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No.Z.21020/78/2017-PH
Government of India
Ministry of Health & Family Welfare
Public Health Division

Nirman Bhawan, New Delhi
Dated the 2.11.2017

ORDER

Subject: Constitution of an Inter-Ministerial Consultative Committee to coordinate and steer the initiatives of different Ministries and Departments on Rare Diseases as laid out in the National Policy for Treatment of Rare Diseases.

The Hon'ble Delhi High Court, vide its order dated 11.8.2017 has directed the Ministry of Health and Family Welfare, Govt. of India to constitute the Inter-Ministerial Consultative Committee to coordinate and steer the initiatives of different Ministries and Departments on Rare Diseases as laid out in the National Policy on Rare Diseases in India. Accordingly it has been decided to constitute an Inter-Ministerial Consultative Committee under the Chairmanship of the Additional Secretary(Health) comprising of the following members as under:

- i. Shri Lav Agarwal, Joint Secretary, Ministry of Health & Family Welfare
- ii. Joint Secretary, Department of Industrial Policy and Promotion
- iii. Joint Secretary, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals
- iv. Joint Secretary, Ministry of Corporate Affairs
- v. Joint Secretary, Ministry of Finance
- vi. Joint Secretary, Ministry of Labour & Employment
- vii. Joint Secretary, Department of Health Research
- viii. Dr Himanshu Chauhan, DADG (H), Member Secretary

2. The Role of Ministries and Departments outlined in the National Policy are as under:

I. Ministry of Health and Family Welfare.

d/c

- a) Health Ministry to create a cell on rare diseases within itself, to be headed by a Joint Secretary. It will act as a nodal agency and coordinate all the activities of the Health Ministry on rare diseases.
- b) Indian Council of Medical Research (ICMR) to constitute a division or identify one of its existing divisions, to promote research and development in the field of rare diseases for diagnosis and treatment of rare diseases, including through international/regional collaborations. An initiative like open source drug discovery and research for rare diseases based on principles of public funding of research and access to any treatments arising from this to be available 'Intellectual Property (IP) - free' and open to competitive manufacturing should be looked into.
- c) Constitute an Inter-Ministerial Consultative Committee to co-ordinate the activities of various ministries and departments on rare diseases

- d) Constitute an Administrative and Technical Committee at Central as well as State levels, for management of corpus funds and developing technical guideline/criteria for - which rare diseases to fund, to what extent, review of treatment etc.
- e) Create a patient registry with information to practitioners and a reporting system of any patient diagnosed with a rare disease. This will be housed in ICMR. Patient registries may serve as appropriate tools to aid in understanding the natural history and clinical characteristics of rare diseases and assess the long-term outcomes of treatment.
- f) Take measures to collect epidemiological data on rare diseases.
- g) Take measures to create awareness among medical professionals, patients and their families and general public on rare diseases.
- h) Develop and conduct training programme for doctors on diagnosis and management of rare diseases
- i) As a strategy for early diagnosis of rare diseases, explore formulating a plan for piloting and depending on feasibility, rolling out progressively, testing for rare genetic diseases in newborns, in tandem with development and standardization of diagnostic modalities and availability of treatment
- j) Strengthen network of laboratories to effectively and accurately diagnose rare diseases
- k) Drug Controller General of India (DCGI) to consider feasibility of amending Drugs and Cosmetics Act or otherwise taking measures under it, to include appropriate provisions on drugs for rare diseases, including provisions to facilitate clinical trials and import of ERTs.
- l) For patients in the BPL category who get diagnosed with rare diseases, make available for free, supportive services, whether in private or government hospital.
- m) ICD 11 classifies about 5000 rare diseases. The centres identified by the Central/State government for categorising rare diseases in India, need to group/put rare diseases under already identified disease classification under ICD 11. If any new rare disease is identified, steps will be taken by the Ministry for sending required evidence to WHO for inclusion of the disease under ICD classification.
- n) As a preventive strategy, consider feasibility of making a plan for providing and progressively scaling up pre-conception and antenatal genetic counseling and screening in a targeted manner, or otherwise, to provide option to parents to prevent conception or birth of a child with a rare genetic disease
- o) Creating a National and State Level Corpus :
1. The Government of India (GOI) to set up a corpus fund with an initial amount of

Rs. 100 crore towards funding treatment of rare genetic diseases. Resources allocated for treatment of rare diseases can be progressively scaled up with regular improvements in availability of epidemiological data, cost estimation studies and measures taken to encourage development of drugs and for reduction in prices of drugs.

2. The States to have a similar corpus at the state level and the GOI will contribute funds towards the State corpus to the ratio of 60:40. It would be open to the states to contribute a larger amount to the corpus. This funding arrangement will be part of the PIP process.

3. The corpus fund will be dedicated for rare disorders. However, it will not fund treatment for blood disorders (hemophilia, thalassemia and sickle cell anemia) as separate government programs for them exist already. Depending on need, the existing programmes for blood disorders shall be scaled up.

4. The corpus will be used for only part funding of the entire treatment cost.

5. To ensure sustainability of the corpus, the Public Sector Undertakings (PSUs) and corporate houses, to be encouraged to make contributions as per Section 135 and Schedule VII of the Companies Act as well as the provisions of the Companies (Corporate Social Responsibility Policy) Rules, 2014 (CSR Rules)

p) Creating a web-based application for online application process: To ensure timely decisions and release of funds, a web-based application would be developed for creating online mechanism for applying to the corpus. Central government will create this web-based application within 6-12 months of the release of this policy. It will have the details of the corpus and instructions and mechanism for applying for funding. It would be open to individuals institutions as well as state governments to apply for funds by entering details on the web application as per instructions provided.

II. Ministry of Commerce, Department of Industrial Policy and Promotion (DIPP)

- a. Constitute a Cell within DIPP to promote local development and manufacture of drugs for rare diseases at affordable prices
- b. Take legal/legislative measures for creating a conducive environment for indigenous manufacturing of drugs for rare diseases at affordable prices. For instance, ensuring strict scrutiny of patent applications related to rare diseases to ensure they meet the strict patentability of the Indian patent law and issuing compulsory licenses under Patents Act 2005, to ensure affordability of patented drugs for rare diseases.
- c. Encourage PSUs for local manufacturing of drugs for rare diseases

III. Ministry of Chemicals and Fertilizers, Department of Pharmaceutical (DoP), National Pharmaceutical Pricing Authority (NPPA)

Take measures to document and make publicly available the prices of drugs for rare diseases and work towards affordability of drugs for rare diseases, in consultation with the Ministry of Health and Family Welfare.

IV. Ministry of Corporate Affairs.

Encourage PSUs and corporate houses to contribute to the corpus as per the Section 135 and Schedule VII of the Companies Act as well as the provisions of the Companies (Corporate Social Responsibility Policy) Rules, 2014 (CRS Rules). Preventive and promotive health care is included in the list in the Schedule for CSR activities.

V. Ministry of finance.

- a) Department of Revenue to consider removing import duty on ERTs as well as on assistive devices.
- b) Department of Financial Services to consider, on the basis of actuarial studies, whether insurance sector could cover cost of treatment of rare genetic diseases and amend the Insurance Act accordingly. It is necessary to bring in health insurance reforms through IRDA (Insurance Regulatory and Development Authority of India) and government intervention.

VI. Ministry of Labour and Employment.

Employees State Insurance Corporation (ESIC) to consider removing/increasing the ceiling limit on funding treatment for rare diseases.

3. The activities listed above are indicative and can be expanded depending on improvement in our knowledge and understanding of rare diseases and the type of response it will require, based on availability of data and evidence generated through research and studies.

4. Secretary(HFW) will oversee, coordinate and steer the initiatives taken by the different Ministries and Departments. Its meetings could be held at least once in a year.

5. This issues with the approval of Secretary(Health & Family Welfare).



(Ajaya Kumar K.P.)
Under Secretary to the Government of India
Tel.No.23061342

To

1. Joint Secretary, Department of Industrial Policy and Promotion, Udyog Bhawan, New Delhi.
2. Joint Secretary, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, Shastri Bhawan, New Delhi.
3. Joint Secretary, Ministry of Corporate Affairs, Shastri Bhawan, New Delhi.
4. Joint Secretary, Ministry of Finance, North Block, New Delhi.
5. Joint Secretary, Ministry of Labour & Employment, Shram Sakthi Bhawan, New Delhi.
6. Joint Secretary, Department of Health Research, ICMR, New Delhi.
7. Dr Himanshu Chauhan, DADG (IH), Member Secretary, DGHS

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6-11-17

Copy to:-

1. PPS to Hon'ble HFM
2. PPS to Secretary (H)
3. PPS to AS (H)
4. PPS to JS(LA)

[Handwritten notes and signatures]
Johit
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Signature valid

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