

INDIAN PHARMACOPOEIA COMMISSION

MEMORANDUM OF ASSOCIATION

AND

RULES AND REGULATIONS

**MEMORANDUM OF ASSOCIATION AND THE RULES
RELATING TO ESTABLISHMENT OF THE
INDIAN PHARMACOPOEIA COMMISSION
AT GHAZIABAD, U.P.**

In the matter of the Societies Registration Act, 1860 (Act No. 21 of 1860) for the Registration of Literary, Scientific and Charitable Societies, and

In the matter of the Indian Pharmacopoeia Commission, hereinafter referred to as “The Society”.

MEMORANDUM OF ASSOCIATION

1. **NAME OF THE SOCIETY:**

The name of the Society shall be the Indian Pharmacopoeia Commission.

2. **REGISTERED OFFICE:**

The Registered Office of the Society shall be situated at the Central Indian Pharmacopoeia Laboratory, Sector 23, Raj Nagar, Ghaziabad-201 002, U. P. INDIA.

3. **AREA OF WORK:**

All over India.

4. **AIMS AND OBJECTS OF THE COMMISSION:**

4.1 The Society is established with the object to administer and manage the Indian Pharmacopoeia Commission, Ghaziabad, U. P.

4.2 The functions of the Society shall be to:-

4.2.1 revision and publication of the Indian Pharmacopoeia at suitable intervals and of such addenda or supplementary compendia during the intervening periods as may be deemed necessary; releasing the publications for public use from a date when they are to become official, the said date to be at least six months from the date of its release;

4.2.2 revision and publication of the National Formulary of India at regular intervals with a view to make it a reliable source of information on rational use of medicines including their pharmacological actions, therapeutic indications, adverse reactions, contra-indications, drug interactions, poisoning and its first-aid treatment and similar issues concerning medicines for use in humans and animals;

4.2.3 publish regularly or at suitable intervals other related scientific information as authorised under the rules and procedures of the Commission;

- 4.2.4 exchange information and interact with international counterparts in other countries and with expert committees of the World Health Organization and other international bodies with a view to harmonise the Indian pharmacopoeial standards with those internationally accepted;
- 4.2.5 arranging studies either under its own auspices or through collaborative work to establish reliable and economical criteria for identity, purity and safety of drugs included or to be included in the Indian Pharmacopoeia and its addenda or supplementary compendia or other authorised publications;
- 4.2.6 arranging procurement, preparation, evaluation, containerisation and distribution of Chemical Reference Materials/ Standards;
- 4.2.7 nurturing and promoting quality and excellence in pharmaceutical analysis and research;
- 4.2.8 creating a central facility of pharmaceutical instrumentation and analysis which may be available for use by others engaged in pharmaceutical analysis and research;
- 4.2.9 acting as a nucleus for interaction between analytical laboratories, industry and academia by encouraging exchange of scientific and technical staff and information and by undertaking and sponsoring funded research as well as consultancy projects between the Commission and the analytical laboratories-industry-academia;
- 4.2.10 organising national/international symposia, seminars, meetings and conferences in selected areas from time to time;
- 4.2.11 receiving grants, contributions, sale proceeds of its publications and reference standards, income from any other source, managing the funds and properties of the Society;
- 4.2.12 acquire purchase or otherwise own or take on lease or hire in the Union Territory of Delhi or outside, temporarily or permanently, buy and moveable or immovable property necessary or convenient for the furtherance of the objectives of the Society;
- 4.2.13 draw, make accept, endorse, discount, execute, sign, issue and otherwise deal with cheques, drafts, certificates, receipts Government securities, bill of exchange or other instruments and securities whether negotiable or transferable or not;
- 4.2.14 build, construct, maintain, repair, alter, improve or develop or furnish and buildings or works necessary or convenient for the purposes of the Society;
- 4.2.15 all incomes, earnings, moveable, immovable properties of the society shall be solely utilized and applied towards the promotion of its aims and objects only as set forth in the Memorandum of Association and no profit thereof shall be paid or transferred directly or indirectly by way of dividends, bonus, profits, or in any manner whatsoever to the present or past members of the Society or to any person claiming through any one or more of the present or the past members. No member of the society shall have any personal claim on any moveable or immovable properties of the Society or be entitled to make any claim whatsoever by virtue of his/her membership;

- 4.2.16 make Rules and By-laws for the conduct of the affairs of the Society and to add, to amend, vary or rescind them from time to time with the approval of the Central Government;
- 4.2.17 administer all matters concerning the Society in accordance with the rules and procedure of business;
- 4.2.18 do all such things as may be necessary, incidental or conducive to the attainment of all or any of the objects of the Society; and
- 4.2.19 delegate any or all of its powers to the Commission or to any of the committee or committees or expert panels or working groups constituted by it.

5. **GOVERNING BODY:**

The names, addresses, occupations and designations of the first members of the Governing Body to whom the management of the society is entrusted are as follows:

<u>S. No.</u>	<u>Name</u>	<u>Address</u>	<u>Occupation</u>	<u>Designation</u>
1)	Ms. Jyoti Rao, IAS	Additional Secretary(Health) Government of India Ministry of Health & Family Welfare Department of Health Nirman Bhavan, New Delhi	Service	Chairman
2)	Sh. Sanjiv Misra, IAS	Additional Secretary & Finance Advisor Government of India Ministry of Health & Family Welfare Department of Health Nirman Bhavan, New Delhi	Service	Member
3)	Ms. Rita Teatota, IAS	Joint Secretary (Drugs) Government of India Ministry of Health & Family Welfare Department of Health Nirman Bhavan, New Delhi	Service	Member
4)	Shri Ashwini Kumar	Drugs Controller General (India), Dte. General of Health Services, Nirman Bhavan, New Delhi	Service	Member

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|----|-------------------------|---|-----------|----------------------|
| 5) | Sh. Rajesh Bhushan, IAS | Director, (Drugs)
Government of India
Ministry of Health &
Family Welfare
Department of Health
Nirman Bhavan,
New Delhi | Service | Member |
| 6) | Dr. N. K. Ganguly | Director,
National Institute of Biologicals
(Min. of Health & F. W.)
A-32, Sector 62,
Institutional Area, Noida | Service | Member |
| 7) | Dr. Nitya Anand | Ex-Director
Central Drugs Research Institute
B-62, Nirala Nagar,
Lucknow. | Scientist | Member |
| 8) | Dr. G. N. Singh | Director,
Central Indian Pharmacopoeia Laboratory,
Sector 23, Rajnagar,
Ghaziabad-201 002. | Service | Member-
Secretary |

6. **DESIROUS PERSONS:**

We, the several persons whose names and addresses are given below, having associated ourselves for the purpose described in the Memorandum of Association, do hereby subscribe our names to this Memorandum of Association, and set our several and respective hands hereunder and form ourselves into a Society under the Societies Registration Act, 1860 (Act No.21 of 1860), this 06th day of December, 2004.

<u>S.No.</u>	<u>Name</u>	<u>Occupation & Address</u>	<u>Signature</u>
1)	Ms. Jyoti Rao, IAS	Additional Secretary (Health) Government of India Ministry of Health & Family Welfare Department of Health Nirman Bhavan, New Delhi	
2)	Sh. Sanjiv Misra, IAS	Additional Secretary & Finance Advisor Government of India Ministry of Health & Family Welfare Department of Health Nirman Bhavan, New Delhi	

- 3) Ms. Rita Teatota, IAS Joint Secretary (Drugs)
Government of India
Ministry of Health &
Family Welfare
Department of Health
Nirman Bhavan, New Delhi
- 4) Shri Ashwini Kumar Drugs Controller General (India),
Directorate General of Health Services,
Nirman Bhavan,
New Delhi
- 5) Sh. Rajesh Bhushan, IAS Director, (Drugs)
Government of India
Ministry of Health &
Family Welfare
Department of Health
Nirman Bhavan,
New Delhi
- 6) Dr. N. K. Ganguly Director,
National Institute of Biologicals
(Min. of Health & F. W.)
A-32, Sector 62,
Institutional Area, Noida
- 7) Dr. Nitya Anand Ex-Director
Central Drugs Research Institute
B-62, Nirala Nagar,
Lucknow.
- 8) Dr. G. N. Singh Director,
Central Indian Pharmacopoeia Laboratory,
Sector 23, Rajnagar,
Ghaziabad-201 002.

INDIAN PHARMACOPOEIA COMMISSION

RULES AND REGULATIONS

1. NAME OF THE SOCIETY:

The name of the Society shall be the Indian Pharmacopoeia Commission.

2. REGISTERED OFFICE:

The Registered Office of the Society shall be situated at the Central Indian Pharmacopoeia Laboratory, Sector 23, Raj Nagar, Ghaziabad-201 002, U. P. INDIA.

3. AREA OF WORK:

All over India.

4. DEFINITIONS:

In this Memorandum and the Rules made thereunder unless the context otherwise requires

4.1 'Society' shall mean the Indian Pharmacopoeia Commission.

4.2 'General Body' shall mean the General Body of Indian Pharmacopoeia Commission.

4.3 'Governing Body' shall mean the Governing Body of Indian Pharmacopoeia Commission.

4.4 'Scientific Body' shall mean the Scientific Body of Indian Pharmacopoeia Commission.

4.5 'Commission' shall mean the Indian Pharmacopoeia Commission, Ghaziabad, U.P.

4.6 'Central Government' shall mean the Government of India.

4.7 'Fund' shall mean the Indian Pharmacopoeia Commission Fund maintained by the Society.

4.8 'Laboratory' shall mean Central Indian Pharmacopoeia Laboratory, Ghaziabad.

4.9 'Staff' means the staff of the Indian Pharmacopoeia Commission and includes the staff of the Central Indian Pharmacopoeia Laboratory, Ghaziabad on deputation to the Society.

4.10 'Scientific Director' shall mean the Secretary-cum-Scientific Director of the Indian Pharmacopoeia Commission.

4.11 'Member-Secretary' shall mean the Secretary-cum-Scientific Director of the Indian Pharmacopoeia Commission.

5. AIMS AND OBJECTS OF THE COMMISSION:

5.1 The Society is established with the object to administer and manage the Indian Pharmacopoeia Commission, Ghaziabad, U. P.

- 5.2 The functions of the Society shall be to:-
- 5.2.1 revision and publication of the Indian Pharmacopoeia at suitable intervals and of such addenda or supplementary compendia during the intervening periods as may be deemed necessary; releasing the publications for public use from a date when they are to become official, the said date to be at least six months from the date of its release;
 - 5.2.2 revision and publication of the National Formulary of India at regular intervals with a view to make it a reliable source of information on rational use of medicines including their pharmacological actions, therapeutic indications, adverse reactions, contra-indications, drug interactions, poisoning and its first-aid treatment and similar issues concerning medicines for use in humans and animals;
 - 5.2.3 publish regularly or at suitable intervals other related scientific information as authorised under the rules and procedures of the Commission;
 - 5.2.4 exchange information and interact with international counterparts in other countries and with expert committees of the World Health Organization and other international bodies with a view to harmonise the Indian pharmacopoeial standards with those internationally accepted;
 - 5.2.5 arranging studies either under its own auspices or through collaborative work to establish reliable and economical criteria for identity, purity and safety of drugs included or to be included in the Indian Pharmacopoeia and its addenda or supplementary compendia or other authorised publications;
 - 5.2.6 arranging procurement, preparation, evaluation, containerisation and distribution of Chemical Reference Materials/ Standards;
 - 5.2.7 nurturing and promoting quality and excellence in pharmaceutical analysis and research;
 - 5.2.8 creating a central facility of pharmaceutical instrumentation and analysis which may be available for use by others engaged in pharmaceutical analysis and research;
 - 5.2.9 acting as a nucleus for interaction between analytical laboratories, industry and academia by encouraging exchange of scientific and technical staff and information and by undertaking and sponsoring funded research as well as consultancy projects between the Commission and the analytical laboratories-industry-academia;
 - 5.2.10 organising national/international symposia, seminars, meetings and conferences in selected areas from time to time;
 - 5.2.11 receiving grants, contributions, sale proceeds of its publications and reference standards, income from any other source, managing the funds and properties of the Society;
 - 5.2.12 acquire purchase or otherwise own or take on lease or hire in the Union Territory of Delhi or outside, temporarily or permanently, buy and moveable or immovable property necessary or convenient for the furtherance of the objectives of the Society;

- 5.2.13 draw, make accept, endorse, discount, execute, sign, issue and otherwise deal with cheques, drafts, certificates, receipts Government securities, bill of exchange or other instruments and securities whether negotiable or transferable or not;
- 5.2.14 build, construct, maintain, repair, alter, improve or develop or furnish and buildings or works necessary or convenient for the purposes of the Society;
- 5.2.15 all incomes, earnings, moveable, immovable properties of the society shall be solely utilized and applied towards the promotion of its aims and objects only as set forth in the Memorandum of Association and no profit thereof shall be paid or transferred directly or indirectly by way of dividends, bonus, profits, or in any manner whatsoever to the present or past members of the Society or to any person claiming through any one or more of the present or the past members. No member of the society shall have any personal claim on any moveable or immovable properties of the Society or be entitled to make any claim whatsoever by virtue of his/her membership;
- 5.2.16 make Rules and By-laws for the conduct of the affairs of the Society and to add, to amend, vary or rescind them from time to time with the approval of the Central Government;
- 5.2.17 administer all matters concerning the Society in accordance with the rules and procedure of business;
- 5.2.18 do all such things as may be necessary, incidental or conducive to the attainment of all or any of the objects of the Society; and
- 5.2.19 delegate any or all of its powers to the Commission or to any of the committee or committees or expert panels or working groups constituted by it.

6. **MEMBERSHIP:**

- 6.1 The General Body shall consist of official as well as non-official members. Official members shall hold membership by virtue of their official position. The non-official members will be nominated by the Central Government.

6.2 **Subscription:**

No subscription will be charged from the members of the Society.

6.3 **General condition for Membership:**

If a member of the Society shall change his/her address he/she may notify to the Secretary his/her new address, but if he/she fails to notify such new address, his/her address as recorded in the roll of the members shall be deemed to be his/her address.

6.4 **Termination of Membership:**

- a) Where a member of the Society becomes such member by reason of the office he/she holds, his/her membership shall terminate when he or she ceases to hold that office.

- b) A member of the Society representing a department of the Central Government shall continue to be such member during the pleasure of the Central Government.
- c) A member of the Society representing a State Government shall continue to be member during the pleasure of the concerned State Government.
- d) Every other member of the Society shall cease to be such a member on the expiry of five years from the date of his/her appointment or nomination but shall be eligible for reappointment or renomination, as the case may be.

However, a member of the Society shall cease to be such member if he or she (a) dies or (b) resigns his or her membership or (c) becomes of unsound mind or (d) becomes insolvent or (e) is convicted of a criminal offence involving moral turpitude or (f) if he or she is removed by the Central Government from the membership of the Society (g) if, excepting in the case of Director of the Society, he or she accepts a full-time appointment in the Society or (h) if he or she fails to attend three consecutive meetings of the Society without the leave of the Chairman.

- 6.5 A member of the Society (other than an *ex-officio* member, or a member representing the Central Government or a member representing a State Government) may resign office by a letter addressed to the Chairman and such a resignation shall take effect from the date it is recommended by the Chairman and accepted by the Government of India.
- 6.6 The Chairman of the Society may resign from office by a letter addressed to and accepted by the Government of India.
- 6.7 Any casual vacancy in the Society shall be filled by the appointment or nomination of a member by the appropriate authority entitled to make such appointment or nomination and the member appointed or nominated to fill such casual vacancy shall hold office for the remainder of the term, if any, of the member in whose place he or she has been appointed or nominated.
- 6.8 The Society shall function notwithstanding any vacancy therein and notwithstanding any defect in the appointment, nomination or co-option of any of its members, and no act or proceeding of the Society or the Board shall be called in question merely by reason of the defect in the appointment, nomination or co-option of any of its members.

7. **AUTHORITIES OF THE COMMISSION:**

The Society shall consist a) General Body; b) Governing Body and c) Scientific Body

8. **GENERAL BODY:**

8.1 **Composition:**

The General Body of the Indian Pharmacopoeia Commission shall be composed of the following members:-

- (i) Chairman who shall be person of eminence with academic distinction in teaching and/or research in pharmaceutical and allied sciences or quality assurance of drugs or with experience in regulatory affairs relating to drugs
- (ii) Financial Advisor to the Department of Health, Ministry of Health and Family Welfare, Government of India, (*ex-officio*).
- (iii) Joint Secretary (Drugs) to Government of India, Ministry of Health & Family Welfare, New Delhi (*ex-officio*).
- (iv) Drugs Controller General of India, (*ex-officio*).
- (v) One Director of a Central Drugs Control Laboratory (*ex-officio*).
- (vi) to (viii) Three professional experts drawn one each from industry, academia and regulatory bodies
 - 1. From Industry:
 - 2. From Academia:
 - 3. From Regulatory Bodies:
- (ix) Director, National Institute of Biologicals (*ex-officio*).
- (x) and (xiv) Commissioners in charge of Drugs Control Administration of five states
 - 1.
 - 2.
 - 3.
 - 4.
 - 5.

- (xv) Director, National Institute of Pharmaceutical Education and Research, NIPER, Mohali.
- (xvi) President, Indian Drug Manufacturer Association (IDMA), Mumbai
- (xvii) President, Organisation of Pharmaceutical Producers of India (OPPI), New Delhi
- (xviii) President, Association of Manufactures of Ayurvedic Medicines.
- (xix) Director, Central Indian Pharmacopoeia Laboratory, Ghaziabad - Member Secretary-cum-Scientific Director (*ex-officio*).

Except the *ex-officio* members, all other members shall be nominated by the Govt. of India.

8.2 **Meeting of the General Body:**

- 8.2.1 The General Body shall meet atleast once a year or whenever the Chairman thinks fit. Provided that the Chairman shall call a meeting of the Society upon a written requisition of not less than three members.
- 8.2.2 For every meeting of the General Body, not less than fifteen days' notice shall be given to the members.
- 8.2.3 One third of the members including the Chairman and an official member shall constitute a quorum at any meeting of the Society.
- 8.2.4 In case of a difference of opinion amongst the members, the opinion of the majority shall prevail.
- 8.2.5 Each member of the Society, including the Chairman, shall have one vote and if there shall be an equality of votes on any question to be determined by the Society, the Chairman shall in addition have and exercise a casting vote.
- 8.2.6 Every meeting of the Society shall be presided over by the Chairman and, in his/her absence from any meeting, by a member chosen from amongst themselves by the members present at the meeting.
- 8.2.7 Any resolution except such as may be placed before the meetings of the Society may be adopted by circulation among all its members and any resolution so circulated and adopted by a majority of the members who have signified their approval of the resolution shall be as effectual and binding as if such resolution had been passed at a meeting of the Society.

8.3 **Powers and Functions of the General Body:**

8.3.1 Without prejudice to the generality of the foregoing and subject to the provisions of the Memorandum, the General Body of the Society may:-

- (i) prepare and execute detailed plans and programmes for technical and scientific work of the Society and to carry on its administration and management;
- (ii) forward to the Central Government, before October each year, Annual Report/Audit Report (both English and Hindi versions) of the previous year;
- (iii) prescribe rules and regulations for carrying out the work of the Society in conformity with the policy approved in this behalf by the Central Government;
- (iv) regulate financial transactions of the Society as per the provisions of General Financial Rules of the Govt. of India as amended from time to time
- (v) consider and pass such resolutions on the annual report, the annual accounts and the financial estimates of the Commission as it thinks fit. The Society shall submit such annual reports, annual accounts and financial estimates alongwith the resolution passed thereon by the Society to the Central Government;;
- (vi) make, adopt, amend, vary or rescind, from time to time, By-laws (a) for the conduct of the business of the Society and the committees to be appointed by it, (b) for delegation of its powers, (c) for fixing the quorum and
- (vii) perform such additional functions and to carry out such duties as may from time to time be assigned to it by the Central Government.

8.3.2 The General Body shall manage the affairs of the Indian Pharmacopoeia Commission:-

- (i) The General Body shall generally pursue and carry out the objects of the Society, as set forth in the Memorandum of Association.
- (ii) The affairs and funds of the Society shall be managed, administered and controlled by the General Body subject to rules and bye-laws framed for the purpose and the directions of the Government of India.
- (iii) The General Body shall enter into agreement(s) with the Government of India and other State Governments and other public or private organizations or individual within the country for screening and accepting grant-in-aid, endowments, donations of gifts to the Society on actually agreed terms and conditions:

Provided that such terms and conditions shall not be contrary to or inconsistent or in conflict with the objectives of the Society.

Provided further that for any such agreements with an foreign and/or international agencies or organizations prior approval of the Government of India, shall be obtained.

- (iv) However, creation of all scientific, administrative, ministerial and other posts under the Society shall vest in the Central Government which shall ensure that the posts are created for the efficient management of the affairs of the Society. The Central Government shall have power to regulate the recruitment and conditions of service of the staff.

9. **GOVERNING BODY:**

9.1 **Composition:**

The following shall constitute the Governing Body:-

- i) The Chairman.
- ii) Member-Secretary and
- iii) 06 members.

9.2 **Membership:**

The members of the Governing Body shall be taken from the General Body with the same terms and conditions.

9.3 **Powers and Functions of Governing Body:**

- 9.3.1 The Governing Body shall generally pursue and carry out the objects of the Commission, as set forth in the Memorandum of Association and in doing so shall follow and implement the policy directions and guidelines laid down by the General Body.
- 9.3.2 The affairs and funds of the Commission shall be managed, administered and controlled by the Governing Body subject to rules, and orders of the Commission.
- 9.3.3 Receive grants and contributions and have custody of the funds of the Society and to manage the properties of the Society.
- 9.3.4 Prepare the budget estimates of the Society for each year and to sanction expenditure within the limits of the budget as approved by the Central Government.
- 9.3.5 Engage staff supports on contractual basis for carrying out administrative and other functions of the Society with the prior approval of the Central Government.
- 9.3.6 Collaborate with any other organisation in the matter of establishing and validating various tests and procedures to determine the identity, purity and safety of drugs included or to be included in the Indian Pharmacopoeia; enter into agreements for and on behalf of the Society.
- 9.3.7 Appoint committees/panels/working groups for the disposal of any business of the Society or for tendering advice in any matter pertaining to the Society.

9.3.8 Delegate to such extent as it may deem necessary any of its powers to any officer or committee/panel/working group of the Commission.

9.4 **Meetings of Governing Body:**

9.4.1 All meetings of the Governing Body shall be called by notice in writing by and under the hand of the Member-Secretary.

9.4.2 Every such notice for calling the meeting shall state the date, time and venue of the meeting and shall be served upon every member of the Governing Body, as the case may be, not less than fifteen clear days before the day appointed for the meeting.

9.4.3 Every meeting of the Governing Body shall be presided over by the Chairman and in his/her absence a member chosen by the members present on the occasion shall function as Chairman-cum-presiding officer to conduct and hold the meeting.

9.4.4 The Governing Body shall meet at least twice a year at such time and place as the Chairman shall decide. Other meetings of the Governing Body may be held at any time during the year as the Chairman may decide.

9.4.5 Four members of the Governing Body including the Chairman shall constitute a quorum at any meeting of the Governing Body. If at any meeting of the Governing Body there is no quorum, the meeting shall stand adjourned to any other time on the same date or to a date to be fixed by the Chairman as the case may be. If at any adjourned meeting, there is no quorum the members present shall constitute the quorum.

9.4.6 Every notice of the extraordinary meeting of the Governing Body shall state the date, time and place of the meeting and six clear days notice shall be given to each member.

9.4.7 The Chairman may himself/herself call by a requisition in writing signed by him/her may require the Member-Secretary to call a meeting of the Governing Body at any time and on receipt of such a requisition, the Member-Secretary shall forthwith call such a meeting.

9.4.8 Each member of the Governing Body shall have one vote and if there shall be an equality of votes on any question to be decided by the Governing Body, the Chairman shall have a casting vote.

9.4.9 The proceedings of meetings of the Governing Body shall be recorded in a minute book to be maintained by the Member-Secretary for the purpose and shall be signed by the Chairman of the meetings after they are duly confirmed.

10.1 **FUNCTIONS AND POWERS OF THE CHAIRMAN:**

(i) The Chairman shall exercise such powers for the conduct of the business of the Commission as may be delegated to him/her, if any by the General Body.

- (ii) The Chairman may in writing delegate such his/her powers as he/she may think necessary to the Member-Secretary for efficient administration of the Commission.

10.2 **FUNCTIONS AND POWERS OF THE MEMBER-SECRETARY:**

- (i) Subject to any order that may be passed by the Chairman in exercise of the powers delegated to him/her, if any, by the Governing Body and the decisions of the Governing Body, the Member-Secretary shall be responsible for the proper administration of the affairs and funds of the Commission under the direction and guidance of the Governing Body. He/She shall be vested with such executive and administrative powers of the Commission as may be necessary or incidental to the purpose subject to the Rules and Regulations.
- (ii) He/She shall coordinate and exercise general supervision over all the activities of the Commission.
- (iii) He/She shall forthwith comply with any direction issued in writing by the Ministry of Health & Family Welfare, Government of India and shall report such matter to the Governing Body and the General Body at the earliest opportunity thereafter.

11. **FUNCTIONS OF CENTRAL INDIAN PHARMACOPOEIA LABORATORY:**

On the date of registration of the Indian Pharmacopoeia Commission as a Society, the Central India Pharmacopoeia Laboratory, Ghaziabad shall be merged with the Society which shall as on date take over all assets – moveable as well as immoveable and all liabilities of the Central India Pharmacopoeia Laboratory, Ghaziabad. The existing staff of the Central India Pharmacopoeia Laboratory, Ghaziabad shall be taken on deputation to the Society and shall be governed by rules and orders of the Central Government regulating the deputation of the Central Government employees to autonomous bodies. They shall, however, retain their lien in the Central Government Service.

12. **FUNDS OF THE INDIAN PHARMACOPOEIA COMMISSION:**

12.1 The funds of the Society will consist of the following:

- (i) All moneys provided by the Central Government.
- (ii) All moneys provided by the State Governments.
- (iii) All fees and others charges received by the Society.
- (iv) All moneys received by the Society by way of grants-in-aid, donations, benefactions, bequests or transfers.

- (v) All moneys received by the Society by sale of its publications and reference materials/standards.
 - (vi) All moneys received by the Society in any other manner or from any other sources.
- 12.2 All funds of the Society shall be kept in a bank account maintained with a scheduled bank. All funds of the Society shall be paid into the Society's account and shall not be withdrawn except on a cheque signed by the Secretary- cum- Scientific Director and such other officer as may be duly empowered by the Governing Body. All funds of the Commission shall be paid into the Commission's account and shall not be withdrawn except on a cheque signed by the Secretary-cum- Scientific Director or such other officer as may be duly empowered in this behalf by the Secretary- cum- Scientific Director, or by the Commission or by the Body).
- 12.3 No benefaction shall be accepted by the Society, which, in its opinion, involves conditions or obligations opposed to the spirit and objects of the Commission.

13. **ACCOUNTS OF THE COMMISSION:**

- 13.1 The Society shall prepare and maintain proper accounts and other relevant records and prepare an annual statement of accounts including the balance sheet in such form as may be prescribed by the Central Government.
- 13.2 The Accounts of the Society shall be audited annually by the Comptroller and Auditor General of India or any other authority as may be decided by the Central Government. Any expenditure incurred in connection with the audit shall be payable by the Commission.
- 13.3 The Accounts of the Society as certified by the Comptroller and Auditor General of India or any other authority as may be decided by the Central Government, together with the Audit Report thereon shall be forwarded annually to the Central Government.

14. **GOVERNANCE OF THE COMMISSION:**

- 14.1 For the purpose of Section 6 of the Registration of Societies Act, 1860, (Act 21 of 1860), the person in whose name the Society or the Commission may sue or be sued shall be the Secretary- cum- Scientific Director and in all suits brought against the Society or the Commission the said Secretary- cum- Scientific Director shall represent the Society or the Commission and shall sign all petitions, pleadings, Vakalatnamas and Warrants of Attorney, etc.
- 14.2 All contracts for and on behalf of the Society or the Commission shall be expressed to be made in the name of the Society or the Commission.
- 14.3 Subject to the prior approval of the Central Government, the Society may alter, extend or abridge any purposes for which it is established, provided that the procedure prescribed in that behalf by the Societies Registration Act (Act 21 of 1860) has been followed.

- 14.4 These Rules may be altered by the Society with the prior approval of the Central Government at any time by a resolution passed by a majority of two-thirds of the total members present at any meeting of the Society which shall have been convened for the purpose after giving due notice of such resolution to the members of the Society.
- 14.5 The Society shall appoint a legal adviser after registration of the Society to sue and defend all legal proceedings on behalf of the Society.
- 14.6 The Society may appoint committees/panels/working groups as it deems necessary for the broad functions relating to administration, buildings and their maintenance, finance, purchase of equipment and stores, and recruitment of scientific and other staff.
- 14.7 All provisions contained in the Societies Registration Act, 1860 (Act 21 of 1860) shall apply to this Commission, including Sections 4, 6, 12, 13 and 14.
- 14.8 The Indian Pharmacopoeia Commission shall be a legal entity which will include a General Body, Governing Body and Scientific Body.
- 14.9 The general governance, direction and control of the affairs of the Society and its income and property shall be vested in the Governing Body of the Indian Pharmacopoeia Commission, Ghaziabad, U.P.

15. **DOCUMENTS OF THE COMMISSION:**

15.1 **Register of Members:**

The Commission shall maintain a roll of members indicating their full names addresses and occupations and every member shall sign the same. If a member of the Commission changes his/her address, he/she shall notify his new address to the Secretary-cum-Scientific Director of the Commission who shall have the entry in the roll of members changed accordingly. Where, however, a member does not notify any change of address to the Secretary-cum-Scientific Director his/her address as given in the roll of members shall be deemed to be his/her correct address.

15.2 **Proceeding Register:**

A Proceeding Register shall be maintained by the Commission for recording all the proceeding held a financial year.

15.3 **Stock Register:**

A Stock Register shall be maintained by the Commission for maintaining all the stock in a financial year.

15.4 **Cash Book:**

A Cash Book shall be maintained by the Accountant of the Commission as per the Central Govt. norms.

16. **DISSOLUTION OF THE COMMISSION:**

- 16.1 The Central Government may at any time appoint one or more persons to review the work and progress of the Commission and hold an inquiry into the affairs thereof and to report thereon, in such manner as the Central Government may stipulate. Upon receipt of any such report, the Central Government may take such action and issue directions as it may consider necessary in respect of any of the matters dealt with in the report regarding the Commission, as the case may be, and the Society shall be bound to comply with such directions.
- 16.2 In case the Central Government is satisfied that the Society or the Commission is not functioning properly, the Central Government shall have the power to take over the administration and assets of the Society / Commission.
- 16.3 If, on the winding up or dissolution of the Society, there shall remain, after satisfaction of all its debts and liabilities, any assets and property whatsoever, the same shall not be paid to or distributed among the members of the Society or any of them but shall vest in the Central Government which shall deal with these assets and property in such a manner as the Central Government may determine.

17. **INDIAN PHARMACOPOEIA COMMISSION SCIENTIFIC BODY:**

The technical work of the Society shall be vested in the body, which shall be called the Indian Pharmacopoeia Commission, Scientific Body, hereinafter referred to as the as the Scientific Body.

- 17.1 The Scientific Body shall be of 15 to 23 experts from various disciplines of science and technology connected with pharmacopoeial standards. They shall be nominated by the Board of Governor on the basis of merit, competence and willingness to devote their time to the work of the Commission with the approval by Govt. of India. The Commission may be composed of members from the following areas:

- (i) **CHAIRMAN:** A person of eminence with academic distinction in teaching and/or research in pharmaceutical and allied sciences or quality assurance of drugs or with experience in regulatory affairs relating to drugs.

To be nominated by the Ministry.

- (ii) An expert in the field of pharmaceutical technology or pharmaceuticals from an academic institution.
- (iii) An expert in the field of medicinal chemistry or pharmaceutical chemistry from an academic institution.

- (iv) An expert in the field of natural products or pharmacognosy from an academic institution.
- (v) An expert in the field of clinical medicine from an academic institution.
- (vi) An expert in the field of pharmacology or clinical pharmacology and therapeutics from an academic institution.
- (vii) An expert from the field of biotechnology as applicable to pharmaceutical and health sciences.
- (viii) An expert from the pharmaceutical industry experienced in technical operations involved in manufacture of dosage forms.
- (ix) An expert from the pharmaceutical industry experienced in technical operations involved in manufacture of active pharmaceutical ingredients (bulk drugs).
- (x) An expert from the pharmaceutical industry engaged in analysis of active pharmaceutical ingredients, excipients and/or dosage forms.
- (xi) An expert from the pharmaceutical industry engaged in research on development of active pharmaceutical ingredients, excipients and/or dosage forms.
- (xii) An expert in manufacture and/or quality control of biological products.
- (xiii) An expert in veterinary sciences with special knowledge in manufacture and/or quality control of medicines used in veterinary practice.
- (xiv) An expert from one of the laboratories under the Central or State Government or autonomous/semi-autonomous bodies like BARC, CSIR, DRDO, etc engaged in research or development of active pharmaceutical ingredients, excipients and/or dosage forms.
- (xv) An expert from a Central Government laboratory engaged in analysis of active pharmaceutical ingredients and dosage forms.
- (xvi) An expert from a State Government laboratory engaged in analysis of active pharmaceutical ingredients and dosage forms.
- (xvii) An expert from a non-governmental laboratory, approved under the Drugs and Cosmetics Act, engaged in analysis of active pharmaceutical ingredients and dosage forms.
- (xviii) An expert from the Central Drug Standards Control Organisation engaged in regulation of import, manufacture and quality control of medicines under the Drugs and Cosmetics Act.

- (xix) An expert from a State Drug Control Organisation engaged in regulation of manufacture and quality control of medicines under the Drugs and Cosmetics Act.
- (xx) Director of the Central Indian Pharmacopoeia Laboratory, Ghaziabad (*ex-officio*)-As Secretary-cum-Scientific Director.
- (xxi)– (xxiii) The Chairman at his discretion may co-opt up to three experts from the fields like sera and vaccines for veterinary use, radio-pharmaceuticals, methods of assay dependent on radio-immunoassay techniques, medical devices, etc.

17.2 **Membership of the Scientific Body:**

- (i) The process of selection of members shall be initiated by the Secretary-cum-Scientific Director of the Society who shall pay regard to (a) the overall balance of disciplines represented, (b) balance between members in public service, in academic and research activity and in industry, (c) representation from different parts of the country and (d) even representation of the medical profession, veterinary sciences, pharmaceutical technology and pharmaceuticals, pharmaceutical and medicinal chemistry, immunology and biological products.
- (ii) All members of the Commission except the Secretary-cum- Scientific Director, who will be there in *ex-officio* capacity, shall be nominated in their individual capacities on the basis of merit.
- (iii) As the Secretary-cum- Scientific Director of the Society becomes a member of the Commission by reason of the office he or she holds, the membership of such person shall terminate when he or she ceases to hold that office.
- (iv) The membership of the Commission of a person drawn from the Central Drug Standards Control Organisation or from a State Drug Control Organisation shall terminate when he or she ceases to hold that office under the Central or State Government.
- (v) Every other member of the Commission shall cease to be such member on the expiry of 5 years from the date of his or her nomination but shall be eligible for re-nomination.

Provided that one-third of the members of the first Commission shall retire on the expiry of two years and another one-third on the expiry of further two years.

Provided further that the names of such retiring members shall be decided by draw of lots.

Provided further that any of the retiring members may be re-nominated on the Commission and the term of office of such members shall count from the date of new nomination

- 17.3 A member of the Commission shall cease to be such member if he or she (a) dies or (b) resigns his or her membership or (c) becomes of unsound mind or (d) becomes insolvent

or (e) is convicted of a criminal offence involving moral turpitude or (f) if he or she is removed by the Central Government from the membership of the Commission (g) if, excepting in the case of Member Secretary and Scientific Director of the Society, he or she accepts a full-time appointment in the Commission or (h) if he or she fails to attend three consecutive meetings of the Society without the leave of the Chairman.

17.4 A member of the Commission, other than the ex-officio Secretary cum- Scientific Director , may resign office by a letter addressed to the Chairman and such a resignation shall take effect from the date it is accepted by the Chairman.

17.5 Any casual vacancy in the Commission shall be filled by the nomination of a member by the appropriate authority entitled to make such nomination and the member nominated to fill such casual vacancy shall hold office for the remainder of the term, if any, of the member in whose place he or she has been nominated.

17.6 **Powers and Functions of Scientific Body:**

The Scientific Body shall generally pursue and carry out the objects of the Commission, as set forth in the Memorandum of Association and in doing so shall follow and implement the policy directions and guidelines laid down by the General body and Governing Body.

17.7 **Meetings of the Scientific Body:**

The Commission shall function notwithstanding any vacancy therein and notwithstanding any defect in the appointment, nomination or co-option of any of its members, and no act or proceeding of the Commission shall be called in question merely by reason of the defect in the appointment, nomination or co-option of any of its members.

- (i) The Commission shall meet whenever the Chairman deems fit at least once every three months provided that the Chairman shall call a meeting of the Commission upon a written requisition of not less than five members.
- (ii) For every meeting of the Commission, not less than fifteen days' notice shall be given to the members.
- (iii) Five members including the Chairman shall constitute a quorum at any meeting of the Commission.
- (iv) In case of difference of opinion amongst the members, the opinion of the majority shall prevail.
- (v) Each member of the Commission, including the Chairman, shall have one vote and if there shall be an equality of votes on any question to be determined by the Commission, the Chairman shall in addition have and exercise a casting vote.
- (vi) Every meeting of the Commission shall be presided over by the Chairman and in his absence from any meeting by a member chosen from amongst themselves by the members present at the meeting.

- (vii) Any resolution or technical and scientific matter except such as may be placed before the meetings of the Commission may be adopted by circulation among all its members and any resolution or technical and scientific matter circulated and adopted by a majority of the members who have signified their approval of the resolution on technical and scientific matter shall be as effectual and binding as if such resolution or technical and scientific matter had been passed at a meeting of the, Commission.

17.8 **Functions and Powers of the Chairman:**

- (i) The Chairman of the Scientific Body shall exercise such powers for the conduct of the business as may be delegated to him/her, if any by the Commission.
- (ii) The Chairman may in writing delegate such of his/her powers as he/she may think necessary to the Secretary-cum-Scientific Director for efficient administration of the Society for the Commission.

17.9 **Functions and Powers of the Secretary- cum- Scientific Director**

- (i) The Director, Central Indian Pharmacopoeia Laboratory shall function as the Secretary-cum-Scientific Director. The Central India Pharmacopoeia Laboratory will be part of the permanent support structure of the Society and the Commission.
- (ii) The Secretary- cum-Scientific Director shall be the Chief Scientific and Executive Officer of the Society and shall be responsible for the proper administration of the Society and for the maintenance of discipline therein. He/she shall be the custodian of the records and such property as the Board of Governors may commit to his or her charge.
- (iii) The Secretary- cum -Scientific Director shall have such other powers and perform such other duties as may be delegated or assigned to him or her by the Governing Body.
- (iv) The Secretary- cum- Scientific Director shall, exercise such financial powers as may be delegated to him by the Governing Body and such delegation of powers shall be approved by the Central Government.
- (v) The Secretary- cum- Scientific Director shall, act as the Secretary, the Governing Body, the Commission and such other Committees as the Governing Body or the Commission may decide.
- (vi) In the event of the post of the Director, Indian Pharmacopoeia Commission remains vacant or the Director being absent or unable to perform his/her duties for any reason, it shall be open for the Society to direct any officer or officers in the service of the Commission or a member of the Commission to exercise temporarily such powers and perform such functions and duties of Secretary-

cum- Scientific Director, Indian Pharmacopoeia Commission as the Society may deem fit.

- 17.10 The members of the Governing Body or the Commission or of any Committee appointed by the Commission, except the Secretary- cum- Scientific Director, Indian Pharmacopoeia Commission shall not be entitled to any remuneration from the Central India Pharmacopoeia Commission, but they shall be paid such travelling and daily allowances as may be provided for by the By-laws to be made in this behalf, in respect of any journeys undertaken by them for attending the meetings of the Governing Body or the Commission or any Committee, or in connection with any of their other business.
