



PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

E-MAIL : registrar@pci.nic.in
WEBSITE : www.pci.nic.in
Telephone : 011-61299901
011-61299902
011-61299903

NBCC Centre, 3rd Floor,
Plot No.2, Community Centre
Maa Anandamai Marg
Okhla Phase I
NEW DELHI – 110 020

Ref. No. 14-136/2017-PCI | 8427

3 FEB 2021

-To all institutions approved by PCI for –

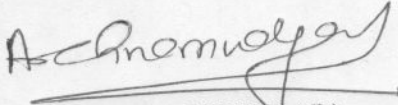
- u/s 12 of the Pharmacy Act.
- conduct of course.

Sub: Pharmacy Ethics related to the Covid-19 Pandemic based on Core Ethical Principal Version 1.0.- FIP, documents, UNESCO Chair in Bioethics International Pharmacy Panel Ethical Guidelines for Pharmacy October 2020.

Sir/Madam

With reference to the subject cited above, it is informed that the subject cited issue was considered by the 339th Executive Committee of the PCI in its meeting held in January, 2021, which decided to forward the “Guidelines on Pharmacy Ethics Related to the Covid-19 Pandemic Based on Core Ethical Principles: Version 1.0” to all institutions for their use. A copy of the said guidelines is enclosed herewith as **Appendix – I** for ready reference.

Yours faithfully


(ARCHNA MUDGAL)
Registrar-cum-Secretary

Pharmacy Ethics Related to the Covid-19 Pandemic Based on Core Ethical Principles Version 1.0

UNESCO CHAIR IN BIOETHICS
International Pharmacy Panel
Ethical Guidelines for Pharmacy

October 2020

Members of the Panel

Timothy F. Chen, B.Pharm., DipHPharm, Ph.D., FFIP
Professor of Medication Management
The University of Sydney
Sydney, Australia

Pierre Essa, Ph.D.,
Professor
School of Pharmacy
Cameroon, Africa

Mahendra G Patel, B.Pharm., Ph.D., FRPharmS, FHEA, Co-Chair
Visiting and Honorary Professor
University of Bradford
United Kingdom

Helder Mota-Filipe, Pharm.D., Ph.D. FPPS, AFPLP
Associate Professor
Faculty of Pharmacy, University of Lisbon
Lisbon, Portugal

Shailendra Saraf, M.Pharm., Ph.D.
Professor
University Institute of Pharmacy
Pt. Ravishankar Shukla University
Vice President, Pharmacy Council of India
Raipur, India

Richa Dayaramani, M.Pharm., Ph.D.
Professor and Principal
Khyati College of Pharmacy
Palodiya, Ahmedabad, India

Henri R. Manasse, Jr., Ph.D., Sc.D. (Hon.), FFIP, Co-Chair
Professor and Dean, emeritus
College of Pharmacy, University of Illinois at Chicago
Chicago, Illinois USA

Consultative Guidance

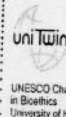
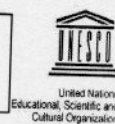
Maria Eugenia Olivera, B.S. Pharm., Ph.D.
Associate Professor
National University of Cordoba
Cordoba, Argentina, South America

Convening Authority

Russell Franco D'Souza, MBBS, MD, FCGP, DPM, MPM, CCTMg
Head, Asia Pacific Division
Director of Education
UNESCO Chair in Bioethics
Melbourne, Australia

Mary Mathew MD, DCH, PGDMLE, FIIOPM
Head, Indian Program, International Network of the UNESCO Chair in Bioethics (Haifa)
International Council Member, Department of Education,
International UNESCO Chair in Bioethics (Haifa)
Head, Manipal Unit of the UNESCO Chair in Bioethics (Haifa)

Guidelines on Pharmacy Ethics Related to the Covid-19 Pandemic Based on Core Ethical Principles: Version 1.0



In 2005, the United Nations, at its 33rd General Assembly, adopted a 26 article Universal Declaration of Bioethics and Human Rights. These principles coupled with the many discussions that have followed provide a pragmatic lens through which to view the present SARS-COVID-19 global pandemic [See <https://unesdoc.unesco.org/ark:/48223/pf0000142825.page=80> for full text of this Declaration].

As the world experiences a global pandemic of the novel Covid-19, and given the absence of a viable vaccine nor effective and safe treatment of patients having been infected with the novel virus, the international leaders of the profession of pharmacy are gathered to present these guidelines to the pharmacy practitioner community. Once a vaccine becomes available and when medicines are approved for treatment of COVID-19, these guidelines may require some modification.

The guidelines intended to provide the necessary guidance to pharmacy practitioners as they apply their knowledge, skills and clinical experience to the care of patients and colleagues in other professions in different parts of the world. Furthermore, in order to assure the most effective and safe caring of patients with whom pharmacists interact, that these guidelines can assure fundamental principles of ethical behavior and practice. [Based on Stephenson, LA et al., 2012]

Based on Core Ethical Principles we must consider the following:

1. **Nonmaleficence**—intent that actions undertaken will be done without harm

The assurance of *efficacy* and *safety* of vaccines, biologicals, medicines and contrast media serves as the underlying requirement for authorized use of these agents. Meeting the requirements under these two themes is the necessary element of assuring least harm. It must be understood however, that the use of all medicinal agents carries some element of risk. Mitigating that risk on behalf of the patient, under the principle of 'do no harm' is a key responsibility of the pharmacist. The latter is particularly important when medicines are used within an 'off-label', 'experimental' and 'compassionate use' protocol.

2. **Autonomy**—respect for independence of thought, intention, and action

Pharmacist must recognize that the patient is an autonomous decision-maker about their use of vaccines, biological agents, medicines and contrast media. The patient holds the ultimate decision regarding their willingness to be vaccinated and/or engage in a treatment modality that is based on medicinal agents. Notwithstanding that autonomy, public health priorities and goals must be made clear to the patient in order to preserve the health of the community. Furthermore, there may be occasions where the patient is unresponsive and under the supervision of a caregiver. In these latter circumstances, respectful application of patient desires is paramount in both receiving or declining treatment.

3. **Justice**—awareness that burdens and benefits must be distributed equally and equitably

Equality and equity in all aspects of the medication use process, from prescribing to ultimate use must be performed in a way that assures equal treatment to all. Moreover, government bodies, policy makers and health care providers everywhere including pharmacists must respect equality in access to and utilization of vaccines and medicines. It is their task to apply judicious decision-making in all aspects of access and use of medicinal agents.

4. Beneficence—intent of striving for net benefit for individual involved.

In the professional relationship between patient and pharmacist, there must be a primary focus of helping and healing the patient. This professional bond must be founded on competent practice and ethical foundations.

5. Truthfulness—commitment to openness and honesty

The care of the patient by pharmacists must be grounded in the best available scientific and professional knowledge, and must be truthfully conveyed to the patient. While there may be competing opinions on a particular aspect of care, the pharmacist must engage in applying their best skills and knowledge with honesty. In cases where there may be conflict, any judgment made would need to have due consideration around the principles of beneficence and non-maleficence. Each patient nevertheless must be approached individually, and at a level that addresses appropriately his or her needs and interests.

6. Solidarity- working toward a common social objective to keep people healthy and safe

The emphasis on human solidarity is essential in the search for survival solutions, in particular the research, production and accessibility of vaccines and appropriate therapeutic treatments. The humanism of the health professions requires that medicines become a common public good for the health and safety of all requiring such intervention. Relevant data, knowledge and findings should be promptly shared with others in order to prevent and/or reduce harm.

Working under the framework of Ethical Principles iterated above, the pharmacist holds to assuring a standard of care that meets both legal and ethical standards. While these may vary based on social, cultural and ethnic norms of a given country, the core ethical principles should be adhered to. As we examine the major facets of the Medication Use Process, we find important applications to an acceptable standard of patient care. These follow below: (Based on Galt, K et al., 2005)

1. Prescribing

Which vaccine (assuming that there will be choices) should be administered to the patients and what safety and efficacy criteria should be applied in this decision?

Which medicines should be prescribed in the mitigation and treatment of a COVID-19 positive patient?

Should only authorized medicines be prescribed (e.g. no off label use)? What about 'experimental' or 'compassionate use' designated medicines?

2. Clinical evaluation

What clinical markers establish the base level of patient evaluation for use of vaccines and/or medicines? How should these clinical markers be monitored and evaluated and used throughout the treatment process?

Are there particularly vulnerable patients for whom the vaccine and/or medications might not be suitable or recommended?

What documentation systems need to be in place for each patient which might be further used for patient evaluation and monitoring?

3. Preparation and dispensing

How will access to vaccines and medicines for COVID-19 treatment be assured to all peoples in a given country and what advocacy efforts should the profession of pharmacy be engaged in to assure an ethical foundation (including payment) for access to these agents? What consideration must be given to applying an equal and equitable payment mechanism with regard to co-payment, full payment or full subsidization in order to assure full population uptake?

Will the pharmacist workforce be effectively trained and utilized, including vaccinating patients, in order to assure meeting community immunization goals?

How will off-label prescribing and utilization of unapproved/unsubstantiated treatments be managed by pharmacists?

4. Counselling and Advising

What authoritative and clinically substantiated source of information will be utilized to guide the counselling and advising of patients, especially in a time of dynamic development of findings?

Is there a fundamental core of information that must be given to every patient, allowing for some individualization and recognition of challenges in health literacy where necessary??

How does the professions assure public and patient understanding related to the use of vaccines and authorized medicines? What special considerations must be given to patient education when using experimental or compassion use designated medicines?

What additional resources and tools (e.g. pictograms) are necessary for pharmacist counselling? Cultural beliefs and attitudes and how to deal with these?

5. Monitoring and Pharmacovigilance

What patient-specific monitoring must be in place for every patient who is administered a vaccine and/or or given medicines for treatment?

Should there be a national and/or pharmacovigilance system put in place in every country to assess safety signals and adverse events?

Are there any 'black box' warnings that will be required for vaccines and/or medicines for COVID-19?

[https://yellowcard.mhra.gov.uk/assets/files/Healthcare-Professional-Yellow-Card-Reporting-Form-\(July-2019\).pdf](https://yellowcard.mhra.gov.uk/assets/files/Healthcare-Professional-Yellow-Card-Reporting-Form-(July-2019).pdf)
Medicines and Health Regulatory Authority (MHRA)

In order for a medicine to be authorised by a regulatory authority for use in the UK, the benefits and risks of a medicines are carefully considered. It is impossible for absolutely all information about a medicine to be known prior to it obtaining a marketing authorisation, so a balance must be struck between making a new medicine available to patients and having adequate information on a product's safety and efficacy. Once a medicine is launched, ongoing safety monitoring is crucial, because at the time the marketing authorisation is granted the medicine will have been tested in a relatively small number of patients for a limited amount of time in clinical trials.

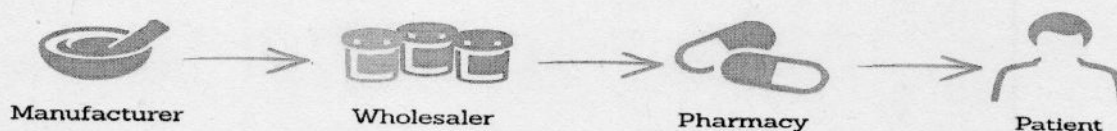
The black triangle has been running in the UK for many years to highlight medicines that are subject to intensive safety monitoring. The black triangle aims to ensure that the safety of any new medicine is monitored closely. Since 2013 the black triangle has become part of an EU wide scheme and is now known as additional monitoring.

The scheme ensures that the same monitoring methods are used EU wide, so that European regulatory authorities can share the information from the individual EU countries. This provides larger amounts of information for regulators to evaluate when making decisions, and enables them to act quickly to ensure patient safety is protected, when required. For example, regulators can alert patients and healthcare professionals about newly established warnings and special precautions associated with the use of a product or they may restrict the way a medicine is used.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/396808/Black_Triangle_Scheme_-_new_medicines_and_vaccines_subject_to_EU-wide_additional_monitoring.pdf

<https://www.gov.uk/drug-safety-update/the-black-triangle-scheme-or>

Supply chain and formulation



In addition to these practice and patient care related matters, the drug discovery continuum also need to be addressed from an ethical perspective. The development of a safe and effective armamentarium of vaccines and medicines should be guided by the following: (Based on FIP, 2012)

1. Issues related to efficacy and safety with appropriate information and data need to be well elaborated for professional and patient purposes
2. The vaccine itself needs to be well formulated for maximum effectiveness (e.g. adjuvants, stabilizers, preservatives)
3. Vaccines and medicines should be well characterized in order to determine supply chain challenges and how these might be understood, mitigated and resolved (e.g. temperature sensitivity)
4. Labeling, in all its forms, must be nation specific with appropriate prescriber and patient information
5. The selection of research subjects for vaccine and drug testing must adhere to well-established norms of consent and use of human subjects for research
6. Curricular emphasis in schools of pharmacy must include the most update practice and drug standards related to the prevention and treatment of COVID-19
7. There should be a single international repository for all new developments in science, practice and clinical experience which can be easily accessed by all pharmacy personnel
8. Assuring the integrity of the supply chain is paramount for all countries and must be taken seriously by both government and industry
9. How can we assure equity and equality of vaccine and drug access across all countries?

10. How does the profession of pharmacy assure solidarity of ethical commitment and professional quality across all countries?
11. How will governments, manufacturers and others associated with the economics of medication use, establish a pricing model for vaccines and drug therapies that are effective and safe for use?
12. How will pricing models be applied to the various countries in the world taking into account the nature of a given countries' economic condition and payment capacities?

A CALL TO ACTION

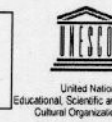
The International Pharmaceutical Federation (FIP), which represents over 150 national pharmacy organisations around the world, calls on governments and other stakeholders to support pharmacists and their teams as key partners in this global health crisis so that people can continue to count on pharmacists in the weeks and months to come.

https://www.fip.org/files/content/publications/2020/FIP-call-to-action-to-support-pharmacists-and-pharmacy-workers-on-the-coronavirus-COVID-19-frontline.pdf?fbclid=IwAR2cgjwprRDR_0EHV5Ixs4PpgTL4LiS9RIYiqswvsbzx4If7YA09P8KHBXM
September, 2020

Additional Issue Areas of Consideration

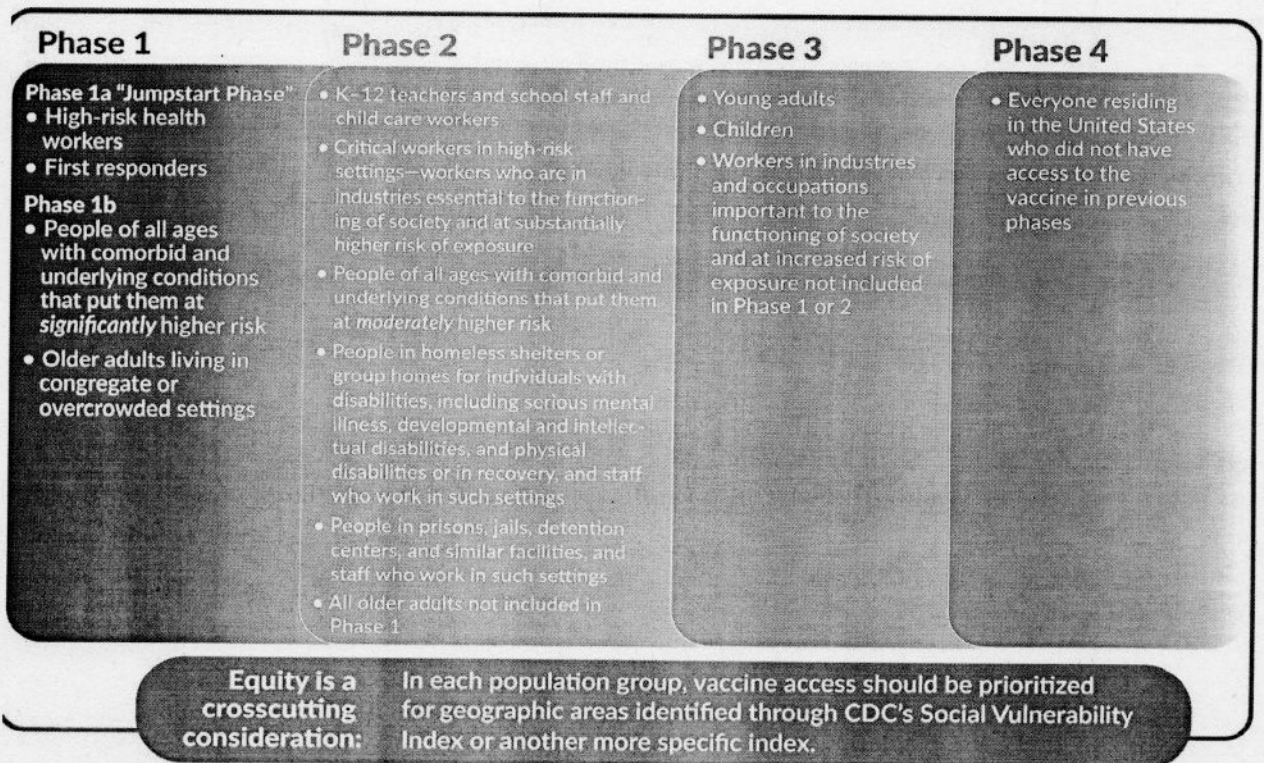
1. Safety of pharmacists working in various areas/environments
2. Triaging of various services offered by pharmacists involved in different work settings
3. Deployment strategies for pharmacists on the field
4. Recognition of pharmacists as health services providers by various Non-Governmental and Governmental organizations
5. Issues with respect to willingness and consent from pharmacists to provide their services
6. Confidentiality issues for and from the pharmacist in their relationship with patients and other providers
7. support and availability of special allowances for special duty, including access to protective equipment
8. In case of death or serious injury, what should be the support provided to family of the deceased or injured?
9. Logistics and transportation of material (medications and other materials required for appropriate dispensing and patient education) in a safe and confidential manner

Guidelines on Pharmacy Ethics Related to the Covid-19 Pandemic Based on Core Ethical Principles: Version 1.0



10. Leadership and leadership training and development for various roles and organized efforts related to patient care and provision of pharmacist's professional services

In so far as fair and equitable allocation of a vaccine against the COVID-19 virus is concerned, we incorporate into this narrative what has been developed by the National Academy of Medicine of the National Academy of Sciences in the United States. The priority scheme is offered below:



National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for equitable allocation of COVID-19 vaccine*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25917>.

Appendix I Suggested Readings

Sin, JH, Richards, II, and Ribisi, MS, Maintaining Comprehensive Pharmacy Services During a Pandemic: Recommendations from a Designated COVID-19 Facility, *Am J Health-Syst Pharm*, 77:18, September 15, 2020, pp. 1522-1528.

Wallis, N, et al. Frontline Pharmacist. Implementation of Field Hospital Pharmacy Services During the COVID-19 Pandemic, *Am J Health-Syst Pharm*, 77:19, October 1, 2020, pp. 1547-1551.

Lat, I, et al. Position Paper on Critical Care Pharmacy Services: 2020 Update, *Am J Health-Syst Pharm*, 77:19, October 1, 2020, pp. 1619-1624.

International Pharmaceutical Federation, FIP Statement of Policy: The Role of the Pharmacist in Promoting Patient Safety, The Hague, The Netherlands, 2020.

International Pharmaceutical Federation, FIP Statement of Policy: Sustainability of Pharmacist-Delivered Professional Services Through Viable Remuneration Models, The Hague, The Netherlands, 2020

Rees, H, Is COVID-19 the Long Overdue Wake-Up Call for Pharma Supply Chains?, *Industrial Pharmacy*, 66, September 2020, pp 9-12.