

PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

E-MAIL WEBSITE Telephone

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NBCC Centre, 3rd Floor, Plot No.2, Community Centre

Maa Anandamai Marg

Okhla Phase I

NEW DELHI - 110 020

Ref.No. 1-2/2022-PCI (Part -A) 11275

1-2/2022-PCI (A)

14-56/2022-PCI (Approval Process for 2022-2023 a.s.)

0 8 JUN 2022

To

All Inspectors

Starting of inspection process 2022-2023. Sub:

Council's circular No.14-56/2022-PCI (Approval Process for 2022-2023 a.s.) / Ref: 9687-88 dt.24.5.2022.

Sir/Madam

This has a reference to the subject cited above. In this connection, I am directed to state that inspections which were kept on hold are going to be started very soon for consideration of approval u/s 12 of the Pharmacy Act, 1948. The inspections will be surprise.

On 24.5.2022, all institutions have been asked to be ready for inspection and provide all necessary documents to the inspectors. A copy of Council's circular letter dt.24.5.2022 is enclosed as Annexure-1 for your ready reference.

In this connection, it is further stated that -

A text message and e-mail will come to deputed inspector to accept or reject the inspection. Inspector has to accept or reject within 6 hours.

The provision to accept or reject is available on your mobile phone and system (e.mail). If you deny the inspection twice, your name will be added in defaulters list for further action as deemed fit by the Council.

- Once inspection is confirmed, inspector will get only the station to be reached. The name of institution and other details for the inspection will be known only 3 hours before the inspection.
- Inspection report be made in following two parts:-
 - Inspection report with regard to physical verification which can be sent to Institution.
 - ii) Specific Observations of inspectors which is not to be shared with institution. For this separate space is provided to inspectors at the end of the inspection report under the title "Specific Observations".
- Without filling "specific observations" in the mobile app, the inspectors will not be able to submit the IR i.e. submission of observations is a mandatory field.
- The inspectors are required to give their comments under the column "comments". Please ensure to fill all the columns.
- 6. Please also ensure to comments on practical training imparted in D.Pharm and B.Pharm. A copy of template is enclosed as Annexure-2. This template is a part of the Inspection Report.
- Whether equipments are in working conditions or not along with the audit report, fund allocation etc. of last financial year be indicated in the mobile app and reflected in the IR A copy of template for audit report and fund allocation is enclosed as Annexure-3. This is also a part of the Inspection Report.
- Institutions have been instructed that Principal / HOD along with faculty as reflected in the online SIF shall be present at the time of inspection. In case there is a change in the teaching staff position, relieving letter of the faculty which has left the institution along with documentary evidence of new faculty with joining report and relieving from the previous institution shall be verified at the time of inspection.

Faculty part in the mobile app should capture the reason for absence of faculty along with documentary proof at the time of inspection. A drop down has been provided giving the reasons such as -

- Casual leave
- Medical leave
- Resignation
- If resignation whether relieving letter is shown to inspectors
- Other reasons
- 9. Documentary evidence of having conducted the classes like practical notebooks of students, attendance register of faculty and students etc. be verified.
- 10. Original bills of equipments, chemicals and glassware etc. be verified.
- 11. Record of sessional exams like sessional papers, answer sheet of students, record of sessional marks etc. be verified.

- 12. Compliance of Council's circulars regarding payment of salary to teaching faculty be needs to be verified.
- 13. In case of Pharm.D inspection, physical verification of hospital facilities and internship record be verified.

Important -14.

14A. Specific Verification to be done by Inspectors

Kindly look into the SIF of the institution and in case the institution has applied for raise in admission and / or introduction of new course then the following documents need to be verified at the time of inspection and also enclosed with the inspection report.

a) For B.Pharm course

- i) Consent of affiliation of Examining Authority.
- ii) NOC of the State Government.

In case, the State Government has done away with the issuance of NOC of the State Government for starting of pharmacy course, in that case enclose the said communication from the State Government as a documentary evidence.

- b) For D.Pharm / Pharm.D & Pharm.D (Post Baccalaureate) / new M.Pharm course and introduction of new M.Pharm specialization / B.Pharm (Practice) course
 - Consent of affiliation of the Examining Authority.
 - MOU with 300 bedded hospital (applicable for Pharm.D course only) in the prescribed format.

14 B. Specific attention

All inspectors are required to note that the Inspection Report is a legal document under the Pharmacy Act, 1948 and is open to scrutiny by the courts. Based on the information provided by the inspectors in the Inspection Report, decisions regarding approval or otherwise are taken by the PCI.

Hence all information given in the Inspection Report should be thoroughly verified, authenticated and correct failing which action shall be intimated against the inspectors

- removal from the PCI inspectors panel.
- Pharmacist registration No. with State Pharmacy Council will be cancelled.
- Faculty registration will be on PCI faculty portal will be cancelled.
- Any other legal action as deemed fit by the PCI.

14 C. Specific instructions

Please make sure that all columns in the Inspection Report are filled and your comments and specific observations are legible. In case it is not complied with PCI may not release the honorarium.

15. For travel (home to home) and stay arrangement, PCI has hired the services of Balmer Lawrie & Co. Ltd.

You will get prior information from Balmer Lawrie & Co. Ltd. with regard to your stay and travel arrangement through e.mail. However, in case you have any problem, you can contact the following persons -

Name	E.Mail	Mobile
Ms. Ridhi Sharma	ridhi.s@vacationsexotica.com	9599775892
Ms. Sonia Bhasin	sonia.bhasin@vacationsexotica.com	7905598238

In case of an emergency if that you are not able to go for inspection, immediately same shall be intimated to Balmer Lawrie & Co. Ltd. for cancellation of the bookings.

Yours faithfully

(ARCHNA MUDGAL) Registrar-cum-Secretary

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Ref.No.14-56/2022-PCI (Approval Process for 2022-2023 a.s.) | 9687-88

2 4 MAY 2022

To

The Principals / Head of Departments All Institutions -

- Approved u/s 12
- · Approved for conduct of course of study

Sub: Starting of inspection process 2022-2023.

Sir/Madam

This has a reference to the subject cited above. In this connection, I am directed to state that inspections which were kept on hold are going to be started very soon for consideration of approval u/s 12 of the Pharmacy Act, 1948. However, the inspections will be surprise.

In view of above, all institutions are advised to co-operate with the inspection team and ensure that -

- a) Principal / HOD along with faculty as reflected in the online SIF shall be present at the time of inspection. In case there is a change in the teaching staff position, relieving letter of the faculty which has left the institution along with documentary evidence of new faculty with joining report and relieving from the previous institution shall be produced before the inspection team for verification.
- b) the students shall be available.
- documentary evidence of having conducted the classes like practical notebooks of students, attendance register of faculty and students etc. be kept ready.
- d) record of practical training imparted to
 - i) D.Pharm students under "Education Regulations, 1991 for the Diploma course in Pharmacy" (ER-91) / "The Education Regulations, 2020 for Diploma Course in Pharmacy" (ER-20). (regulation 20 of ER-91 and regulation 18 of ER-20)
 - ii) B.Pharm students under "The Bachelor of Pharmacy (B.Pharm) Course Regulations, 2014". (regulation 7)
 - iii) internship record in respect of Pharm.D students as per Pharm.D Regulations, 2008.
- e) original bills of equipments, chemicals and glassware etc. are available for verification.

- f) record of sessional exams like sessional papers, answer sheet of students, record of sessional marks etc. be shown to inspectors.
- g) compliance of Council's circulars regarding payment of salary to teaching faculty.

All institutions are requested to keep the documentary evidence / records ready for cross verification by inspectors during inspection

Yours faithfully

(ARCHNA MUDGAL) Registrar-cum-Secretary

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Template for practical training

For D.Pharm course

Fixed fields		Comments by Inspectors (To be verified from the old record)	
a)	Whether prescribed 500 hours training is imparted spread over a period of not less than 3 months.		
b)	 Training is imparted in - i) Hospitals / Dispensaries run by Central/ State Governments. ii) A pharmacy licensed for retail sale of drugs under the Drugs and Cosmetics Rules, 1945 having the services of registered pharmacists. 		

For B.Pharm course

Fix	ed fields	Comments by Inspectors (To be verified from the old record)	
a)	Whether prescribed 150 hours training is imparted spread over a period of not less than 1 month.		
b)	Training is imparted in -		
	i) Pharmacy Practice (Hospital / Community Pharmacy)		
	 ii) Pharmaceutical Industry Manufacturing Quality Control Quality Assurance R&D 		

The Template for audit report and fund allocation

Fixed fields	Budget provision (to be filled by Inspectors) (in Rs. per month)
Total No. of faculty	(m Rs. per month)
Total No. of students in all pharmacy courses (in all years)	
Salary to faculty	
Purchase of equipments	
Purchase of glassware and chemicals	
Gas, water and electric supply	
Telephone, Internet expenditure, stationary	
Basic amenities like drinking water, toilets	
Maintenance of building and equipments	
Any other	