

2869

Kind Regards,
Gaurav Chaudhary
Young Professional (NIPER Division)
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Mobile: +918178106089

From: "Varshneya Singh" <varshneya.singh@dbt.nic.in>
To: "Ms S. Aparna" <secy-pharma@nic.in>
Cc: "Dr Rajesh S Gokhale" <secy@dbt.nic.in>, "Jyoti Malik Logani" <jyoti.logani@nic.in>
Sent: Friday, July 14, 2023 2:35:17 PM
Subject: URGENT: Rajya Sabha Unstarred Question No. 136 for 20-7-2023- National Biopharma Mission

Kind Attn: PPS to Secretary, Department of Pharmaceuticals

Sir/Madam,

Please find enclosed Rajya Sabha Unstarred Question No. 136 for 20-7-2023- National Biopharma Mission. The text of the Parliament question is reproduced below:

136 Shri B. Parthasaradhi Reddy:

Will the Minister of Science and Technology be pleased to state:

(a) Measures being taken under the National Biopharma Mission to strengthen infrastructure facilities in the pharmaceutical industry;

(b) Steps being taken to increase the human capital in the pharmaceutical sector;

(c) Details of the Mission's achievements in supporting pharmaceutical Micro, Small and Medium Enterprise (MSMEs); and

(d) Measures being taken under the Mission to strengthen the ecosystem for affordable pharmaceutical products?

Inputs if any pertaining to part (b) of the Parliament Question may please be shared with the undersigned latest by **12 pm , 15th July 2023** for preparing a consolidated reply.

With regards,

Varshneya Singh

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S.A.S. NAGAR

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राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान
**NATIONAL INSTITUTE OF PHARMACEUTICAL
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(Ministry of Chemicals & Fertilizers Govt. of India)
Sector 67, S.A.S Nagar (Mohali) Punjab - 160062 (India)
Tel.: +91-172-2214682-87, Website : www.niper.gov.in
Fax : +91-172-2214692, 2230068

NIPER/RGO/Parliament Q./2023/ 1609

17th July, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), Gol,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, Gol,
Shastri Bhawan, New Delhi

Subject: **Rajya Sabha Unstarred Question No. 136 for 20-7-2023- National Biopharma Mission reg.**

Madam,

This refers to Ministry email dated 17th July 2023 whereby Rajya Sabha Unstarred Question No. 136 for 20-7-2023- National Biopharma Mission was forwarded seeking input on point '*(b) Steps being taken to increase the human capital in the pharmaceutical sector*'. The reply of the Institute on said point (b) is as under: -

1. NIPER-SAS Nagar has been training meritorious students for their Masters and Ph.D. degrees in the field of pharmaceutical sciences. Every year, NIPER-SAS Nagar is training more than 250 candidates for Master's degree and more than 20 candidates for Ph.D degrees (on an average). All the students trained by NIPER-SAS Nagar get absorbed in leadership positions in various industrial or academic positions across the country. Thus, NIPER-SAS Nagar is significantly contributing to increase the human capital in the pharmaceutical sector. In addition, NIPER-SAS Nagar provides several training programs in the form of workshops, conferences, symposia etc. especially in the field of Small and Medium Pharmaceutical Industry Centre (SMPIC), Technology Development Centre - Dosage Form (Formulations) etc. Specific programs are scheduled to upgrade the skill sets of the already working human resources in pharmaceutical industries.
2. The number of Master's and Ph.D. admitted annually in different programs of pharmaceutical sciences at NIPER SAS Nagar has increased. The annual intake for the last students admitted at NIPER Mohali is provided in the table below:

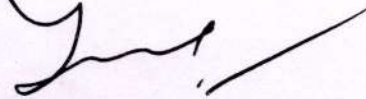
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Sr. No.	Year	No. of Masters Student Admitted	No. of Ph.D. Students Admitted	Total Students Admitted
1.	2019-20	251		
2.	2020-21	262	17	268
3.	2021-22	276	9	271
4.	2022-23	283	52	328
			61	344

This issue with the approval of Competent Authority.

Thanking you,

Sincerely yours,



[विंग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव

<registrar@niperahm.ac.in>, Registrar NIPER R <registrar@niperraebareli.edu.in>, Registrar 2875
NIPER G <registrar@niperguwahati.ac.in>, Registrar Niperk <registrar@niperkolkata.edu.in>,
Registrar NIPER Hyderabad <registrar.niperhyd@gov.in>, Mr Sameer Dhingra
<registrar@nipershajipur.ac.in>, Ravichandiran V <director@niperkolkata.edu.in>
CC:Richa Pandey <richa.p@gov.in>, Aparna Lal <aparna.lal@gov.in>, Deepak Kumar
<kumar.deepak86@nic.in>

Most Urgent

Respected Sir/Madam,

Greetings of the Day!

Please find below Lok Sabha Unstarred: Diary No : 7856: Answer Date: 04-08-2023:

Funds for Research & Development of New Drugs

Will the Minister of CHEMICALS AND FERTILIZERS:

- (a) the details of the funds allocated for Research and Development of new drugs/vaccines in the country for the last three years, year-wise;
- (b) whether the Government has prepared any roadmap for pharma industry to reduce dependency for raw materials on foreign nations; and
- (c) if so, the details thereof?

2. It is requested to kindly provide the inputs of the above mentioned Parliament Question, which may be shared with the undersigned by **27th July 2023** for preparing a consolidated reply.

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Kind Regards,
Gaurav Chaudhary
Young Professional (NIPER Division)
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Mobile: +918178106089



S.A.S. NAGAR

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

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NIPER/RGO/Parliament Q./2023/ 1683

27th July, 2023 2880

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), GoI,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, GoI,
Shastri Bhawan, New Delhi

Subject: **Lok Sabha Unstarred Question No. 7856 regarding Funds for
Research & Development of New Drugs.**

Madam,

This refers to Ministry email dated 26th July 2023 whereby Lok Sabha Unstarred Question No. 7856 regarding Funds for Research & Development of New Drugs was forwarded to the Institute with a request to provide inputs by 27th July, 2023. The point-wise reply of the Institute is as under: -

- (a) The vision of NIPER SAS Nagar (Mohali) is "To become a globally recognized brand in the areas of education and research in pharmaceutical sciences for the benefit of people of India and other countries and the growth of the pharmaceutical industry." The institute is working with the mission of Promotion of innovative and translation research for Research and Development of new drugs. NIPER SAS Nagar is not receiving any separate money for new drug development. Department of Pharmaceuticals is allocating regular adequate funding for Grant in Aid for research, academic, and other routine activities of the institute. The table provided below contains the Grant in Aid received by NIPER SAS Nagar (Mohali) in last three financial years.

	(All fig. in Crore)		
	FY 2020-21	FY 2021-22	FY 2022-23
Grant in Aid- Salary	29.55	25.00	24.00
Grant in Aid-General	16.00	22.00	30.00
Grant in Aid-CCA	15.00	4.00	30.05
Total	60.55	51.00	84.05

Further, funds provided under the head Grant in Aid-General are utilized for lab consumables, repairs, purchase of equipments/ instruments, creation &

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upgradation of Research infrastructure and other institutional infrastructure.

NIPER SAS Nagar areas for research and development of new drugs

1. Neglected diseases and AMR – Drug discovery is carried out in the areas of leishmaniasis, tuberculosis, anti-malarial, anti-bacterial, anti-fungal, and antiviral etc. New molecules are being synthesized and their mechanisms of action are being worked out.

2. Other diseases


Drug discovery and metabolic pathways in diseases like inflammation, infection, cancer, diabetes, obesity, Parkinson's disease, and neurodegeneration etc is being worked out.

(b) & (c) The Institute has no response to offer as these points pertain to the Government and the Ministry may like to reply.

This issue with the approval of Competent Authority.

Thanking you,

Sincerely yours,



[विंग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव ४/१३

Richa Pandey <richa.p@gov.in>, Geetha Ashok <geetha.ashok@gov.in>, Deepak Kumar <kumar.deepak86@nic.in>
Niper Section DOP <nipersection-dop@gov.in>

2883

Respected Sir/Madam,

Please find trailing mail dated November 24, 2023, received from the DST on the subject mentioned above.

It is requested to kindly provide your input/comment, if any, on the pt.
(c) and (d) of the below PQ latest by 28-11-2023 5:00 PM:

(c) the details of innovations and research works done in various manufacturing fields in the country during the last five years; and

(d) the steps taken or proposed to be taken by the Govt. using such innovation for making more entrepreneurs in the country?

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Kind Regards,
Gaurav Chaudhary
Young Professional (NIPER Division)
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Mobile: +918178106089

From: "Sapana Kaushik" <sapana.kaushik@nic.in>
To: "Dr Rajesh S Gokhale" <secy@dbt.nic.in>, "Shailja Sharma" <shailja.sharma@nic.in>, "Xavier Minj" <xavier.minj@nic.in>, "Xavier Minj" <so-pvgrc@dbt.nic.in>, "secy-ipp" <secy-ipp@nic.in>, "Rajesh Kumar Kanaujia US" <rajeshkr.kanaujia@nic.in>, "dawras" <dawras@ias.nic.in>, "Sandeep Kumar" <sandeep.kr75@gov.in>, "Dr. Arunish Chawla" <secy-pharma@nic.in>, "Awadhesh KumarChoudhary" <srea-dop@gov.in>, "Gayatri Nair" <gayatri.nair@nic.in>, "Shamim Uddin Ansari" <su.ansari@nic.in>, "Atul Kumar Tiwari" <secy-msde@nic.in>, "Vibha Mehta" <vibha.mehta@nic.in>, "Sandip Kumar PS" <kumar.sandip25@nic.in>, "Shri Sanjiv Kumar" <sanjiv.kmr@nic.in>, "Office of Secretary CPC" <sec.cpc@nic.in>, "K.P. BALAJI" <kp.balaji@nic.in>, "Deepi Prasad" <deepti.p@nic.in>, "Gopal Kumar Roy" <pqcandf@nic.in>
Cc: "Praveen Roy" <praveen.roy@nic.in>
Sent: Friday, November 24, 2023 12:12:22 PM
Subject: MOST IMMEDIATE - Inputs for Parliament Question (Rajya Sabha) Dy. No.S2008 due for reply on 07/12/2023(Thursday)-reg. 'Innovations and entrepreneurs in the country'.

Dear Madam/Sir,

Kindly refer to the Provisionally Admitted Question for the Rajya Sabha bearing Diary No. S2008 on 'Innovations and entrepreneurs in the country' to be answered on – 07/12/2023(Thursday) as reproduced below:

Will the Minister of Science and Technology be pleased to state

(a) Whether it is a fact that our country lagging behind other countries in innovation and research despite having more merit and talent than others;

(b) if so, details thereof and Govt's response thereto;

(c) the details of innovations and research works done in various

manufacturing fields in the country during the last five years; and

(d) the steps taken or proposed to be taken by the Govt. using such innovation for making more entrepreneurs in the country?

It is requested that the inputs/comments on the pt. (c) and (d) of above PQ available with your department/organization may kindly be sent through email at the earliest to the undersigned (sapana.kaushik@nic.in) with CC to Mr. Praveen Roy, Scientist-F & Head, NEB, DST (praveen.roy@nic.in) latest by 29-11-2023 5:00 PM, 2023.

This may kindly be accorded TOP Priority.

With best regards

Sapana

Dr. SAPANA KAUSHIK
Scientist-'E'
Department of Science & Technology,
New Mehrauli Road, New Delhi-110 016
Phone: 011-26590289

From: "DEVARAJAN K.R." <parldst@nic.in>
To: "Praveen Roy" <praveen.roy@nic.in>
Cc: "Sapana Kaushik" <sapana.kaushik@nic.in>
Sent: Wednesday, November 22, 2023 5:11:09 PM
Subject: Fwd: Innovations and entrepreneurs in the country

आदरणीय महोदय/महोदया | Respected
Sir(s)/Madam,

Kindly refer trailing mail from Question Branch of Rajya Sabha Secretariat, forwarding therewith provisionally admitted Parliament Question Diary No. S2008, due for reply on 07/12/2023 (Thursday) in Rajya Sabha.

2. In view of instructions of Dept. of Administrative Reforms and Public Grievances(DARPG) regarding increasing efficiency in governance by reducing the number of channel of submissions and with the approval of Secretary DST in this regard, it is reiterated that the channel of submission to be followed in respect of e-files containing replies to Parliament Questions will be as per DST's OM No. H-11011/19/2021-PU dated 06.09.2021 i.e. e-files containing draft replies to Parliament Questions are to be submitted by Head of Division concerned to Secretary, DST and then to Hon'ble MoS (IC) for approval. Once approved by Hon'ble MoS(IC), the file will be sent to Parliament Unit for checking whether the guidelines issued by Lok Sabha/ Rajya Sabha Secretariat are being followed and for getting it translated to Hindi and for preparing sufficient copies for sending to the House concerned.

3. Further, all Divisions are to save draft replies to questions only under draft as DFA in the e-files and not in any other place in the e-file, so that revisions can be made/tracked in draft replies and final/approved version of the reply can be easily obtained.

4. In view of the directions of the Hon'ble Minister of State (I/C) for Science and Technology & Earth Sciences during the meeting taken by him in DST campus on 10.7.2021, NEB Division is requested that the reply to Parliament Question be prepared from provisionally admitted version of the Question i.e. without waiting for its admitted version and submitted for his approval through channel of submission as mentioned in para 2 above.



S.A.S. NAGAR

SPEED (U)

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस
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**NATIONAL INSTITUTE OF PHARMACEUTIC
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NIPER/RGO/Parliament Q./2023/ 2176

29th November, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), GoI,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, GoI,
Shastri Bhawan, New Delhi

Subject: Inputs for Parliament Question (Rajya Sabha) Dy. No.S2008 due for
reply on 07/12/2023(Thursday)-reg. 'Innovations and entrepreneurs in
the country'.

Madam,

This refers to Ministry email dated 28th November, 2023 whereby
inputs/comments on point (c) and (d) of the Parliament Question (Rajya
Sabha) Dy. No.S2008 due for reply on 07/12/2023(Thursday) 'Innovations and
entrepreneurs in the country' have been sought from the Institute.

The point-wise replies of the Institute is as under: -

(c) NIPER is not involved in any manufacturing activity. However, the institute is
involved in the development of some Active Pharmaceutical Ingredients/key
starting materials processes at the gram scale by the institutes. These following
processes are available for technology transfer and can be taken by industry

- A PROCESS FOR PREPARING 2-OXINDOLES FOR THE SYNTHESIS OF PHARMACEUTICAL DRUGS
- A PROCESS FOR THE PREPARATION OF CLEMIZOLE HYDROCHLORIDE
- A GREEN SYNTHESIS PROCESS FOR PREPARING SILDENAFIL
- A PROCESS FOR PREPARING DIOXOPYRROLIDINE BENZOATE COMPOUNDS FOR THE SYNTHESIS OF PHARMACEUTICALS
- AN IMPROVED PROCESS FOR THE PREPARATION OF A QUINAZOLINE COMPOUNDS
- AN IMPROVED PROCESS FOR PREPARATION OF 1_H_-PYRROLO [2.3_B_] PYRIDINE-3-CARBALDEHYDE COMPOUNDS

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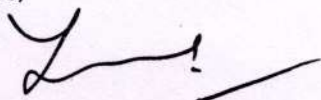
THE INSTITUTE HAS A CENTER FOR PHARMACEUTICAL INNOVATION AND ENTREPRENEURSHIP FOR INCUBATION AND INNOVATION ACTIVITIES IN PHARMACEUTICALS AND COMMON RESEARCH & TECHNOLOGY DEVELOPMENT HUB (CRTDH) SPONSORED BY DSIR FOR THE INNOVATION IN NEW MATERIALS/CHEMICAL PROCESSES SECTOR.

- (d) The Institute has no response to offer as these points pertain to the Government and the Ministry may like to reply.

This issue with the approval of Competent Authority.

Thanking you,

Sincerely yours,



[विग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव

2896

MINISTRY OF CHEMICALS & FERTILIZERS
Department of Pharmaceuticals
(Parliament Cell)
LOK SABHA/RAJYA SABHA

Admitted No. 27

This ~~Starred~~ Unstarred Question is admitted and will be placed on the list of business for the meeting on the 05/12/2023

1. Date on which notice received in this Ministry.....
2. Date in which extract sent to the Section.....
3. Name of the Section..... Policy
4. Position..... 12th

Potential of phyto-pharmaceutical products in the country

27 Dr. Sonal Mansingh:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) whether India, with its rich biodiversity and abundance of flora and fauna, has immense potential to incorporate phyto-pharmaceutical products into the global value chain;
- (b) whether efforts are being made by Government to integrate traditional medicines and phyto-pharmaceuticals into mainstream public practices; and
- (c) whether adequate steps being taken to strengthen Research and Analysis and innovation to achieve global recognition for these medicines, if so, the details thereof?

MINISTRY OF CHEMICALS & FERTILIZERS

Department of Pharmaceuticals

(Parliament Cell)

LOK SABHA/RAJYA SABHA

Admitted No...175.....

This Starred\Unstarred Question is admitted and will be placed on the list of business for the meeting on the ..05/12/2023

1. Date on which notice received in this Ministry.....
2. Date in which extract sent to the Section.....
3. Name of the Section..... Policy.....
4. Position.....

Recruitment of people for clinical trials of new medicines

175 Shri Jaggesh:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) whether it is a fact that several international clinical trials of new medicines have over-recruited participants from India;
- (b) the percentage of Indian participants in clinical trials of new medicines;
- (c) whether planning to recruit a large number of participants from India for common conditions is justified;
- (d) whether all trials in India have received regulatory permission;
- (e) whether the process of issuing regulatory permission is being used in a casual manner; and
- (f) if so, the details thereof?



S.A.S. NAGAR

21441/21

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

**NATIONAL INSTITUTE OF PHARMACEUTICAL
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2891

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NIPER/RGO/Parliament Q./2023/ 2178

30th November, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), Gol,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, Gol,
Shastri Bhawan, New Delhi

Subject: **Rajya Sabha Unstarred Question with admitted number 175 raised by Shri Jaggesh regarding recruitment of people for clinical trials of new medicines reg.**

Madam,

This refers to Ministry email dated 29th November, 2023 whereby inputs/comments have been sought from the Institute by 30th November, 2023 on the subject cited above.

In this regard, it is intimated that '*No information available at NIPER – SAS Nagar*' on any of the points (a) to (f) as raised by the Hon'ble Member of Parliament.

This issue with the approval of Competent Authority.

Thanking you,

Sincerely yours,

[विग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव



S.A.S. NAGAR

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

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NIPER/RGO/Parliament Q./2023/ 2184

4th December, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), Gol,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, Gol,
Shastri Bhawan, New Delhi

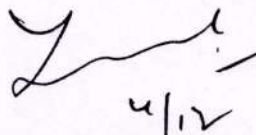
Subject : NIPER SAS Nagar Inputs for parliament (Rajya Sabha)
admitted Starred Question No. 27 for answer on 05/12/2023 regarding
"Potential of phyto-pharmaceutical products in the country".

Madam,

This refers to the ministry email dated 1st December, 2023 whereby inputs on
Rajya Sabha admitted **Starred Question No. 27 for answer on
05/12/2023** regarding "Potential of phyto-pharmaceutical products in the country".
have been sought from the institute

The pointwise replies of the institute are as under:

- (a) Yes, India has immense potential to incorporate phyto-pharmaceutical products into global value chain because of its rich biodiversity and abundances of flora and fauna; which is utilized by Indian Traditional Medicine system like Ayurveda, Unani and Siddha. Ancient scriptures like Charaka Samhita and Susurutha mentions medicinal values of plants. Indian Western Ghats and Indian Himalayas along with north-east Indian terrains are major biodiversity hotspots. In 2015 Central Drugs Standard Control Organization (CDSCO), Ministry of Health, Government of India published guidelines for phyto-pharmaceuticals which indicate that Government is focusing on phyto-pharmaceutical research and development along with their regulatory guidelines. Establishing evidence-based scientific evaluation of traditional system will surely promote phytopharmaceuticals in global market.


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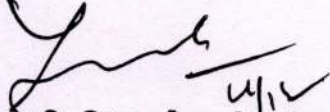
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- (b) Yes, the Ministry of AYUSH is a testament to the efforts of the Government towards this cause in integrating traditional medicines and phytopharmaceuticals into mainstream. There are AYUSH centres in Governments hospital providing services to the public. Also, the Government has actively provided liberal R&D funding to researchers working to establish evidences to traditional system of medicines.
- (c) Yes, the Government has been taking steps to strengthen research, analysis, and innovation in traditional medicines, including Ayurveda, Unani, Siddha, and others, to achieve global recognition. The government has established research institutions dedicated to traditional medicine systems. Institutions like the Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Unani Medicine (CCRUM), and Central Council for Research in Siddha (CCRS) and Departments of Natural Products, National Institutes of Pharmaceutical Education and Research (NIPERs) particularly at NIPER-Mohali and other Institutions are working towards standardization of traditional medicines. The Indian Pharmacopoeia Commission is also working on including monographs on Phytopharmaceuticals ingredients in Indian Pharmacopoeia. Recently, the Government has launched an ambitious scheme PRIP to the tune of Rs. 5000 crores encouraging Industry to open up R&D centres including those in public Research and Education Institutes, which are open to any Industry including herbal drug industry. All these efforts will lead to global recognition of phytopharmaceuticals.

This issue with the approval of Competent Authority.

Thanking you,

Sincerely yours,



[विंग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव

OFFICE MEMORANDUM

**Subject: Lok Sabha Starred Question No. 108 for answer on 11.12.2023 on "Tribal Development"-
reg.**

The undersigned is directed to refer to the Lok Sabha Starred Question No. 108 for answer on 11.12.2023 on the above subject and to reproduce the text of the Question as under:-

- (a) whether the Government of India has transformed its approach to tribal development in the last nine years;
 - (b) if so, the key milestones and achievements of the Government's tribal development initiatives;
 - (c) whether the Government has received any proposal from the State Government of Karnataka for inclusion of Koli Kabbaliga Community in the List of Scheduled Tribes (ST);
 - (d) if so the details thereof; and
 - (e) the details of the communities which have been included in Scheduled Tribe category since 2014, particularly from Karnataka?
2. It is requested to provide inputs along with **note for supplementary** for framing the reply of the above question by E-mail at **satyendra.chadha@gov.in** or **rahul.kumar54@gov.in** in MS Word format (along with signed PDF file) latest by **06.12.2023 by 3 PM** positively.



S.A.S. NAGAR

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान 241/

**NATIONAL INSTITUTE OF PHARMACEUTICAL
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SPEED POST

NIPER/RGO/Parliament Q./2023/2240

8th December, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), GoI,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, GoI,
Shastri Bhawan, New Delhi

Subject : Lok Sabha Starred Question No. 108 for answer on 11.12.2023 on
"Tribal Development"- reg.

Madam,

This refers to the ministry email dated 7th December, 2023 whereby Lok Sabha Starred Question No. 108 on "Tribal Development" was forwarded to the Institute to provide comments/inputs on point on points/question (a) and (b).

With regard to points/question (a) and (b) it is intimated that the Institute has incurred Approx. Rs 16.00 Cr in last 9 years for the ST Community mainly Salary, Stipend payment & other amenities etc.

This issues with the approval of Director of the Institute.

Thanking you,

Sincerely yours,

[विग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कूलसचिव

MINISTRY OF CHEMICALS & FERTILIZERS
Department of Pharmaceuticals
(Parliament Cell)
LOK SABHA/RAJYA SABHA

Admitted No. + 2176

This Starred \ Unstarred Question is admitted and will be placed on the list of business for the meeting on the 15/12/2023

- 1. Date on which notice received in this Ministry.....
- 2. Date in which extract sent to the Section.....
- 3. Name of the Section..... *Perching*
- 4. Position.....

Drug Price Control Mechanism

†2176. SHRI GAJANAN KIRTIKAR:

Will the Minister of CHEMICALS AND FERTILIZERS

रसायन और उर्वरक मंत्री

be pleased to state:

- (a) whether life-saving drugs and some other drugs are being sold at very high prices due to its shortage in the country;
- (b) if so, the details thereof along with the percentage rise in the price of each of the medicines;
- (c) the steps taken/proposed to be taken by the Government to ensure that the prices of the said drugs are maintained within affordable limit in the country;
- (d) whether the Government has laid down any criteria to maintain the minimum stock of life-saving drugs in the country and if so, the details thereof;
- (e) whether the Government has constituted/ proposes to constitute any high-powered committee to review the drug price control mechanism in the country and if so, the details thereof; and
- (f) the steps taken/proposed to be taken to strengthen research and development in this regard so as to explore the possibility of low cost production of drugs in the country?



S.A.S. NAGAR

57.

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

**NATIONAL INSTITUTE OF PHARMACEUTICAL
EDUCATION AND RESEARCH (NIPER)**

(Ministry of Chemicals & Fertilizers Govt. of India)
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Fax : +91-172-2214692, 2230068

29/28

NIPER/RGO/Parliament Q./2023/ 2269

13th December, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), GoI,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, GoI,
Shastri Bhawan, New Delhi

Subject : Lok Sabha Unstarred Question No. 2176 dated 15.12.2023.

Madam,

This refers to the ministry email dated 11th December, 2023 whereby Lok Sabha Unstarred Question No. 2176 dated 15.12.2023 was forwarded to the Institute to provide comments/inputs.

The pointwise replies of the Institute are as under:

a. Whether life saving drugs and some other drugs are being sold at very high prices due to its shortage in country

NIPER SAS Nagar Response: Not pertaining to NIPER SAS Nagar

b. If so, the details thereof along with the percentage rise in the price of each of the medicine

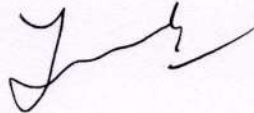
NIPER SAS Nagar Response: Not pertaining to NIPER SAS Nagar

c. The steps taken/proposed to be taken by the Government to ensure that the prices of the said drugs are maintained within affordable limit in the country

NIPER SAS Nagar Response: Not pertaining to NIPER SAS Nagar

d. Whether the Government has laid down any criteria to maintain the minimum stock of life saving drugs in the country and if so the details thereof

NIPER SAS Nagar Response: Not pertaining to NIPER SAS Nagar

 Contd...2

e. Whether the government has constituted/proposes of constitute any high powered committee to review the drug price control mechanism in the country and if so the details thereof, and

NIPER SAS Nagar Response: Not pertaining to NIPER SAS Nagar

f. The steps taken/proposed to be taken to strengthen research and development in this regards so as to explore the possibility of low cost production of drugs in the country

NIPER SAS Nagar is working on the following research areas for the development of affordable healthcare:

A. Neglected diseases - Drug discovery is carried out in the areas of leishmaniasis, tuberculosis, and malaria. New molecules are being synthesized and their mechanisms of action are being worked out.

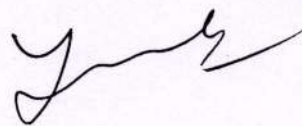
B. Other diseases

Drug discovery for metabolic pathways in diseases like inflammation, infection, cancer, diabetes, obesity, Parkinson's disease, neurodegeneration are being worked out.

C. Drug development and formulation development

- i. Improvement of oral bioavailability, synergistic anticancer efficacy and reduced toxicity of drugs.
- ii. Sustainable Active Pharmaceutical Ingredient (API) development
- iii. New formulations are being developed
- iv. Standardization of Herbal drugs and formulations
- v. Toxicological studies

Contd...3



D. Other areas

- i. Biopharmaceuticals
- ii. Epigenetics
- iii. Chemo-enzymatic synthesis of drugs
- iv. Monograph on herbals is being developed
- v. Study of the effect of RNA aptamers on stabilization of misfolded proteins
- vi. Assessment of an appropriate and reliable method to diagnose neuropathic pain
- vii. Artificial intelligence, Machine Learning, Big data Analytics
- viii. Utility of Physiology Based Pharmacokinetic (PBPK) Modeling in prediction of PK of drugs in special populations and in study of food effects on drug PK
- ix. Health Economics and Outcomes Research (HEOR), Pharmacovigilance, etc.

This issues with the approval of Director of the Institute.

Thanking you,

Sincerely yours,



[विंग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव

registrar

From: Gaurav Chaudhary <gaurav.dop@govcontractor.in>
Sent: 07 दिसम्बर 2023 10:44
To: Director NIPER A; director@niper.ac.in; Director NIPER Hyderabad; V Ravichandran; Dr USN Murty; Ravichandiran V; directorniperkolkata@gmail.com; registrar@niper.ac.in; Avdhesh Nautiyal; Registrar NIPER G; Registrar Niperk; Registrar NIPER Hyderabad; Mr Sameer Dhingra
Cc: Richa Pandey; Geetha Ashok; Deepak Kumar; Niper Section DOP
Subject: Lok Sabha Diary No. 4941 on 'Artificial Intelligence and Block Chain Technologies in Pharmaceutical Sector' to be answered on – 15/12/2023- reg.

Importance: High

Most Urgent
Parliament Question for 15.12.2023
Time Bound

Dear Madam/Sir,

Kindly refer to the Provisionally Admitted Lok Sabha bearing **Diary No. 4941** on '**Artificial Intelligence and Block Chain Technologies in Pharmaceutical Sector**' to be answered on – 15/12/2023 (Friday) as reproduced below:

Will the Minister of CHEMICALS AND FERTILIZERS:

- (a) whether the Government has taken note that the importance of advanced technologies such as Artificial Intelligence, Block chain etc. can play a major role in boosting our pharmaceutical sector in the country;
- (b) if so, the details thereof; and
- (c) the steps taken/proposed to be taken by the Government to leverage these technological developments to the sector's advantage in the country?

2. **It is requested that the inputs/comments on the above PQ** be kindly sent through email at the earliest to the undersigned (gaurav.dop@govcontractor.in) with CC to Mr. Deepak Kumar, Section Officer (kumar.deepak86@nic.in), at the latest by **08-12-2023, 2023.**

3. This may kindly be accorded **TOP Priority.**

--

Kind Regards,
Gaurav Chaudhary
Young Professional (NIPER Division)
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Mobile: [+918178106089](tel:+918178106089)



S.A.S. NAGAR

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

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NIPER/RGO/Parliament Q./2023/2242

8th December, 2023

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), Gol,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, Gol,
Shastri Bhawan, New Delhi

Subject : Lok Sabha Diary No. 4941 on '*Artificial Intelligence and Block Chain Technologies in Pharmaceutical Sector*' to be answered on - 15/12/2023

Madam,

This refers to the ministry email dated 7th December, 2023 whereby Lok Sabha Diary No. 4941 on '*Artificial Intelligence and Block Chain Technologies in Pharmaceutical Sector*' was forwarded to the Institute to provide comments/inputs.

The pointwise replies of the Institute are as under:

(a) whether the Government has taken note that the importance of advanced technologies such as Artificial Intelligence, Block chain etc. can play a major role in boosting our pharmaceutical sector in the country;

Yes, AI and block chain can play a major role in boosting pharmaceutical sector in the country.

(b) If so, the details thereof; and

AI may make incredible strides in pharmaceutical research from rapid decoding of intricate molecular structures to predict intricate drug interactions, diagnostic imaging, precision mapping of personalized treatment trajectories, and the discerning identification of potential drug candidates, AI exemplifies its multifaceted influence on pharmaceutical research and development. Beyond these, AI extends its reach into the realms of genomics, where it enables accelerated genome sequencing and analysis, facilitating the

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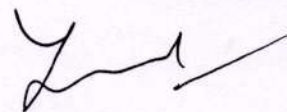
identification of crucial biomarkers and novel therapeutic targets. Moreover, AI empowers researchers to sift through vast volumes of medical literature and patient data, expediting the process of clinical trial design and patient care. AI can be used from target identification to patient care at every step. AI can lead to exciting breakthroughs in medicine. Furthermore, AI aids in the continuous monitoring of patient responses during clinical trials, providing valuable real-time insights that can enhance treatment strategies and mitigate potential risks.

Blockchain may play a crucial role in monitoring the complete lifecycle of a drug, tracing it from the initial stages as raw materials to its delivery to patients. The immutability of blockchain records and transparent nature make it exceptionally difficult for counterfeiters attempting to compromise the supply chain. Patients can validate the authenticity of their medications by tracking their origins on the blockchain. This enables individuals to make well-informed choices regarding the medications they consume. Preserving data integrity holds the utmost importance in clinical trials and research. The blockchain guarantees the accurate recording of research findings, patient data, and clinical trial results, preventing retrospective alterations. This fosters confidence among the general public, regulators, and researchers. Blockchain has the potential to enable stakeholders to securely exchange data while retaining authority over confidential and sensitive information. While maintaining confidentiality, the essential data is available for use by researchers, clinicians, manufacturers, and regulators.

(c) the steps taken/proposed to be taken by the Government to leverage these technological developments to the sector's advantage in the country?

Allocating funds for AI-driven research and development projects in the pharmaceutical sector, and pharmaceutical institutions to encourage innovation and the discovery and development of new drugs, treatments, and technologies. Similar to INAI (Intel AI), an applied AI research center in collaboration with the International Institute of Information Technology, Hyderabad (IIIT-H), Public Health Foundation of India (PHFI), and Intel India; other centers may be established to focus on solving challenges in healthcare and pharmaceutical research in India.

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Centralised data repositories in usable and downloadable format may be created like IBDC at RCB to be freely accessible to researchers including patient data, images, biological data of small molecules, assay data on the Indian population, etc.

NIPER SAS Nagar is employing AI methods in two ways.

1. Classification approaches
2. Generative approaches

The methods like Support Vector Machines (SVM), Random Forest method (RF), etc. are being used to classify compounds as drugs or non-drugs (anti-cancer, anti-biotic, anti-viral) etc.

We are able to adopt encoder-decoder, LSTM, etc. methods to generate new molecules and submit them for Pharmacoinformatics to identify new lead molecules.

We also carry out quantum chemistry, synthesis of the newly generated molecules.

Currently, the efforts are at the primitive level in pharmaceutical research. AI methods can be employed in Ayurinformatics also.

NIPER will be able to adopt AI and Ayurinformatics in a big way with the help of the Government of India.

This issues with the approval of Director of the Institute.

Thanking you,

Sincerely yours,



[विग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव

<director@nipershajipur.ac.in>; Dr USN Murty <director@niperguwahati.ac.in>; Ravichandiran V
<director@niperkolkata.edu.in>; directorniperkolkata@gmail.com; registrar@nipr.ac.in; Avdhesh Nautiyal
<registrar@niprahm.ac.in>; Registrar NIPER G <registrar@niperguwahati.ac.in>; Registrar Niperk
<registrar@niperkolkata.edu.in>; Registrar NIPER Hyderabad <registrar.niperhyd@gov.in>; Mr Sameer Dhingra
<registrar@nipershajipur.ac.in>; Registrar NIPER R <registrar@niperraebareli.edu.in>
Cc: Richa Pandey <richa.p@gov.in>; Geetha Ashok <geetha.ashok@gov.in>; Deepak Kumar
<kumar.deepak86@nic.in>; Niper Section DOP <nipersection-dop@gov.in>
Subject: Lok Sabha D.No. 2867 for answer on 09/02/2024 on "Generative AI in Pharmaceutical Research"- reg.

Most Urgent
Parliament Question for 09.02.2024
Time Bound

Respected Madam/Sir,

Please refer to the Lok Sabha D.No. 2867 for answer on 09/02/2024 on "**Generative AI in Pharmaceutical Research**"

- (a) whether the Government is aware that Generative AI (Gen AI) can revolutionize pharmaceutical research by predicting how specific compounds interact with different targets in the body, expediting drug discovery and development, can identify potential drug candidates more rapidly, leading to breakthrough treatments for various diseases, and can also assist in identifying suitable patient cohorts for clinical trials, optimizing the research process and accelerating the delivery of innovative therapies to patients in need;
- (b) if so, the details thereof; and
- (c) the steps proposed to be taken by the Government to speed up the traditional drug discovery process in the country which is time-consuming and expensive?
2. It is requested that the inputs/comments on the above PQ be kindly sent through email at the earliest at the latest by **February 2, 2024, please.**
3. This may kindly be accorded **TOP Priority.**

Kind Regards,
Dr. Gaurav Chaudhary

Young Professional (NIPER Division),
Department of Pharmaceuticals,
Ministry of Chemicals & Fertilizers.
Email: gaurav.dop@govcontractor.in
Tel: 23323292



S.A.S. NAGAR

राष्ट्रीय औषधीय शिक्षा एवं अनुसंधान संस्थान

**NATIONAL INSTITUTE OF PHARMACEUTICAL
EDUCATION AND RESEARCH (NIPER)**

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NIPER/RGO/Parliament Q./2024/420

2nd February, 2024

Dr. Richa Pandey
Deputy Secretary (R&D, NIPER), GoI,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers, GoI,
Shastri Bhawan, New Delhi

Subject : Lok Sabha D.No. 2867 for answer on 09/02/2024 on "Generative AI in
Pharmaceutical Research.

Madam,

This refers to the ministry email dated 31st January, 2024 whereby Lok Sabha Questions bearing D.No. 2867 was forwarded to the Institute to provide comments/inputs.

The pointwise replies of the Institute are as under:

(Q1a) Yes, the government has acknowledged the promising capabilities of Gen AI in predicting compound interactions with various targets in the body, and identification of suitable patient cohorts for clinical trials, thus expediting traditional drug discovery and development. The potential to identify drug candidates more rapidly holds great promise for breakthrough treatments across a spectrum of diseases. Generative AI can speed up the process of traditional drug discovery by rapidly identifying different compounds for different targets by employing modern computational methods like generative AI, Network pharmacology, & CADD (computer-aided drug design). Generative AI in drug discovery refers to the application of artificial intelligence (AI) and machine learning (ML) techniques to generate novel molecules. This approach has gained significant attention in recent years due to its ability to accelerate the drug discovery process, reduce costs, and improve the chances of identifying effective drug candidates. For example, ALPHAFOLD is an AI system used for predicting the 3D protein structure based on amino-acid sequences which can be used for structure-based drug design.

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o/c

The government has released the National Strategy for Artificial Intelligence, aiming to foster an ecosystem for AI research and adoption. Following the vision to 'Make AI in India and Make AI work for India,' Government has sanctioned the implementation of the 'National Program on Artificial Intelligence', designed to develop AI-based solutions, ensuring responsible and transformational use of AI across various sectors, including pharmaceutical research, in the country.

NIPER S.A.S. Nagar has also collaborated with Panjab University and other Institutes and applied for setup of Centre of Excellence (Preproposal submitted to Ministry of Education).

There are different training algorithms for training the models. NIPER S.A.S pioneered in the field of Pharmacoinformatics, which includes Artificial Intelligence since 2003. In fact, NIPER S.A.S is the first institute in the world to offer PG degrees and Ph.D in Pharmacoinformatics. NIPER S.A.S has been working in the field of AI by developing AI tools like DeepADRA2A, FGRF1pred, Andropred for predicting various molecules against different targets Like anticancer, antibiotic, antidiabetic, etc. Recently NIPER S.A.S also started working in generative AI to identify potent antibacterial molecules that can be beneficial for reducing antimicrobial resistance.

NIPER, SAS Nagar has also have come up with a few potential molecules for two therapeutic targets in the area of cancer. Gen AI falls under ligand based drug design methods which has to be studied using structure based drug design strategies for further insights. The identified molecules are taken up for other computational studies and wetlab experiments.

Though GE AI can identify potential molecules rapidly, the molecules have to be subjected for other strategies of drug discovery process including synthesis, biological studies, novelty search, ADMET etc.

Recently A drug INS018_055 was the first AI-generated drug that is under clinical trial for lung disease
NIPER S.A.S conducted an AI spark symposium on October 9-11 2023 in which National and International experts of AI delivered their lectures on different aspects of generative AI in drug discovery

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(Q1b) Gen AI holds immense potential to revolutionize pharmaceutical research across multiple facets. It can be used to predict how specific compounds interact with different targets in the body through advanced simulations and analyses. For instance, a Gen AI-based model could analyze the molecular structure of a compound and predict its interactions with specific proteins, providing valuable insights into its potential as a targeted therapy. AI can automate the analysis of research literature, extracting relevant information to inform the design of new experiments, providing data-driven insights.

Steps involve in Generative AI

- Data collection
- Data preprocessing
- Training the model
- Generation of new molecules
- Validation of molecules using CADD Tools
- Synthesis and Biological Activity
- Drug-Target interaction
- Toxicity Prediction etc

(Q1c) Some strategies may include:

1. Invest in and incentivize the adoption of advanced technologies.
2. Develop programs to enhance the skills of researchers in emerging technologies and methodologies such as Gen AI. Encourage cross-disciplinary training to foster a more holistic approach to drug discovery.
3. Encourage the use of adaptive clinical trial designs to allow for real-time adjustments based on accumulated data.
4. A triangle made of CADD+AI scientists, synthetic chemists and biologists can be initiated to work on a therapeutic target of interest.

Currently, NIPER S.A.S Nagar is working on Ayur informatics which it focuses on applying above mention methods incorporated with the Ayurveda system of medicine.

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-4-

NIPER S.A.S Nagar in Collaborating research with Shri Dhanwantri Ayurveda College and Hospital (SDSS), Chandigarh has come up with seven therapeutically active compounds from three ayurvedic formulations in the past 1.5 years.

Similarly, NIPER S.A.S Nagar will organize an ayur-informatics symposium on March 15- 16 2024 in collaboration with All India Institute of Ayurveda (AllA), New Delhi.

This issues with the approval of Director of the Institute.

Thanking you,

Sincerely yours,



[विंग कमांडर पी.जे.पी. सिंह वडैच (सेवानिवृत्त)]
कुलसचिव