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Common GUIDELINES ON PHARMACEUTICAL INNOVATION & ENTREPRENEURSHIP-2022

सत्यमेव जयते

औषध विभाग
Department of
Pharmaceuticals

DEPARTMENT OF PHARMACEUTICALS, MINISTRY OF CHEMICALS & FERTILIZERS,
NEW DELHI

ABOUT DEPARTMENT OF PHARMACEUTICALS (DoP)

The Department of Pharmaceuticals (DoP) was established on the 1st of July in the year 2008 in the Ministry of Chemicals & Fertilizers with the objective to give greater focus and thrust on the development of the pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to the pharmaceutical sector which required integration of work with other Ministries. Department of Pharmaceuticals was established with a vision to make India the largest global provider of quality medicines at reasonable prices.

Department of Pharmaceuticals undergoes with a mission to ensure the availability of quality drugs at reasonable prices as per the Pharma Policy. DoP has a mandate to establish the National Institute of Pharmaceutical Education and Research (NIPERs) as a nationally and internationally recognized brand in the field of education and research of pharmaceutical sciences for the benefit of humankind. DoP is actively involved in encouraging environmentally sustainable development of the Pharmaceutical Industry since its inception. The Department is entrusted with the responsibility of policy, planning, development, and regulation of Pharmaceutical Industries.

1. INTRODUCTION

India is leading to become a five trillion-dollar economy by 2024. To reach the mark, it needs to evolve systems and mechanisms to convert the present demographic dividend into high-quality technical human resources capable of doing cutting-edge research and innovation and deep-tech entrepreneurship. The "National Innovation and Entrepreneurship Policy 2019" is a guiding framework towards start-ups and entrepreneurship opportunities. The policy will be building a strong ecosystem for nurturing creativity and entrepreneurial abilities amongst the youth as well as creating a conducive environment for entrepreneurial projects. As required, technological institutions may have a key role to play in this ecosystem. Fostering such innovations will lead to innovation-driven growth, sustainable employment creation and equitable economic development. The vision behind the initiative is to facilitate the engagement of pharmaceutical professionals in innovation and entrepreneurship which will drive sustainable economic growth. Innovation and entrepreneurship have emerged as one of the key points of the higher education system with a focus to give impetus to overall economic development for realizing the vision of self-reliant India (Atmanirbhar Bharat).

The guidelines provide ways to Indian Higher Education Institutes (HEIs) for developing entrepreneurial agenda, managing Intellectual Property Rights (IPR) ownership, technology licensing and equity sharing in Start-ups or enterprises established by faculty and students.In India, innovation is still not the epicentre of education. In order to achieve the cultural and attitudinal shift and to ensure that 'Innovation and Start-up' culture is the primary fulcrum of our higher education system, a policy framework and guidelines are the need of this hour. These guidelines will enable institutions to actively support their faculty, staff and students to participate in innovation and entrepreneurship (I&E) related activities, thus encouraging students and faculty to consider start-ups and entrepreneurship as a career option. Moreover, these guidelines will facilitate the Department of Pharmaceuticals in potentiating innovation and entrepreneurship, precise IPR ownership management, technology licensing and institutional start-ups policy, thus enabling the creation of a robust innovation and Start-up ecosystem across all HEIs. These guidelines will also help emphasize that entrepreneurship is all about creating a business, which is financially successful and serving mankind in a true sense.

Several important initiatives have been taken by the Government at the national, state and institutional levels that focus on supporting inventions, innovations, entrepreneurship and start-ups in higher educational institutions. e.g. Start-up India, Atal Innovation Mission (AIM), Scheme for Facilitating Start-ups Intellectual Property Protection (SIPP) by DPIIT etc. These initiatives have already started bearing fruits as demonstrated by the commercialization of socially impactful innovations. Several policies

of the Government of India and its agencies continue to promote the involvement of faculty at educational institutions towards entrepreneurship-related activities.

Successful commercialization of academic research is the key to its social impact, however, this translation into clinical impact cannot be fulfilled by the academic institutes alone. To accomplish this, an institute needs help from diverse areas of expertise. Therefore, the necessity to develop a suitable mechanism through policy intervention for promoting inter-disciplinary research is of paramount importance in the current context.In pharmaceutical research leading to IP and thus entrepreneurship, pharmaceutical professionals/scientists play a pivotal role for success as they possess deep and meaningful involvement throughout the innovation cycle. Their role is vital not only in the identification of unmet clinical/therapeutic needs but also to position and support the innovation during various stages of its development.

2. VISION, MISSION &OBJECTIVES OF THE POLICY

The Policy Guidelines on Pharmaceutical Innovation & Entrepreneurship target to encourage innovation, entrepreneurship, and creation of, or participation in, spin-offs & start-ups by faculty members/scientists/staff members/trainees/alumni of academic pharmaceutical institutions based on innovative ideas and research output of the former with impactful commercialization of these innovations. Keeping this in view, DoP targets to facilitate their personnel to innovate; based on these guidelines for Innovation and Entrepreneurship. The vision, mission statements, and key objectives of the guidelines are as follows:

VISION:
To build the nation through an innovation-led entrepreneurial ecosystem for supporting pharmaceutical innovation and nurturing start-ups in India with the ultimate goal of positively impacting human health and well-being.

MISSION:
To establish and educate overarching guidelines for creating Nationwide innovation & entrepreneurial framework and considering entrepreneurship as a preferred career with helping and creating a larger number of sustainable start-ups in pharmaceutical domain towards impactful social benefits.

OBJECTIVES:
The objectives of these guidelines are

1. To encourage and promote students faculty and staff members to pursue innovation and entrepreneurship.
2. To create enabling policies and foster an ecosystem to generate ideas across disciplines that can be transformed into successful innovative technologies, products, and services.
3. To establish a mechanism for technology development and technology transfers.

4. To create an institutional framework for effective implementation, monitoring, and evaluation of the policy.
5. To promote pharmaceutical innovation and entrepreneurship to foster the unmet therapeutic/clinical need-driven, socially impactful technologies delivering benefits to mankind.

3. SCOPE OF THE POLICY GUIDELINES

The scope of the current guidelines is to cover all stages of the innovation &entrepreneurship continuum, in accordance with the existing national innovation and start-up Policies potentially in view of the prevailing therapeutic/clinical needs in the pharmaceutical sector. The scope of the guideline is to promote, educate, and support students/faculty/staff members for potential careers at the convergence of basic and translational research, cutting-edge therapeutic delivery, science, and emerging medical device technologies. Further, this will foster the development of career paths that incorporate new analytical or technological tools, including medical devices for students, faculty and staff members.

This policy framework covers innovation in all facets that impact the creation and functioning of the national pharmaceutical system. This includes innovations in Public health delivery systems, Healthcare Business Model Innovations (including digital healthcare delivery systems) and category-specific innovations such as those pertaining to Pharmaceuticals (Active pharmaceutical ingredients (APIs), Repurposing of the drug candidates, Modified drug delivery systems and Biosimilars), Nutraceuticals, Vaccines, Diagnostics, and Medical Devices (including healthcare software systems and health and wellness mobile apps as medical devices) and inter-disciplinary innovations.

The scope of the current policy framework also includes diagnostics, medical devices, healthcare IT, online pharmacy, personal health management, home healthcare, telemedicine, biotech R&D, genomics and bio-pharma. Currently in the country start-ups are operating in one of these verticals and are using Artificial Intelligence or Machine Learning and other modern technologies to improve the quality of healthcare, access, and affordability.

4. NOTEWORTHY FEATURES

Aspects of innovations with translational outcomes in the pharmaceutical sector had been challenging in the past due to the rigors of academic careers, milestones for faculty and institutions, and limitations arising from financial concerns or mistrust of developing partnerships with the industry. However, in the current scenario innovationis now becoming the fourth pillar of pharmaceutical academic excellence. It is therefore imperative to develop a holistic ecosystem where faculties/students and staff can be more effective innovators and translate their solutions for beneficial impact to society.

4.1. FOR THE INSTITUTES

a) The Institute shall encourage participation of it's personnel in entrepreneurship and enable formation of legal entity in the following manner:

- Company owned jointly by faculty members, staff, Students and Alumni
- Company owned by faculty members along with external entrepreneurs
- Section-8 Company other Society/Non-profit Organization
- Special Purpose Vehicle (SPV) such as LLP, Society, Trust etc.

b) Institute should provide necessary infrastructural facility for innovation and start-up activities such as *ready to use* infrastructure such as office space with amenities, security etc.

c) Facilities such as research and testing labs, design studios, Technology transfer cell, IPR cell, Promotion cell etc. need to be made available

d) The availability of resources needs to be ensured for pre-incubation and providing common facilities as a part of the Institute's financial strategy for prospective inventors and entrepreneurs. The budgetary provisions should be available in terms of:

- Allocation of a fixed percentage (such as not less than 1%) of annual Institute's budget for funding, promoting and supporting innovation and startups related activities.
- Fund raising from Government (State and Central) funding agencies such as such as DOP, DST, DBT, MHRD, AICTE, TDB, TIFAC, DSIR, CSIR, BIRAC, NSTEDB, NRDC, Startup India, Invest India, MSME, etc. and other private networks.
- Support from Alumni networks and corporates under CSR activities as per Section 135 of the Company Act 2013.

e) Promotion of Innovation and Entrepreneurship should be one of the agenda in annual planning of the Institute as a part of planning strategy. Proper mechanisms need to be established for monitoring and assessment to facilitate the development goals as per annual planning.

f) The institutes should work to expedite decision-making processes and minimize hierarchical barriers. Also, individual autonomy and ownership of initiatives should be promoted.

g) The Institute shall participate in various events/activities conducted by MoE, UGC, AICTE and similar Government bodies for promotion of innovation and start-ups. The Institute should regularly mobilize students for Smart India Hackathon (SIH) and other initiatives/competitions/seminars related to innovation, entrepreneurship and start-ups.

h) In return of the services and facilities, the Institute may take a fixed percentage of (2% to 9.5%) equity in the start-up/spin-off company, based on employee contribution, support provided and use of institute's IP.

i) The entrepreneurial initiatives shall be evaluated on a regular basis using well defined impact assessment parameters, such as:

- **a.** IP filed/products developed and commercialized
- **b.** Number of employments generated; start-ups created

4.2. FOR INNOVATORS

4.2.1. STUDENTS

a) Relaxation in attendance should be provided to enable them to dedicate time for entrepreneurial activities, and they should be allowed to sit for the examination, even if their attendance is less than 75%.

b) The Institutes should provide relaxation to the PhD students in terms of a semester/year break (or more, if needed) to devote time on the start-up ventures.

c) Institutes shall facilitate the Startups founded by graduated students till a particular time period (such as 3 years) from their graduation (Alumni).

4.2.2. FACULTY OR STAFF MEMBERS

a) The Institute should allow faculty or staff members to take a semester/year break (or more, if needed) as sabbatical leave for working on technology transfer/start-ups. A maximum period of 2 years of such break may be permissible.

b) The professional and academic benefits during such period may be preserved for such faculty or staff members.

c) The faculty or staff member may ensure that his/her roles and responsibilities towards the Institute conform to his/her Institute's policy regarding Conflict of Interest for Commitment.

d) The faculty or staff member may spend up to 20% of their time on entrepreneurial activities. The equity of 20% (or similar proportion) may be allocated to the research team of the Institute. If the equity is being acquired by the faculty or staff member, the time invested by the faculty or staff member may be considered as "off-duty/leave without pay". Alternatively, if the equity is being taken by the Institute, the invested time of up to 20% should be taken as on duty.

e) The account of the start-up or spin-off company should be kept separate and may be audited periodically by a certified chartered accountant.

f) The Agreements related to financial and non-financial disclosures, collaborative research projects and likewise need to be signed as per existing institute norms.

g) Any financial assistance paid to the founding members of the company should be considered as income of the associated faculty or staff member during the incubation period within the Institute.

4.3. OUTSOURCING OF SPONSORED RESEARCH/CONSULTANCY ASSIGNMENT

If the equity has been transferred through empanelled techno-legal facilitator agencies, such techno-commercial facilitators may be allowed to take up to 2% equity for their role. The outsourcing of institute's projects (part or full) to faculty owned company, if permissible, would be governed by the Institute's existing policy. However, in absence of such policy, the outsourcing decision may be Head of the Institute.

5. INTELLECTUAL PROPERTY

The role of Intellectual Property protection and ownership is to prevent an invention from being replicated, created, used and sold by another party without permission and thus promote successful commercialization of innovations.

Implementation of the IP Policy will enable Institutes to acquire a portion of the recurring revenue stream from the commercialization of an invention, which in turn can help make the intra-mural innovation process more effective.The effective implementation would require putting in place techno-legal-administrative framework in place to complete the circuit from institutional ownership of IP to licensing it, realizing royalty on it and then re-investing the collected royalty into further innovations.

- The Faculty, Students, and Staff of the Institute should aim to establish inventions, discoveries, copyrightable material, and new knowledge domain that constitute the intellectual property of the Institute.
- The Institute should seek to promote the application of that knowledge for the benefit of society while protecting the interests of the Institute, its faculty, students and staff.
- The institute should provide legal and research support towards innovative technology-based research with third-parties.
- The institute has to set out well-defined procedures on identification, ownership, protection and commercialization of IP
- The institute must ensure timely and efficient IP management and protection.
- The economic incentivization arising from IP commercialization is distributed in an equitable and fair manner while acknowledging the contributions of the inventors, and other relevant stakeholders should be assured by the host institute.
- Institute should encourage to make these policies more innovator and innovation friendly, and must be aligned with the relevant national goals.
- Institute should maintain a pool of funds dedicated for the management of IP/ Technology Transfer activation.
- Institution shall have a duly constituted IP and Technology Transfer Committee to facilitate the translational aspects. A person designated as point of contact for all IP related matters shall be identified by the Committee and/or the Institute.
- The constituted committee should respond with a decision in no more than 30 days about requests pertaining to IP ownership.

- The institute shall have a comprehensive IP policy describing in detail about questions pertaining to ownership and protection of IP and laying down standard operating procedures for creation, management, protection, licensing and monetization of IP.
- The holistic goal of an institutional IP policy shall be to promote innovation and facilitate its rapid, successful and scalable translation to societal impact.

Institutes with existing IP Policies may continue to follow the same policy with refinements from time-to-time as necessary. However for the institutes that do not have the IP and Technology transfer policy, the "National IPR Policy" and "National Innovation and Startup policy" shall be the guiding force based on which the Institutes may formulate their own IP Policy.

5.1 INSTITUTE OWNERSHIP

Provisions should be drafted to determine the conditions for IP ownership of the Institute. Such conditions may include:

a) If the IP has been created with the significant use of funds or facilities provided by the Institute.

b) If the IP has been created (i) as a part of the 'normal professional duty' *or* (ii) work for hire.

c) If the IP has been created in the course of or pursuant to a sponsored/consultancy research agreement with the Institute. In such cases, specific provisions related to IP made in contracts governing such activity will determine the ownership of IP.

d) As if, the intellectual property has been created as a part of academic research and training leading towards a degree or otherwise.

5.2 INVENTOR OWNERSHIP

Provisions should be drafted to determine the conditions for IP ownership of the inventor. Such conditions may include:

a) Inventor(s) will own IP when none of the above four situations defined under "Institute Ownership" apply.

b) If after evaluation of the IP, the Institute decides not to take responsibility for the protection of the IP, then it can assign the IP rights to the inventor(s).

5.3 THIRD-PARTY OWNERSHIP

Provisions should be drafted to determine the conditions for IP ownership of the Third Parties. Such conditions may include:

a) Funds provided partially or fully by a third-party to the Institute will be governed by specific provisions in the contract between the third-party and the Institute.

b) Exchange programs between the Institute and third-party institutions will be governed by specific provisions in the contract between the third-party

and the Institute.

5.4 DISCLOSURES, CONFIDENTIALITY AND ASSIGNMENT OF RIGHTS

The Institute may formulate provisions related to Disclosures, Confidentiality and Assignment of Rights for:

a) Sponsored and/or collaborative work
b) Faculty and Employees leaving the Institute (or retiring)
c) Graduating students involved in IP creation/management

5.5 CONTRACTS AND AGREEMENTS

The Institute should make provisions for a well-defined approval process for evaluating and approving IP-related Contracts and Agreements. The appropriately authorized signatory may be designated (as per statutes).

5.6 COMMERCIALIZATION

The Institute may formulate provisions to facilitate the IP Commercialization and Technology Transfer procedures. Provisions may be formulated for:

a) identifying potential licensee(s)
b) facilitating Technology Transfer support
c) Review and validation of commercialization efforts by faculty/staff/students
d) Validation and implementation of corrective measures and lessons learned

5.7 REVENUE SHARING

The IP Licensing Agreement executed with a company or a legal entity or with the institutional employee/ affiliate, the company may have suitable provisions regarding equity or royalty sharing on successful commercialization. A reasonable part of such revenue may be pooled back by the company to the institute(s), as per Institute's IP Policy/guidelines.

The demarcated provisions should be established for distributing the net earnings arising from the commercialization of IP. The institutional IP policy should state about the allocation of generated revenue to the innovator, the Institute, and towards the service account towards promotion and up-gradation of the invention. Unused funds from the service account may be used for the promotion of commercialization, IP protection and any other related activities.

5.8 INFRINGEMENTS, DAMAGES, LIABILITY AND INDEMNITY INSURANCE

Well-defined provisions should be formulated in any contract between the licenseeand the Institute to seek indemnity from any legal proceedings including without limitation manufacturing defects, production problems, design guarantee, upgradation and debugging obligation. The Institute may also ensure that the Institute's faculty/staff personnel have an indemnity clause built into the agreements

with the licensee(s) while transferring technology or copyrighted material to licensees. The Institute should retain the right to engage or not in any litigation concerning patents and license infringements.

5.9 DISPUTE RESOLUTION

The Institute should define the Dispute Resolution Body/Authority in case of any disputes between the Institute and the inventors regarding the implementation of the IP-related provisions of the policy.

5.10 JURISDICTION

The Institute should include in the policy, the Jurisdiction wherein the Agreements to be signed would be applicable.

6. TAXATION OF INNOVATION, ENTREPRENEURSHIP AND START-UPS

The statutory provisions related to tax applicability for legal entities, royalty, fee proceeds,income etc. as notified periodically by Government will prevail for all legal purposes.

7. CONFLICT OF INTEREST AND ITS RESOLUTION

a) The Institute shall formulate provisions to ensure disclosure of any conflict of interest or potential conflict of interest by the inventor(s) and/or their legal representatives.

b) The development of a Conflict-of-Interest Management Plan is a necessary activity for the faculty member while ensuring that the entrepreneurial activities do not have an adverse impact on teaching, research and any other institutional responsibilities assigned to him/her.

c) The entrepreneurial activities (including the formation of a company, association with existing enterprises etc.) should only be started after taking requisite prior permissions from the Institute.

d) Wherever applicable, the inventor(s) would comply with institute incubator policy and research spin-off policy.

e) Under no circumstance the inventor should circumvent the prevailing policies for making use of the institute'sfacilities forthebenefitofthe Companyand/or anyassociatedenterprise.

f) Theinventorshallcomplywiththedifferentprovisions&Governmentrules&regulations.

g) Appropriate mechanisms for complaint redressal and resolution of the conflict of interest shall be formulated by the Institute. In case of any disputes which are not settled within the Institute, the resolution could be sought *via* arbitration/ conciliation as per the Arbitration and Conciliation Act 1996amended as on date.

8. REVIEWM ECHANISM

Astandingsub-committeecould be formulated by DoP in order to carry out review of the policy on periodic basis or *as required* to address the road blocks faced in its implementation and for effective turnouts.

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