: Department of Electronics and Information Technology (DEITY), Bureau of Indian Standards (BIS), Indian Institute of Technology, Madras (IIT-M), Indian Institute of Technology, Delhi (IIT-D), Indian Institute of Science, Bangalore (IISc-B), Central Institute of Plastics Engineering (CIPET), Defence Research and Development Organization(DRDO). These Centres of Excellence would support:
    - Product development – design and prototyping
    - Validation and certification of the medical use of devices

- Adopt, implement and advocate policies on efficacy and safety testing

- Strengthen a Made in India marking (BIS) specific to Medical devices in line with international standards like CE and FDA
- Set up a Skill Development Committee under National Medical Devices Authority with representatives from Medical devices industry, academia (NIPERs) and Healthcare Sector Skill Council (HSSC) under National Skill Development Council (NSDC), which would:
    a. Identify skill gaps and reduce shortages
    b. Design curriculum and explore possibilities for on-line/ e-learning modules to meet specific requirement of medical device segment
    c. The committee would engage with HSSC affiliated Vocational Training Providers as well as potential ITIs, Polytechnic and other institutes for skill development
    d. Set up satellite training campus around manufacturing hubs for skill upgrading
    e. Liaise across the Medical devices industry for job placements.
    f. Provide counseling to candidates seeking skill development and address issues like student loan, scholarships, job placements etc.
- Since the medical devices sector is highly innovation and technology intensive, it is recommended to create a system where Industry may place/ make available their IP in non-core activities available to the exchange which may help technological up-gradation of the sector.
- Set up/ promote Incubation centers through appropriate incentive structure/ cost sharing.Such centers would address gaps in capabilities within R&D infrastructure, testing calibration etc.

(iv) Affordability:

- Separate price control for medical devices- The medical devices may be included as separate entry in the list of commodities controlled under the Essential Commodities Act.
- The Government may announce a separate policy enunciating the principles for regulating the prices of identified medical devices and implement the same by notifying a separate Medical Devices Prices Control Order (MDPCO).
- A separate division may be created in National Pharmaceuticals Pricing Authority for pricing of the devices by suitably amending the resolution constituting NPPA.

4. Implementation:

In the first phase, the Department of Pharmaceuticals will within six months, bring a detailed proposal for creation of the National Medical Devices Authority with vision, mission, objectives, constitution, Head Quarters and likely budgetary allocation for appraisal and approval of the competent authority. The Department of Pharmaceuticals will come up with separate proposals for amending the Essential Commodities Act, amending the scope of functions of NPPA, and the National Medical Devices Pricing Policy.

xxxxx