

NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry of Health & Family Welfare, Govt. of India)

Information under Section 4(1) (b) of the Right to Information Act, 2005

1. The particulars of its organisation, functions and duties:

National Institute of Biologicals an autonomous Institution under the Ministry of Health & Family Welfare (MOHFW)-Government of India is a premier Scientific Organization and a Centre of Excellence to ensure quality of biologicals and vaccines in the country.

The Institute responsibly assures and reviews the quality of number of Biological products available through domestic manufacturers or imports. The operations are carried out in the state of the art facility of the Institute and in close co-ordination with Government of India regulatory authorities as Office of Drug Controller of India, Indian Pharmacopoeia's Commission.

With the current science and technology leading to the development of newer biologicals in the domestic market, the testing and specifications may vary for each specific products which requires an improved understanding of quality and safety issues. In recent years, the licensing and quality control for manufacturer and National Regulatory Authorities alike has become even more complex. With this overall objective and to strengthen the regulations of biologicals in India, NIB, which is supported by the authorities constituted of Governing body and General body of the Institute plays a vital role.

Functions:

- The Institute will undertake systematic examination of the quality of biological and immunobiological products, with a view to enable the release of indigenous & imported products after certification, according to the procedures prescribed under the Drugs and Cosmetics Act.
- The Institute will establish National Reference Standards and serve as a repository and National Bank for Reference Standards and Reagents for biologicals and immunobiologicals.
- The Institute will develop suitable network / linkages with related institutions set up by the Central Government or within Universities so as to effectively disseminate knowledge, develop manpower and act as a resource backup for development of Standard Operating Procedures, Reference Standards and quality manuals.
- The Institute will, in consultation with the Indian Pharmacopoeia Committee develop and establish pharmacopoeial specifications.
- The Institute may function as an accredited testing and reference laboratory for quality control of biological products available in the future and it may evaluate and advise on the emerging technologies in these fields in terms of their specificity, sensitivity and replicability.
- The Institute will provide training to scientific and technical personnel in the procedures for development of standardization and quality control methods of immune-biologicals.

Document Name: Information under Section 4(1) (b) of the Right to Information Act, 2005	
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Effective From Year: 16 June, 2016	Validity: Till Further Revision
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- The Institute will develop technical guidelines / manuals on standards to be used by manufacturers and also for training scientific technical manpower for standardization and quality control.
- The Institute will monitor ongoing research, establish linkages and exchange personnel with different Institutions in India and abroad for the furtherance of its mandate.

2. The powers and duties of its officers and employees:

The officers and employees are appointed in accordance with recruitment rules / bye-laws of the Institute. They discharge their official duties in accordance with the directions and instructions given by the Institute from time to time.

3. The procedure followed in the decision making process, including channels of supervision and accountability:

The officers and employees follow the procedure laid down in the Bye-laws of the Institute and other applicable rules and regulation as per Govt. of India norms for this purpose.

4. The norms set by it for the discharge of its functions:

The Institute and its officers are discharging their functions and duties in accordance with the provision contained in the Bye-laws of the Institute and relevant rules and regulations.

5. The rules, regulations, instructions, manuals and records held by it or under its control or used by its employees for discharging its functions:

All rules and regulations are available on the Institute's website i.e., <http://nib.gov.in>.

6. A statement of the categories of documents that are held by it or under its control:

The files on the subject matters dealt within each section such as case files, files of correspondences, annual reports, files related to budget and budgetary allocation, parliamentary questions, procurement / tender enquiries, security audit of software, purchase of anti-virus software, website updating, purchase of computers / printer, training of manpower within India and abroad, hiring of vehicles, recruitment of manpower etc.

7. The particular of any arrangement that exists for consultation with, or representation by, the members of the public in relation to the formulation of its policy or implementation thereof:

To achieve the aims and objects laid down in the Memorandum of Association and Bye-laws of the Institute, various regulations have been framed. The Institute has taken lot of initiatives to spread public awareness about the Institute's activities by convening various workshops, CMEs, seminars, deliver lectures etc.

8. A statement of boards, councils, committees and other bodies consisting of two or more persons constituted as its part or for the purpose of its advice and as to whether

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Effective From Year: 16 June, 2016	Validity: Till Further Revision

meetings of those boards, councils, committees and other bodies are open to public or the minutes are accessible for public:

The members of the board constituted for the Institute comprises of Secretary, Addl. Secretary, Joint Secretary of Govt. of India and Scientist and representative from PSUs for achieving the aims and objectives of the Institute. The meetings / minutes are accessible only to the authorised members only.

9. A directory of its officers and employees:

The directory, of its officers and employees along with e-mail id and telephone number, is already available on the Institute's website (<http://nib.gov.in>).

10. The monthly remuneration received by each of its officers and employees, including the system of compensation as provide in its regulation:

The information with respect to monthly remuneration received by each of its officers and employees are provided on the Institute's website (<http://nib.gov.in>).

11. The budget allocated to each of its agency, indicating the particulars of all plans, proposed expenditures and reports on disbursements made:

(Rupees in crores)

Financial Year	Approved B.E.	Approved R.E.	Grant -in-Aid received	Expenditure incurred
2023-24 (Provisional)	61.43	55.32	52.80	53.19
2022-23	65.80	64.80	64.11	62.11
2021-22	47.91	48.90	47.47	48.73
2020-21	43.70	46.65	43.97	44.67
2019-20	46.40	46.15	42.85	43.05
2018-19	41.79	39.05	39.16	37.32
2017-18	39.42	41.32	38.21	37.27
2016-17	37	34	29.62	33.65
2015-16	35	34.6	34.6	31.04
2014-15	31	31	31	30.93
2013-14	25	25	24.74	25.02
2012-13	17	19.5	19.5	19.21
2011-12	17.8	14.4	12.12	13.95
2010-11	17.25	15	13.6	12.77
2009-10	15	11	11	11.48
2008-09	10	10.34	10.34	8.96

12. The manner of execution of subsidy programmes, including the amounts allocated and the details of beneficiaries of such programmes: N.A.

13. Particulars of recipients of concessions, permits or authorizations granted by it: N.A.

14. Details in respect of the information, available to or held by it, reduced in an electronic form:

All the relevant details including the order passed by the Institute from time to time are made available on the Institute's website. Further, other details like employment related issues, procurement / tender enquires etc are also made available on the Institute's website as well as on CPP Portal for ePublishing,

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15. The particulars of facilities available to citizens for obtaining information, including the working hours of library or reading room, if maintained for public use:

The Institute has maintained a library restricted only to its officers and employees. The library is not open for general public. To obtain information under the Right to Information Act, 2005, a person may make a request in writing or through electronic mail along with the prescribed application fee in favour of CPIO, National Institute of Biologicals, Noida.

16. The name, designation and other particulars of the Public Information Officers:

The particulars of PIO and other authorities designated under the RTI Act is furnished on on the Institute's website (<http://nib.gov.in>).

17. Such other information as may be prescribed:

Staff Position as on 31.05.2016 is available on the Institute's website.

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