We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists



185,000

200M



Our authors are among the

TOP 1% most cited scientists





WEB OF SCIENCE

Selection of our books indexed in the Book Citation Index in Web of Science™ Core Collection (BKCI)

# Interested in publishing with us? Contact book.department@intechopen.com

Numbers displayed above are based on latest data collected. For more information visit www.intechopen.com



# Chapter

# Good Pharmacy Practice in India: Its Past, Present and Future with Need and Status in COVID 19

Mrinmoy Roy

# Abstract

The pandemic of COVID-19 has highlighted the importance of emergency preparedness and response (EP and R) in India's education, training, capacity building, and infrastructure growth. Healthcare professionals, especially pharmacy professionals (PPs) in India, continued to provide drugs, supplies, and services during the pandemic. The public-private healthcare system in India is complicated and of varying quality. Patients face problems as a result of gaps in pharmacy practice education and training, as well as a lack of clarity about pharmacists' positions. Job requirements and effective placement of healthcare professionals in patient care, as well as on (EP and R) task forces or policy representation, are complicated by this lack of distinction. We have also seen malpractice and spurious distribution in the healthcare and pharmaceutical domain in terms of personal protective kits, medications, injectable, life-saving oxygen, and other items during this unprecedented pandemic situation. A few of the incidents are as follows. The central division police in Bangalore (the Global BPO & IT Hub of India) booked a case of bed-blocking at a private hospital and arrested three people, one of whom is an Arogya Mitra (primary contact for the beneficiaries at every empaneled hospital care provider), for allegedly extorting ₹1.20 lakh from the son of a COVID-19 patient who later passed away. At least 178 COVID-19 patients in India have died because of oxygen shortage in recent weeks. Another 70 deaths have been attributed to an oxygen shortage by patients' families, but this has been denied by the authorities. The Allahabad High court made a remark "Death of COVID patients due to non-supply of oxygen not less than genocide" on reports circulating on social media regarding the death of COVID-19 patients due to lack of oxygen in Lucknow and Meerut. A day ago, the Delhi police busted an industrial manufacturing unit in Uttarakhand's Kotdwar where fake Remdesivir injections were being manufactured and arrested five people. These depict the ground reality and ethical standards of good pharmacy practice in this country. There is an utmost necessity to relook and re-establish the standards of pharmacy practice in healthcare setups available in each and every corner of the country in line with guidelines provided by the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP). For that, the dependency and responsibilities are very high on healthcare professionals, particularly in this pandemic situation. The pharmacy zone is

adaptable, evolving, and increasingly diverse, offering a wide range of work and management opportunities to execute. PPs are human service professionals whose responsibilities include safeguarding individuals by dispensing medications based on prescriptions. Representing the world's third-largest medicinal services with active gathering, and in India, there are over 1,000,000 (1 million) enrolled PPs employed in various capacities and readily contributing to the country's well-being. Pharmacy practice, which includes clinical, community, and hospital pharmacy, is referred to as total healthcare in its true sense. Through adaptation and implementation of GPP in healthcare setup, PPs form an essential link between physicians, nurses, and patients in the social community group, with an ultimate emphasis on patient well-being and protection. To instill quality and raise the standard in this chaotic situation there are strict measures required in the country. The International Pharmaceutical Federation and World Health Organization define good pharmacy practice (GPP) as practices that meet the personal needs of patients or those using pharmacy services by offering appropriate evidence-based care. In developed countries, pharmaceutical assistance is defined as a pharmaceutical practice model that involves attitudes, ethical values, behaviors, skills, appointments, and coresponsibility to prevent diseases, promote and recovery health in an integrated manner as part of the healthcare process, highlighting, among other, the requirement that the institution fully adopts the GPP. There is a need for a GPP Program designed by the Indian Govt. or its stakeholders in the context of the Indian healthcare system and adopting "new normal" due to the unprecedented event of COVID 19 and also raising the standard and importance of GPP for the healthcare professionals in the current scenario.

**Keywords:** GPP in India, healthcare scams in India, scams during COVID-19, healthcare malpractices in India

# 1. Introduction

The COVID-19 pandemic has brought attention to the necessity of emergency preparedness and response (EP&R) in India's education, training, capacity building, and infrastructure development. During the pandemic, healthcare workers, particularly pharmacy professionals (PPs) in India, continued to deliver medication, supplies, and services. In India, the public-private healthcare system is complex and of variable quality. Gaps in pharmacy practice education and training, as well as a lack of understanding about pharmacists' roles, cause complications for patients. This lack of difference complicates job requirements and successful placement of healthcare professionals in patient care, EP&R task forces, and policy representation. During this unprecedented pandemic situation, we have also observed malpractice and bogus distribution in the healthcare and pharmaceutical arena in terms of personal protective kits, medications, injectable, life-saving oxygen, and other products. The following are a few of the incidents. The central division police in Bangalore (India's Global BPO & IT Hub) filed a complaint of bed-blocking at a private hospital and arrested three people, one of whom is an Arogya Mitra (primary contact for beneficiaries at every empaneled hospital care provider), for allegedly extorting Rs. 1.20 lakh from the son of a COVID-19 patient who later died. In the last few weeks, at least 178 COVID-19 patients in India have died due to a lack of oxygen. Another 70 deaths have been linked by patients' families to a lack of oxygen, though this has been refuted by authorities. "Death of COVID patients due to non-supply of oxygen not less than genocide," the Allahabad High Court ruled in response to reports spreading on social media regarding the

death of COVID-19 patients in Lucknow and Meerut due to a shortage of oxygen [1]. Five persons were arrested after the Delhi police raided an industrial manufacturing site in Uttarakhand's Kotdwar, where duplicate Remdesivir injections were being made. This reflects the reality of Good Pharmacy Practice in this country, as well as the ethical norms that apply to it. It is critical to re-evaluate and re-establish pharmacy practice standards in healthcare settings throughout the country, in accordance with World Health Organization (WHO) and International Pharmaceutical Federation (FIP) principles. As a result, healthcare workers have a great deal of reliance and responsibility, especially in current pandemic circumstances. The pharmacy zone is adaptive, growing, and becoming more diverse, providing a comprehensive range of job and management opportunities [2]. PPs are human service professionals tasked with keeping people safe by distributing drugs according to prescriptions. In India, there are about 1,000,000 (1 million) enrolled PPs working in diverse capacities and contributing to the country's well-being, making it the world's third-largest medical service with active gathering. In its real definition, pharmacy practice, which encompasses clinical, community, and hospital pharmacy, is referred to as overall healthcare. PPs form a crucial link between physicians, nurses, and patients in the social community group through the adaptation and application of GPP in healthcare settings, with the ultimate emphasis on patient well-being and protection. In order to instill quality and elevate the standard in this chaotic scenario, the country must take stringent steps. Good pharmacy practice (GPP) is defined by the International Pharmaceutical Federation and the World Health Organization as practices that fulfill the individual requirements of patients or people who use pharmacy services by providing adequate evidencebased care. Pharmaceutical assistance is defined in developed countries as a pharmaceutical practice model that includes attitudes, ethical values, behaviors, skills, appointments, and co-responsibility to prevent diseases, promote, and recover health in an integrated manner as part of the healthcare process, highlighting, among other requirements, the institution's full adoption of the GPP. In the context of the Indian healthcare system and adopting a "new normal" due to the unprecedented event of COVID-19, there is a need for a GPP program designed by the Indian Government or its stakeholders, as well as raising the standard and importance of GPP for healthcare professionals in the current scenario.

India is a developing country in southern Asia with 29 states and seven union territories, 22 nationally recognized languages, and a population of 1.38 billion. India is a rural country with an agriculture-based economy, with rural areas accounting for over 75% of the population. In recent decades, India's average income has risen dramatically, resulting in growing urbanization, improved middleclass access to a better lifestyle, and increasing awareness of health insurance. Male and female literacy rates have climbed to 82% and 65%, respectively. According to reports, the average life expectancy is 69.9 years [3]. According to World Bank research from 2020, about 400 million Indians live on less than \$1.25 a day, and 44% of children are hungry. Even though the government has taken attempts to reduce baby and maternal death rates, they remain high. Ancient Hindus acknowledged pharmacy as a complementary healing profession, and they specialized in vegetable treatments. Vedic and Brahmanic medicine were the two periods of Hindu medicine. The Vedic period or Vedic age (c.1500-c.500 BCE), and was a rudimentary period. During the Vedic period, sin was thought to be a major source of disease. Between 800 BC and 1000 AD, the Brahmanic period was a high-quality time for Hindu medical education. The works of Charaka, Susruta, and Vagbhat, which are based on ancient Vedic themes, are the three great masterpieces of Brahmanic medicine [4]. The origins of pharmacy in India can be traced back to Ayurveda, which dates to 5000 BC. Lord Brahma initially taught Ayurveda, or "life

science," which was further transmitted by Charaka and Sushruta [5]. The Charaka Samhita, early work on Ayurveda, focuses on vegetable goods as well as some animal and earth goods. The classification of medications in this book is based on how they affect different bodily parts [4]. In 900 AD, Tamilnadu established a hospital to treat piles, jaundice, bleeding, and tuberculosis [5]. Tantrism was a prominent philosophical and religious movement that emerged in India after the downfall of Buddhism; it brought the art and science of the production of metallic compounds, particularly mercury and sulfur, to the fore [4]. In 1811, Scotch M. Bathgate built the first chemist shop in Calcutta, which is regarded as the birthplace of pharmacy practice in India. In December 1860, Madras Medical School began pharmacy instruction, enrolling students with only middle school education; the pharmacy degree was 2 years long. Madras Medical College (MMC), Chennai, established the diploma course in pharmacy in 1874. The Bengal Chemists and Druggists Association was founded in 1926 after the Calcutta Chemists and Druggists Association was founded in 1920. The first issue of the official Indian Journal of Pharmacy was published in 1939. In 1868, the British monarchy released the first Indian pharmacopeia. In 1881, a formal provision for the education and examination of compounders was established in Bengal. In 1920 and 1940, master's degrees in pharmaceutics and applied chemistry were introduced, respectively. Gorakh Prasad Srivastava was the first postgraduate pharmacy student to complete the degree in 1943. In 1945, the first steps toward standardizing pharmacy education were taken. The first annual conference of the Indian Pharmaceutical Congress Association was held in 1948. The Pharmaceutical Association was India's first pharmaceutical society, founded in 1923 and renamed The Pharmaceutical Society of India after 2 years. In 1949, a West Bengal institute introduced a Diploma in Pharmacy, and the Pharmacy Council of India (PCI) approved the diploma as the minimal prerequisite for beginning pharmacy practice in 1953. In 1954, Prof. M.L. Schroff, known as the "Father of Pharmacy in India," was elected president of the PCI.

# 2. Health statistics

Many issues face India's healthcare system, including the need to lower mortality rates, enhance physical infrastructure, provide health insurance, and train healthcare experts and workers. A rise in communicable diseases, lifestyle diseases, and noncommunicable diseases has been recorded. Diseases such as poliomyelitis, leprosy, and newborn tetanus will be eradicated; nevertheless, certain previously controlled infectious diseases, such as dengue fever, viral hepatitis, tuberculosis, malaria, and pneumonia, have resurfaced or developed medication resistance.

Even though Indians are now more affluent as a result of the rise of the middle class, their eating habits have shifted dramatically to unhealthy, high-sugar, highfat diets, leading to an increase in lifestyle diseases such as hypertension, cancer, and diabetes. Furthermore, India's healthcare institutions and services would be burdened by the expanding older population.

Due to a dearth of hospital beds and skilled medical personnel such as doctors, nurses, and pharmacists, the people do not have access to their medical needs. In comparison to urban areas, healthcare services are much scarcer in rural communities. Females have an adversely skewed proportion in the healthcare workforce when compared to males. In the 11th five-year plan, total healthcare expenditure (comprising state funds, private funds, and external flows) accounted for 4.1% of GDP (GDP). The 12th five-year plan (2012–2017) intends to raise public health spending from 1.1% of GDP to 2–3% of GDP [6].

## 3. A look at the healthcare system as a whole

The state is responsible for the healthcare system. This system is currently managed by both public and private (for profit and nonprofit) groups. Policymaking, planning, guiding, aiding, reviewing, and coordinating the activities of various provincial health authorities are all responsibilities of the federal government, as is providing financing to implement national healthcare initiatives [7]. Allopathic hospitals, hospital beds, Indian System of Medicine and Homeopathy hospitals, subcenters, Pharmacy Health Care (PHC), Community Health Center (CHC), blood banks, Eye Bank, psychiatric hospitals, and cancer hospitals are all part of India's healthcare infrastructure [7]. The Department of Ayurveda, Yoga, and Naturopathy, as well as Unani, Siddha, and Homeopathy, provide medical and healthcare services (AYUSH). The ownership of the public sector is split between the federal and state governments, municipalities, and panchayats (local governments). Dispensaries, primary health centers, subcenters, and health posts are among the facilities. Teaching hospitals, secondary-level hospitals, first-level referral hospitals (community health centers/rural hospitals), dispensaries, primary health centers, subcenters, and health posts are among the facilities. Public facilities for specific occupational groups are also included, including organized labor (Employees State Insurance Scheme), defense, government employees (Central Government Health Scheme), railways, post and telegraph, and mining, to name a few. The private sector (profit/nonprofit) is the most prevalent, with services ranging from >1000 beds to two beds. Health-related facilities are available through the federal government healthcare program in 25 cities, with 246 allopathic dispensaries [7]. Private healthcare providers are currently treating 78% of outpatients and 60% of inpatients in India. Private healthcare providers range from world-class hospitals that promote medical tourism by providing world-class treatments to international clients and Indians who can afford it to private doctors who have minimal medical expertise or formal training on the other end of the spectrum. Furthermore, the private sector controls 80% of doctors, 26% of nurses, and 49% of hospital beds, demonstrating its power.

# 4. The country's hospitals

In contrast to India, the number of hospitals in other nations is not given. However, according to World Bank statistics, available at https://data.worldbank. org/indicator/SH.MED.BEDS.ZS India's accessible beds per 1000 population is lower than that of a lot of other countries. As a state of concern, public health and hospitals are largely responsible for the upkeep, providing health treatment to individuals, and maintaining hospital information. However, the following details are provided below:

- i. Number of Primary Health Centers (PHCs), Community Health Centers (CHCs), Sub-District/Divisional Hospitals (SDHs), District Hospitals (DHs), and beds in India, by State/UT, as uploaded by the States/UTs on the Ministry's Health Management Information System (HMIS) portal.
- ii. Number of government hospitals and beds in rural and urban areas in India, broken down by state/UT, as published in National Health Portal 2018.
- iii. The Ministry of AYUSH provides information on the number of AYUSH hospitals and beds in each state/UT.

- iv. Total and state-by-state number of hospitals and beds maintained by the Ministry of Defense.
- v. Number of railway hospitals and beds, as reported in the National Health Portal 2018 publication.
- vi. Number of State Insurance Corporation employees, hospitals, and beds, per state/UT, and total, as published in the National Health Portal 2018.

# State/UT–wise number of PHCs, CHCs, SDHs, DHs, and beds in the country.

State/UT	No. of public facilities					No. of beds available in
	PHC	CHC	SDH	DH	Total	public facilities
Andaman & Nicobar Islands	27	4		3	34	1246
Andhra Pradesh	1417	198	31	20	1666	60,799
Arunachal Pradesh	122	62		15	199	2320
Assam	1007	166	14	33	1220	19,115
Bihar	2007	63	33	43	2146	17,796
Chandigarh	40	2	1	4	47	3756
Chhattisgarh	813	166	12	32	1023	14,354
Dadra & Nagar Haveli	9	2	1	1	13	568
Daman & Diu	4	2		2	8	298
Delhi	534	25	9	47	615	20,572
Goa	31	4	2	3	40	2666
Gujarat	1770	385	44	37	2236	41,129
Haryana	500	131	24	28	683	13,841
Himachal Pradesh	516	79	61	15	671	8706
Jammu & Kashmir	702	87		29	818	11,342
Iharkhand	343	179	13	23	558	7404
Karnataka	2547	207	147	42	2943	56,333
Kerala	933	229	82	53	1297	39,511
Lakshadweep	4	3	2	1	10	250
Madhya Pradesh	1420	324	72	51	1867	38,140
Maharashtra	2638	430	101	70	3239	68,998
Manipur	87	17	1	9	114	2562
Meghalaya	138	29		13	180	4585
Mizoram	65	10	3	9	87	2312
Nagaland	134	21		11	166	1944
Odisha	1360	377	27	35	1799	16,497
Puducherry	40	4	5	4	53	4462
Punjab	521	146	47	28	742	13,527
Rajasthan	2463	579	64	33	3139	51,844

State/UT	N	lo. of p	No. of beds available in				
	РНС	CHC	SDH	DH	Total	public facilities	
Tamil Nadu	1854	385	310	32	2581	72,616	
Telangana	788	82	47	15	932	17,358	
Tripura	114	22	12	9	157	4895	
Uttar Pradesh	3277	671		174	4122	58,310	
Uttarakhand	275	69	19	20	383	6660	
West Bengal	1374	406	70	55	1905	51,163	
All India	29,899	5568	1255	1003	37,725	739,024	

# India, State/UT wise number of government hospitals and beds in rural and urban areas.

States/UTs	Rural	hospitals	Urbar	n hospitals	As on
	No.	Beds	No.	Beds	
Andhra Pradesh	193	6480	65	16,658	01.01.2017
Arunachal Pradesh*	208	2136	10	268	31.12.2017
Assam	1176	10,944	50	6198	31.12.2017
Bihar	930	6083	103	5936	31.12.2016
Chhattisgarh	169	5070	45	4342	01.01.2016
Goa*	17	1405	25	1608	31.12.2017
Gujarat	364	11,715	122	20,565	31.12.2016
Haryana*	609	6690	59	4550	31.12.2016
Himachal Pradesh*	705	5665	96	6734	31.12.2017
Jammu & Kashmir	56	7234	76	4417	30.12.2016
Jharkhand	519	5842	36	4942	31.12.2015
Karnataka*	2471	21,072	374	49,093	31.12.2017
Kerala	981	16,865	299	21,139	01.01.2017
Madhya Pradesh	334	10,020	117	18,819	01.01.2016
Maharashtra	273	12,398	438	39,048	31.12.2015
Manipur	23	730	7	697	01.01.2014
Meghalaya*	143	1970	14	2487	31.12.2017
Mizoram*	56	604	34	1393	31.12.2017
Nagaland	21	630	15	1250	31.12.2015
Odisha*	1655	6339	149	12,180	31.12.2017
Punjab*	510	5805	172	12,128	31.12.2017
Rajasthan	602	21,088	150	10,760	31.12.2016
Sikkim*	24	260	9	1300	31.12.2017
Tamil Nadu*	692	40,179	525	37,353	31.12.2017
Telangana*	802	7668	61	13,315	31.12.2017

States/UTs	Rural h	ospitals	Urbar	n hospitals	As on
	No.	Beds	No.	Beds	
Tripura*	99	1140	56	3277	31.12.2017
Uttar Pradesh*	4442	39,104	193	37,156	31.12.2017
Uttarakhand	410	3284	50	5228	31.12.2015
West Bengal	1272	19,684	294	58,882	01.01.2015
Andaman & Nicobar Islands	27	575	3	500	31.12.2016
Chandigarh	0	0	4	778	31.12.2016
Dadra & Nagar Haveli*	10	273	1	316	31.12.2017
Daman & Diu	5	240	0	0	31.12.2015
Delhi	0	0	109	24,383	01.01.2015
Lakshadweep	9	300	0	0	01.01.2016
Puducherry	3	96	11	3473	01.01.2016
INDIA	19,810	279,588	3772	431,173	

Source: National Health Profile 2018/Directorate General of State Health Services.

Notes: Government hospitals include central government, state government, and local govt. bodies. Figures are provisional.

\*States/UTs provided information for the year 2017 and PHCs are also included in the number of hospitals.

# State-wise distribution of AYUSH hospitals and beds as on 1-4-2017.

Srl no.	State/UT	Ν	umber o	f hospital	S		Number	of beds	
		Govt.	Local Body	Others	Total	Govt.	Local Body	Others	Total
1	Andhra Pradesh	8	0	0	8	365	0	0	365
2	Arunachal Pradesh	11	0	1	12	100	0	25	125
3	Assam	4	0	0	4	205	0	0	205
4	Bihar	8	0	0	8	950	0	0	950
5	Chhattisgarh	7	0	8	15	370	0	470	840
6	Delhi	4	0	1	5	390	0	210	600
7	Goa	0	2	0	2	0	150	0	150
8	Gujarat	35	29	0	64	1495	1763	0	3258
9	Haryana	4	0	7	11	145	0	600	745
10	Himachal Pradesh	34	0	0	34	710	0	0	710
11	Jammu & Kashmir	2	0	0	2	75	0	0	75
12	Jharkhand	1	4	0	5	50	300	0	350
13	Karnataka	156	0	57	213	2455	0	7740	10,195
14	Kerala	162	0	0	162	4054	0	0	4054
15	Madhya Pradesh	23	0	0	23	690	0	0	690
16	Maharashtra	5	0	66	71	812	0	8024	8836
17	Manipur	10	0	0	10	0	0	0	0
18	Meghalaya	10	0	0	10	100	0	0	100

Srl no.	State/UT	N	lumber o	f hospital	s	Number of beds			
		Govt.	Local Body	Others	Total	Govt.	Local Body	Others	Total
19	Mizoram	2	0	0	2	100	0	0	100
20	Nagaland	2	0	0	2	10	0	0	10
21	Odisha	9	0	5	14	593	0	310	903
22	Punjab	5	0	4	9	100	0	108	208
23	Rajasthan	137	0	0	137	1391	0	0	1391
24	Sikkim	1	0	0	1	10	0	0	10
25	Tamil Nadu	293	0	0	293	2381	0	0	7 2381
26	Tripura	4	0	0	4	60	0	0	60
27	Uttar Pradesh	2315	0	1	2316	11,361	0	100	11,461
28	Uttarakhand	404	0	1	405	2023	0	50	2073
29	West Bengal	11	0	11	22	530	0	620	1150
30	Andaman & Nicobar Islands	5	0	0	5	90	0	0	90
31	Chandigarh	0	0	2	2	0	0	80	80
32	Dadra &Nagar Haveli	0	0	0	0	0	0	0	0
33	Daman &Diu	2	0	0	2	20	0	0	20
34	Lakshdweep	0	0	0	0	0	0	0	0
35	Puducherry	0	0	0	0	0	0	0	0
36	Telangana	20	0	0	20	841	0	0	841
	Total (A)	3694	35	164	3893	32,476	2213	18,337	53,026
	S & central nent organizations	50	0	0	50	2216	0	0	2216
	Total (A+B)	3744	35	164	3943	34,692	2213	18,337	55,242

Source: Ministry of AYUSH.

# Number of hospitals and beds maintained by Ministry of Defense, State wise.

S. no.	Name of state	No. of hospitals	No. of beds
1	Assam	8	2357
2	Andhra Pradesh	1	306
3	Andaman & Nicobar Islands	1	107
4	Arunachal Pradesh	1	198
5	Bihar	2	348
6	Delhi	2	1993
7	Goa	2	175
8	Gujarat	5	666
9	Haryana	3	1458
10	Himachal Pradesh	6	699

		No. of hospitals	No. of beds
11	Jammu & Kashmir	11	2643
12	Jharkhand	2	649
13	Karnataka	3	1090
14	Kerala	5	744
15	Madhya Pradesh	7	1402
16	Maharastra	11	4202
17	Manipur		74
18	Meghalaya	1	247
19	Nagaland	2	398
20	Odisha	2	147
21	Punjab	10	2990
22	Rajasthan	11	2115
23	Sikkim	2	247
24	Tamil Nadu	3	373
25	Telangana	3	764
26	Tripura	1	49
27	Uttarakhand	5	1402
28	Uttar Pradesh	15	4570
29	West Bengal	7	2107
	Total	133	34,520
rce: Ministry of I			

# Number of hospitals and beds in railways (as on 21/03/2018).

S. no.	Zone/PU	Total no. of hospitals	Total no. of indoor beds
1	Central Railway	11	1164
2	Eastern Railway	8	1587
3	East central Railway	9	819
4	East coast Railway	4	339
5	Northern Railway	9	1101
6	North Central Railway	5	586
7	North East Railway	6	927
8	North East Frontier Railway	10	1107
9	North Western Railway	8	584
10	Southern Railway	10	1131
11	South Central Railway	7	714
12	South Eastern Railway	6	1086
13	South East Central Railway	5	250
14	South Western Railway	3	300
15	Western Railway	9	976

S. no.	Zone/PU	Total no. of hospitals	Total no. of indoor beds
16	West Central Railway	7	456
17	Intergral Coach Factory	1	101
18	Rail Coach Factory	1	60
19	Chittaranjan Locomotive Works	1	197
20	Diesal Locomotive Works	1	105
21	Diesel Loco Modernisation Works	1	50
22	Rail Wheel Factory		46
23	Research Design and Standards Organization	1	30
24	Metro/Kolkata	1	30
25	MCF/Raibareli	1	2
26	Total	126	13,748

# Employees State Insurance Corporation hospitals and beds (as on 31.03.2017).

S. no.	States/UTs	Total no. of hospital	Total no. of beds
1	Andhra Pradesh	5	345
2	Assam	1	75
3	Bihar	3	50
4	Chandigarh [Adm.]	1	70
5	Chhattisgarh	0	0
6	Delhi	4	1416
7	Goa	1	15
8	Gujarat	12	910
9	Himachal Pradesh	2	150
10	Haryana	7	781
11	Jammu & Kashmir	1	50
12	Jharkhand	3	210
13	Karnataka	11	1675
14	Kerala	12	1178
15	Madhya Pradesh	7	725
16	Meghalaya	0	0
17	Maharashtra	13	2390
18	Nagaland	0	0
19	Odisha	6	325
20	Puducherry	1	75
21	Punjab	8	647
22	Rajasthan	6	495
23	Sikkim	0	0

S. no.	States/UTs	Total no. of hospital	Total no. of bed
24	Tamil Nadu	10	1856
25	Telangana	7	907
26	Tripura	0	0
27	Uttar Pradesh	16	1886
28	Uttarakhand	0	0
29	West Bengal	14	3534
	Total	151	19,765
Source: National	Health Profile 2018.		

# 5. Core pharmacy practices

# 5.1 Hospital pharmacy

The hospital pharmacy is one of the most important departments in the hospital, and it is responsible for drug procurement, storage, compounding, dispensing, manufacturing, testing, packaging, and distribution. This section is also in charge of pharmaceutical science and education research, which is carried out by skilled and knowledgeable pharmacists. The hospital pharmacy has a significant impact on healthcare cost economics. In today's hospital pharmacy, medication monitoring and drug information services are combined. Purchasing, storing, handling, pricing, and dispensing pharmaceuticals are all skills that a hospital pharmacist possesses. In addition, pharmacists give drug information to all healthcare professionals and the public, as well as serve as a link between the patient and the doctor. The criteria for acquiring pharmaceuticals, chemical and biological medications, and other items are provided by hospital pharmacists. They are also in charge of manufacturing and distributing pharmaceuticals like transfusion fluids, parenteral goods, pills, capsules, ointments, stock combinations, and safe drug storage. Hospital pharmacists can sterilize and dispense parenteral drugs made in hospitals. They fill, label, and distribute all medicine packages. Hospital pharmacists oversee purchasing pharmaceuticals, ensuring correct drug storage conditions, keeping records, and distributing pharmaceuticals to the outpatient department. In addition, hospital pharmacists provide drug monitoring services for inpatients and participate in hospital research programs [8]. Due to low wages, the hospital parts of a pharmacist's job have historically been overlooked in India; also, pharmacists have never been trained for a patient-centered role. Medical practitioners have never embraced pharmacists for clinical functions, while pharmacists have been hesitant to accept their profession's clinical obligations. Many Indian hospitals have begun to assign pharmacists a clinical role, with encouraging outcomes, but India still lags behind other countries in this regard. In India, the concept of a hospital pharmacy is confined to the dispensing of medications at hospital pharmacies [9].

Hospital pharmacies require certain personnel.

The dispensing, manufacturing, quality assurance, and clinical pharmacy services are all integrated within the hospital pharmacy. Personnel requirements for an inpatient pharmacy are determined by the nature and scope of services supplied by the department. The number of hospital pharmacists required is determined by the workload and the number of beds in the hospital. Small hospitals typically require a minimum of three pharmacists; however, this varies depending on the number of

beds. **Table 1** shows the number of pharmacists necessary based on the number of beds in a hospital [8].

According to 2011 data, the number of government hospital beds in rural and urban locations is shown in **Table 2**.

Personnel who work in hospital pharmacies must be knowledgeable and welltrained. The director of the pharmacy must have a postgraduate degree in hospital pharmacy, pharmacology, or pharmaceutics and serves as a liaison between pharmacy and non-pharmacy personnel. The hospital pharmacy's structure is depicted in the Flowchart below (**Figure 1**).

Even we have seen the present status, there were no significant improvements.

# 5.2 Community pharmacy

In India, the Pharmacy Act of 1948 was passed to ensure that every practicing pharmacist had a registration certificate [11–13]. On completion of the minimum diploma in pharmacy, educational institutes authorized by the PCI can grant this

Pharmacist requirement	
Bed strength	No. of pharmacists required
Up to 50 beds	3
Up to 100 beds	5
Up to 200 beds	8
Up to 300 beds	10
Up to 500 beds	15

#### Table 1.

Pharmacist requirement in hospitals.

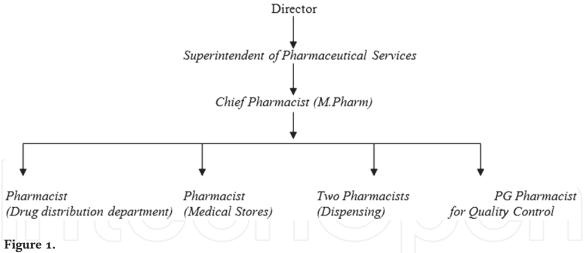
State	Rural hospital beds (government)	Urban hospital beds (government)	Total beds (government)	Proportion of rural and urban beds
Bihar	1830	16,686	18,516	10:90
Chhattisgarh	3270	6158	9428	35:65
Jharkhand	N.A.	N.A.	N.A.	N.A.
Madhya Pradesh	10,040	18,493	28,533	35:65
Odisha	7099	8715	15,814	45:55
Rajasthan	13,754	12,236	25,990	53:47
Uttar Pradesh	15,450	40,934	56,384	27:73
Uttarakhand	3746	4219	7965	47:53
EAG states	55,189	107,477	162,630	34:66
Non-EAG states	114,673	511,187	622,310	18:82
All India	169,862	618,664	784,940	20.5:79.5

N.A., not available.

Source: GOI, Table 6.2.2 State/UT wise number of govt. hospitals and beds in rural and urban areas (including CHCs) in India (provisional), in "Health infrastructure" in "National Health Profile, 2011," Central Bureau of Health Intelligence, Ministry of Health and Family Welfare, 2011.

#### Table 2.

State and union territory wise number hospitals and beds in rural and urban areas in India.



Organization structure of hospital pharmacy. Source: Nahata [10].

credential. A pharmacy diploma involves at least 2 years of education and 500 h of practical training, including three months in a community or hospital pharmacy [11]. These pharmacists with a diploma represent most of the workforce and run most community pharmacies in India today. A bachelor's degree in pharmacy is designed to meet the needs of the pharmaceutical business, with most graduates working in pharmaceutical companies or regulatory agencies. In comparison to community pharmacy, many B. Pharm graduates prefer to work in the pharmaceutical business because of the higher pay scale and other benefits.

In practice, these pharmacists with a diploma or bachelor's degree are still unheard of in half of the community pharmacies. Most patients come to community pharmacists for help on sexually transmitted diseases, minor ailments, contraceptive options, and menstruation issues [11]. The majority of community pharmacies are administered by people with minimal awareness of health issues or medical training, and pharmacists are hired on low pay rates. Most pharmacists in community pharmacies lack counseling abilities and are simply able to deliver medications. Despite the public's negative opinion of pharmacists and the idea that pharmacies are like grocery stores, community pharmacies remain the principal provider of low-cost medical treatment.

#### 5.3 Medicine promotion and marketing

In India nowadays, the average cost of a prescription per patient who visited a private clinic is around 1000–1500 rupees, and the number of prescriptions per drug has increased. The marketing efforts of pharmaceutical companies have a significant impact on doctors' prescribing patterns. Pharmaceutical companies spend less on R&D than they do on marketing. Medical representatives are trained by pharmaceutical companies to advertise and sell pharmaceuticals utilizing printed product materials, medicine samples, and gifts. Around 80,000 medical representatives are hired by pharmaceutical companies in India, and they are paid well.

In addition to their pay, they are offered significant incentives. General practitioners have been found to prescribe new products under the influence of sales reps. Furthermore, medical representatives promote medications by stating more indications than are officially registered.

One of the main tools used by pharmaceutical firms to advertise their medication is gifts (ranging from a table-top reminder to an air conditioner), gratification, foreign excursions, pleasure excursions, and so on. From clocks to air conditioners, calendars to cars, rubber bands to refrigerators, telephone indexes to television, and office items to overseas trips, the variety of gifts includes stationery, timepieces,

bags, books, folders, office desks, medical supplies, and household items—from clocks to air conditioners, calendars to cars, rubber bands to refrigerators, telephone indexes to television, and office items to overseas trips. According to Chren and associates, there is an implicit relationship between doctors and the pharmaceutical industry, which leads to a responsibility to respond to gifts [14].

Advertising has a significant role in the marketing of medicine. Pharmaceutical companies spend a lot of money to advertise in medical and pharmaceutical magazines, which are read by a lot of general practitioners and clinical specialists. Medical journals in India would perish if pharmaceutical companies did not advertise in them. The advertising of pharmaceuticals is strictly monitored, and if there is any false information, harsh action is taken. Drug information should be accurate, current, and balanced, according to the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and The Association of the British Pharmaceutical Industry (ABPI) guidelines. The IFPMA code must be followed by all members of the Organization of Pharmaceutical Producers of India (OPPI). Internal codes and promotional material for the pharmaceutical producers of India must be approved by medical advisers, according to the organization. A Promotional Quality Improvement and Assurance Committee also performs a thorough study of these promotional materials. Furthermore, this committee makes recommendations for marketing enhancements.

Irrational prescription and its consequences are heavily influenced by pharmaceutical marketing and promotional activities. The Medical Council of India has issued a new code of ethics for practitioners who receive any sort of compensation from pharmaceutical companies. New legislation in Rajasthan, India, states that a doctor must only put the generic name of a medicine on a prescription [14].

### 5.4 Pharmacy-related services and activities that are unique

With the advent of clinical pharmacy, which provides high-quality treatment and assistance to patients, a pharmacist's job has been expanded. Pharmacists now provide drug and toxicity information, manage anticoagulation clinics, and administer smoking cessation programs, among other things.

# 6. Education parameters of healthcare workforce

The paramedic education system has been supply-driven, with no regard for industry demand. Allied healthcare providers are the most crucial because, if a patient has a hundred interactions at a hospital, allied healthcare workers account for 80 of those encounters. In India, healthcare is the third most important source of employment. It is broken down into three categories: Doctors make up 10–15% of the healthcare workforce, nurses make up 20–25% of the workforce, and paramedics, also known as allied healthcare professionals or healthcare technicians, make up the largest segment of the healthcare workforce. The doctor-to-allied healthcare-professional ratio in India is 1:4. The advanced countries, such as the United States and the United Kingdom, have a 1:20 ratio. India already employs over 10 million allied healthcare workers, but to meet the 1:20 ratio, we will need to increase this number to 40–50 million in the next few years. Diagnostic, curative, and rehabilitative allied healthcare professions are categorized into three groups. The diagnostic and therapeutic industries in India have been expanding. Allied healthcare professionals such as X-ray technicians and medical app technicians work in diagnostic. Technicians such as OT technicians and emergency medical technicians work in Curative. The difficulty is that in India, only about 7% of

these allied healthcare professionals are certified because there was no centralized authority to certify them until the NSTC was established. Before NSTC, each state certified them at their own level, and the biggest problem today is for quality healthcare services, allied healthcare professionals are the most important because if a patient has a hundred interactions in a hospital, 80 of those interactions are with allied healthcare professionals, and the biggest challenge in India is that there are less than a hundred allied healthcare professionals. Until 2008, there was no centralized body. One of the most significant issues is that, in general, education in India has been supply-driven, with no connection to industry needs. As a result, when compared to worldwide norms, we are one of the least prepared for the workforce. What needs to be done is for education to be driven by demand. It must be presented from the standpoint of the company and how these individuals will work in the sector. To do so, we must recognize three factors—technical training, practical training, and soft skills and grooming training, all of which must be provided so that these individuals are prepared to fully contribute to the workforce in a productive manner when they enter the workforce. Mr. Narendra Modi, Prime Minister of India, believes that ongoing training of the workforce required to combat the COVID 19 crisis is critical. He recommended officials and doctors to hold training sessions and webinars, particularly for paramedics and doctors who work in rural areas. He also requested that the officials endeavor to reduce vaccination waste in the district. Interacting with Varanasi doctors and administrators via video chat Prime Minister Narendra Modi paid a heartfelt tribute to those who died because of COVID-19. He emphasized the necessity of ongoing training for those fighting COVID, advising officials and doctors to hold training sessions and webinars, particularly for paramedics and doctors functioning in remote areas. He also requested that the officials endeavor to reduce vaccination waste in the district. "Jahan Bimar Wahan Upchar," is the new slogan in COVID management in terms of delivering therapy to the patient's doorstep that will minimize the strain on the health system. The doctors from Varanasi updated the other doctors through video conference on the measures made in the last month to restrict the spread of COVID, vaccination status, and ongoing steps and strategies to prepare the district for future difficulties. They stated that they have been vigilant in their response to the threat of mucormycosis and have already taken action and established facilities to handle the condition. Our Prime Minister also praised the microcontainment zones project and praised the home distribution of medicines, and he urged health professionals to make the campaign as widespread as possible in rural areas. He praised the physicians, nurses, technicians, ward boys, ambulance drivers, and other Kashi frontline health professionals for their efforts. He praised the medical staff in Kashi for their efforts in controlling the pandemic to a large extent, but warned against complacency, urging them to fight a lengthy battle right now by focusing on the rural districts of Banaras and Purvanchal. PM emphasized the critical role of Accredited Social Health Activists (ASHAs) and Auxiliary Nursing Midwifery (ANMs) sisters in the ongoing village campaign against COVID-19 and urged health officials to use their potential and experience. The main reason is if the frontline employees had already been vaccinated, they were able to serve the people safely during the second wave. We need to encourage everyone to get the vaccine when it is their turn, that is what has currently been done.

# 7. International standards of good pharmacy practice

Diverse countries and continents, including emerging, transitional, and industrialized countries, have different pharmaceutical practices. The World Health

Organization (WHO)/International Pharmaceutical Federation (FIP) joint guideline of good pharmacy practice (GPP), which was updated in 2011, is meant to account for these changes in practice. The pharmacy profession is rapidly expanding, with new responsibilities being offered and announced not only by pharmacists but also by other medical professionals, national organizations, and institutions. The GPP's guideline is progressive and adaptable, and it must remain relevant when new positions develop. Standardizing many parts of pharmacies is one of the most important techniques of quality control for medications and pharmaceutical services for the public. The GPP Guide is a significant step toward bettering pharmacy services [12]. The GPP guideline is designed for use by national professional pharmaceutical associations, as well as national authorities and other relevant agencies responsible for drafting relevant documents and related laws and regulations in their countries, according to the WHO and FIP. It is not a clear national standard, but it does provide guidance on certain tasks, responsibilities, and actions that help pharmacists to fulfill their mission. Professional issues and attitudes are given specific attention throughout the guideline's content, and the patient's well-being is given priority. However, it should be noted that this is the first time that a legal, economic, and labor framework has been introduced in the context of the GPP structure, and it comes at an appropriate time given global debates on the economic aspects of medicines, access to quality medicines, access to skilled medical workers, the global workforce failure, the increased cost of medical care, and new models of healthcare [13]. The GPP is defined by the WHO and the FIP as a pharmacy practice that satisfies the needs of people who use pharmacists' services to deliver optimal medical care based on evidence-based medicine principles. To support this approach, a national framework of quality standards and guidelines is required. The goal of this project is to investigate the historical stages of development of GPP requirements, as well as to examine modern normative texts proposed by FIP for use in global pharmaceutical practice, as well as to investigate the current state of this issue around the world. The study included the generalization of information material and system analysis methods. The WHO and the FIP have been working together since the late 1980s to define pharmacist duties and functions, as well as produce guidelines for the GPP as a framework for pharmacological care. The WHO amended the medicines strategy, which was accepted by the World Health Assembly in 1986, and two meetings on the function of pharmacists were held in accordance with it. The inaugural meeting was held in Delhi, India, in 1988 [15]. The FIP produced criteria for pharmaceutical services in 1992, and the WHO Information Centers disseminated the approach of good pharmaceutical practice in March 1993. The standards of pharmacy services entitled "GPP in Public and Hospital Pharmacies" were officially issued during the convention in Tokyo, Japan [15]. Under the framework of the Tokyo declaration on quality standards of pharmaceutical services, the FIP congress accepted the FIP/GPP text. The FIP has asked pharmaceutical companies and governments to work together to implement GPP standards or to amend current national standards in countries where they currently exist, according to this paper. Then, in May 1994, the World Health Assembly adopted a resolution on the role of the pharmacist in support of the WHO's new pharmaceuticals strategy. In 1994, a version of the GPP was also presented to the WHO Expert Committee on Pharmaceutical Medicine Specifications in Geneva. In 1999, a joint document of the WHO/FIP of the GPP was published in a series of technical reports of the WHO Expert Committee on concerns of pharmaceutical medicine specification, following the recommendations of the WHO Expert Committee and the approval of the Board of the FIP in 1997. This gave the GPP more formal standing and assured that it was widely distributed around the world [16]. A Soon after, the WHO convened two more meetings on the

pharmacist's role, one in 1997 in Vancouver, Canada, and the other in 1998 in The Hague, Netherlands. These gatherings reinforced the necessity for reforming pharmacy education programs and highlighted the pharmacist's role in self-help and self-healing. The European Union's (EU) pharmaceutical group prepared a paper containing the GPP for Europe in 1998, with special emphasis dedicated to EU countries—"the GPP in Europe." [17]. The "GPP in the New Independent States" was established in 2001. The Copenhagen Center for Drug Policy and Development of Pharmaceutical Practice developed "Guidelines for the creation and implementation of standards" in Denmark. The document examined the state of pharmacy practice and focused on issues such as health education and morbidity prevention, the provision of prescription drugs and their use, self-treatment, the effects of prescription and use of drugs, as well as the method of implementing proper pharmacy practices in developing countries. The WHO experts recommended that European standards for pharmacies be implemented on a par with existing national standards to regulate various aspects of pharmaceutical activity, including the quality of prescription data received by the pharmacist, the development of medical forms, the building of contacts with doctors based on individual recipes, and the evaluation of data on the use of medical products [18]. There is a strategy for establishing national GPP standards, according to FIP recommendations. To begin, fundamental pharmaceutical services must be established, for which a regulatory framework and relevant standards must be created. The secondary and higher education systems in pharmacy should be revised after that because pharmacists will require a more in-depth understanding of pharmacotherapy, pharmacopeia, and communications skills. The provision of more complex professional pharmaceutical services is the ultimate stage. The FIP highlights GPP elements that demonstrate that the pharmacy provides high-quality service and adheres to strict guidelines: The presence of a zone in the pharmacy with information about healthy lifestyles; availability of a pharmacy for people with disabilities and elderly patients; availability of a comfortable waiting area; the possibility of a private conversation between a pharmacist and a patient, including those with disabilities; and the presence of a pharmacist on call. The pharmacist's responsibility in providing successful drug therapy, according to FIP's recommendations, is as follows: Management of therapy, monitoring of treatment success, and disseminating information on the safe and effective use of medications. The pharmacist should evaluate the client's health and needs, taking into consideration his unique qualities. Professional collaboration between the pharmacist and the doctor is an important part of GPP. Each patient's medical and pharmacological information (diagnosis and laboratory data) should be in the first one. It is also crucial to keep track of whether GPP standards are being followed. It can be internal and/or external; it can also be necessary or simply for accreditation/certification purposes. This will disclose the drawbacks of meeting GPP requirements as well as ideas for how to avoid them. One of the simplest ways to ensure that a pharmacy's work is of high quality is to assess customer satisfaction with the service. In 2006, FIP and WHO collaborated to publish the handbook "Developing Pharmacy Practice—A Patient-Centered Approach." This guide introduces the new pharmacy practice paradigm and the approach to pharmaceutical assistance. The FIP has taken the initiative to explore the possibilities of providing technical assistance to its member organizations in Cambodia, Moldova, Mongolia, Paraguay, Thailand, Uruguay, and Vietnam in developing national standards of the GPP in a pilot project to improve standards and practice of medicine distribution and use with the help of the WHO/FIP setting with the GPP as the framework. The "Bangkok declaration of the GPP in public pharmacies" was adopted across Southeast Asia in 2007, and member associations pledged to improve the quality of pharmacy services and professional practice [19].

Significant advances in practice applied science and technology, and pharmaceutical policy has happened since the GPP guideline was accepted in community and hospital settings. Despite changes that have occurred since the GPP's previous guidance in pharmaceutical policy, practice, and applied science was adopted in 2007, FIP was established to investigate the problem of updating the GPP's guiding principles to reflect current standards and professional thinking peculiarities [20]. During the 68th World Congress in Basel, Switzerland, in 2008, the FIP convened expert consultations for this aim. A total of 50 people attended the meeting, including members of the working group (WG), FIP of the GPP, WHO headquarters staff, representatives from the WHO regional office for the Eastern Mediterranean countries, medicines advisers from Ghana, Nigeria, and the United Republic of Tanzania, presidents, and secretaries of six Regional Pharmaceutical Forums, FIP member organizations, and several NGOs [21]. Following these consultations, the FIP GPP working group performed a detailed examination of current national standards for GPP in at least 37 countries and developed a time zone that could allow for adequate consultations with all 120 national associations, relevant experts, and the WHO. In October 2008, a proposal for this project was given to the WHO Expert Committee on concerns of pharmaceutical medicine specification at its 43rd meeting, and an updated report was provided to the Committee of Experts at its 44th meeting in October 2009. Simultaneously, in late 2008, the Pan-American Health Organization prepared "the guide for pharmaceutical services in primary health care" with the help of a group of experts from various pharmaceutical organizations, with the goal of highlighting the role of pharmaceutical experts in Latin America's health system. Following discussion with 120 national members of the FIP in 2011 and changes in the pharmaceutical industry, the GPP recommendations were adopted and updated by the approval of a joint guideline FIP/WHO titled "the GPP: Standards of the quality of pharmacy services." This general guideline was released as new standards of pharmacy service quality in the WHO Expert Committee's 45th report. In addition, this document encourages national pharmacy professional associations to embrace these standards and propose some GPPspecific norms [22]. The GPP establishes standards that are usually higher than the requirements of a country's pharmaceutical legislation. In the modified version of the GPP, pharmacists play many roles:

- 1. Medical product manufacturing, receiving, storage, security, distribution, usage, release, and disposal.
- 2. Ensuring that the pharmacological therapy is properly managed.
- 3. Continuation and enhancement of professional activity.
- 4. Encouraging the system of medical care and health to become more effective [20].

Depending on the duties that each pharmacist does, these positions may differ. Only through national pharmacy professional associations may specific GPP standards be defined. This recommendation is made in the form of a set of professional goals that must consider the needs of patients and other pharmaceutical stakeholders.

In comparison to the previously authorized concept of the GPP, the present updated version reinforces the requirements for the GPP's well-known primary aspects and identifies functions in each pharmacist's position for which minimum national standards should be established. Different countries have different versions of the GPP rules. There are holistic papers in some countries that cover both

requirements for the material-technical base, infrastructure, personnel, and standards for the provision of pharmacological treatment. These rules and regulations are spelled out in numerous documents in other countries. The standards for pharmacists in France, for example, are established in several guidelines. In Austria, on the other hand, nearly all the requirements for pharmacists are encapsulated in a single piece of legislation. There is also a guideline for pharmacists' work, which includes standards for a quality management system in addition to the typical criteria for premises, equipment, and staff. The GPP standards have a recommended status in industrialized countries. As a result, the Norwegian pharmaceutical association's standards of pharmacy practice, created in partnership with other professional groups, include requirements for pharmacy activities that are utilized by pharmacy owners to conduct internal quality control of pharmacy services. The government adopts legislation acts that provide the minimum standards for the functioning of pharmacies [23]. The Pharmaceutical Society of Ireland published a guideline on pharmacy practice to help pharmacists meet legal and regulatory requirements when providing pharmaceutical services [24]. In addition, the GPP is adopted in CIS countries. Belarus has implemented a pharmacy classification system. The GPP was adopted in Kazakhstan in 2006, and the provisions of the GPP of the customs union are currently approved in the Russian Federation. It should be noted that the GPP standard and guidance on the implementation of proper pharmacy practices serve as the foundation for implementing the total quality management (TQM) concept and the international standard of ISO quality management at pharmaceutical companies, both of which have been in use for more than 30 years. The understanding of the existence of an inextricable link between the quality management system and the organization's management system, as well as the understanding that this is an essential tool for continuous improvement and increasing the pharmacy organization's competitiveness in any market, is the foundation of TQM [25]. As a result, by enhancing the requirements to assure the quality of public services, the GPP standards are a significant step toward the expansion and enhancement of pharmacy operations. Despite improvements in pharmaceutical research and practice, the development and implementation of GPP criteria into pharmacy practice is a longterm and ongoing process. The standardization of pharmacists' activity in providing people with medications and medical items receives a lot of attention in GPP guides of all years. Because national regulation of pharmacy practice differs widely among nations, the establishment of GPP standards should be handled at the level of public professional organizations. The results of the study will be used to design and apply GPP national standards around the world, according to future scientific research.

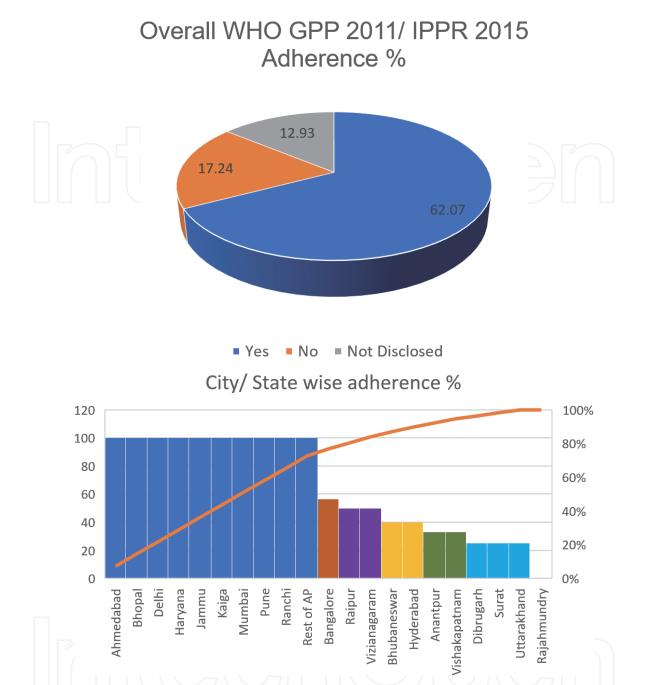
### 8. Current pharmacy practice scenario in India

A recent countrywide survey done by final year postgraduate diploma in management students from Indian Institute of Health Management & Research, Bangalore finds that out of 107 hospitals 66 hospitals only follow the WHO/FIP GPP 2011 or Indian Pharmacy Practice Regulations 2015 which is merely 62% of the entire sample.

Students were asked to conduct a brief analysis and report on the top five hospitals or community pharmacy dept. in their area or where they did train/observer ship whether these guidelines are followed or not and where are the loopholes in following this guideline. There were two kinds of data generated, such as

- 1. Quantitative data by asking close-ended questions, and
- 2. Qualitative data by observation and asking open-ended questions.

The graphical representation of the quantitative survey data is illustrated as follows:



The qualitative observational/survey data is represented as follows:

Qualitative survey result	Observations
Narayana Health City	While working in a Pharmacy Department of the Hospital, many things are founded like:
	<ul> <li>Medicines are not properly arranged.</li> </ul>
	• Medicines of different names and labels are found in different boxes.
	<ul> <li>Some medicines are found unsealed that is a loss of Hospital pharmacy.</li> </ul>
	• One medicine was labeled in two boxes, for example, Flexurra D
	There is a lack of space.
	Staff are not attending calls properly.
	<ul> <li>Medicines were lying on the floor.</li> </ul>
	Pharmacy is not hygienic.

Qualitative survey result	Observations
	<ul> <li>There should be the proper categorization of injections and other items.</li> <li>This difference is due to: <ul> <li>Lack of coordination between the staff.</li> <li>Lack of staff present in the pharmacy.</li> <li>Improper arrangements of the drugs cause difficulty in searching medical items.</li> </ul> </li> <li>Challenges- <ul> <li>Lack of commitment and coordination toward the service delivery</li> <li>Lack of training, shortage of manpower and facilities for pharmacist</li> <li>Recommendation</li> </ul> </li> <li>There should be a proper space in the IP pharmacy.</li> <li>Pharmacists should be provided with more space with more no of counters.</li> <li>Expired medicine should be categorized separately.</li> <li>Medicine should be categorized separately.</li> <li>Medicine should be attended properly by the staff.</li> <li>The pharmacy should categorize the drugs, injections, medical consumables in an order so that anyone can find it quickly.</li> <li>Drinking water facilities should be there.</li> <li>There should be proper lighting facilities.</li> </ul>
Dr. Agarwal's Eye Hospital Chain, S V Hospital & C M N Hospital	<ul> <li>a. There is no particular pharmacist assigned to the pharmacy.</li> <li>b. The pharmacy is left open and can be accessed by anyone including patients.</li> <li>c. There is no proper maintenance of the record of the drugs in the pharmacy.</li> <li>d. The hospital is not departmentalized, hence there is no specific manager for the pharmacy.</li> <li>e. The drug availability is poor and sometimes they borrow from the nearest medical store. The prescribed medicines are not always available in the pharmacy. Which counts a low value for the quality of service provided and lowers down patient satisfaction rate.</li> <li>f. During use of software sometimes the functioning of the system stops and if the the patient is waiting for the bill cannot be generated which increases the time of dispensing of drugs.</li> <li>g. The bulk storage in the side shelves includes tablets which are sometimes difficult to find.</li> <li>h. Difficulty in dispensing both in-patients and out-patients prescriptions at the same time.</li> </ul>
Sagar Hospital	<ul> <li>i. Availability of only two monitors.</li> <li>Most common loopholes and challenges found in the hospital pharmacy.</li> <li>As hospitals have a pharmacy, they mostly followed the FIP guidelines but there are some challenges and loopholes faced by the hospital pharmacy. The challenges related to the pharmacist include the inadequacy of service promotion, absence of service continuity, poor DIC service, and lack of commitment, communication, and confidence among clinical pharmacists. Most respondents declared that poor attitude toward the services, conflict of interest due to the unclear scope of practice, and absence of cooperation are the challenges that radiate from health practitioners such as nurses and physicians. Some respondents also described challenges that arise from the hospital management and its set-up. The challenges they mentioned include lack of training, shortage of skilled manpower, lack of incentives, absence of facilities in the ward for clinical</li> </ul>

Qualitative survey result	Observations
Aditya Netralaya	<ul> <li>pharmacists, and collaboration between academics and hospital clinical pharmacists. The other challenges stated by the respondents were due to the academic policy and the curriculum itself. This encompasses some gaps of the curriculum; absence of clear job description and working guidelines; and documentation system. The major challenges for clinical pharmacy services described were a lack of support from hospital management, absence of clearly defined roles and responsibilities for the clinical pharmacists, a shortage of pharmacy workforce and staff turnover, a lack of follow-up from responsible bodies, and a lack of enough salaries and incentives for the healthcare providers.</li> <li>a. No separate pharmacy is available. No separate pharmacist is available.</li> <li>b. The medicines are available at the reception only along with the billing.</li> <li>c. No proper records are maintained and hence it is difficult to monitor.</li> <li>d. The hospital is not departmentalized; hence, there is no specific manager for the pharmacy.</li> <li>e. Drug availability is limited. No proper records are maintained for particular drugs. So, it will take time to dispense the drugs at the</li> </ul>
Mithra Hospital	<ul><li>counter. It increases the patient waiting time.</li><li>1. The inventory management of medications is not properly followed the guidelines.</li><li>2. Patient counseling is not followed in most cases.</li></ul>
	<ol> <li>The quality of drug maintenance and record maintenance should be more technological and confidential.</li> <li>The up-gradation of storage of medicines is not followed; it follows the medications of doctor's prescription only.</li> </ol>
General	Many of the hospitals do not have an assigned clinical pharmacist, which makes the difficulty in practicing Rule number 2 of the standards of GPP. Workforce shortage during peak OPD hours there should be a training of pharmacists and associated personnel on regular basis. Updating newer guidelines. Sometimes when too much workload is there, pharmacists are unable to properly counsel the patients/attendants regarding doses,
	their uses, drug interactions, etc. Shortage of time for EWS pharmacy. Because medications are not always available, it is extremely inconvenient for patients to return after time. The room does not have adequate light and ventilation. There is a lack of adequate space for the storage area of the pharmacy. No trained personnel in pharmacy, that is, the staff is from nonpharmaceutical or nonmedical backgrounds. No proper support is seen in abiding by policies of government related to health outcomes as per the guidelines of Role 4. Drug availability is not meet the needs of patients. No proper record is maintained in any aspects related to dispensing
	or storing of drugs. No proper follow-up of patient turnaround time at the pharmacy
Narayana Health City	Missing of personnel in the pharmacy increases the patient waiting time
Omni R K Hospital	No trained personnel in pharmacy, that is, staff from nonpharmaceutical or nonmedical background

Pharmacy practice, which includes clinical, community, and hospital pharmacy, is referred to as healthcare in the true sense. PPs establish a vital link between doctors, nurses, and patients in a social community group, with the goal of improving patient welfare and safety [26]. Pharmacists must provide more than only distribution; they must also provide services to society, such as patient counseling, guidance, and the organization of drug data for human services, suppliers, and patients [27]. For example, before the product patent was implemented in India in the early 2000s, the pharma industry thrived successfully after the amendment of new monetary reforms in India in the mid-1990s until the early 2000s [28]. In terms of educational outcomes, the degree of student achievement in pharmacy has improved from 2012 to 2020 and is predicted to continue to climb due to its scope. Many pharmacy graduates have expressed an interest in medication discovery and innovation through research [29]. It has been suggested that pharmacies play an important role in strengthening social security because they work around the clock to maintain a chain of elegant integrity on drugs, particularly during the COVID-19 pandemic. From the standpoint of regulatory authorities, PPs play a variety of roles and duties in the execution of new recommendations based on situational faults [30].

# 8.1 The practice of pharmacy

It entails the implementation, evaluation, and interpretation of pharmacy orders as well as the dispensing of prescriptions. Pharmacists are responsible for providing patient counseling, legislation, and social services to promote pharmaceutical treatment as primary care in all areas of patient health [31]. They are also in charge of segregating and labeling pharmaceuticals and medical devices, as well as guaranteeing the safety of medication and device storage and maintaining adequate records [32].

According to a Supreme Court decision on March 5, 2020, [IN THE SUPREME COURT OF INDIA CIVIL ORIGINAL/APPELLATE JURISDICTION TRANSFERRED CASE (CIVIL) NOS ... ... ... ... OF 2020 [TRANSFER PETI-TIONS (CIVIL) NOS. 87-101 OF 2014] The Pharmacy Council of India. Petitioner Versus Dr. S.K. Toshniwal Educational Trusts Vidarbha Institute of Pharmacy and Ors. Etc. .. Respondents]

- The Pharmacy Act is a nonconstitutional statute.
- There cannot be two regulators at the same time.
- The AICTE Act is a broad statute.
- The Pharmacy Act is a unique piece of legislation.
- The Pharmacy Act is a comprehensive code that includes pharmacy specialists.
- Only the Pharmacy Council of India (PCI) has the authority to set pharmacist qualifications.
- Only PCI has the authority to set standards for pharmacies.
- PCI will be solely responsible for approval and admission to institutes.
- The Pharmacy Act has the power to govern not just pharmacy education but also the profession [33].

In India, there are two types of pharmacists—those who work in hospitals and those who work in

- Pharmaceutical industry
- Pharmacies in the community
- Pharmacovigilance is a term that refers to the monitoring of pharmaceuticals.
- Pharmacy schooling
- Pharmacovigilance procedures

### 8.2 India's first pharmaceutical company

Bengal Chemical and Pharmaceuticals Ltd. was founded in 1892 as an individual initiative by the "Father of Indian Chemistry," Acharya Prafulla Chandra Ray, and is considered the country's first pharmaceutical enterprise. For the first time in more than six decades, Bengal chemicals and medicines Ltd. made a profit in 2016–17 [34].

#### 8.3 Regulation of pharmaceuticals

For the manufacture, distribution, and sale of medications, India has the harshest rules and regulations in the world. The ability of law enforcement is not just determined by good legislation; it also requires stringent regulations and the acceptance of successful challenges. According to the Mashelkar committee's recommendations, one drug inspector should be assigned to every 50 manufacturing units and one to every 200 distribution outlets. In most states, 30–50% of positions are vacant, and the number of positions available is insufficient to expand the pharmaceutical sector. According to the Mashelkar committee report, one drug inspector is assigned to every 200 retailers, and the data from the All-India Organization of Chemists and Druggists (AIOCD) indicates that there are approximately 8.5 lakh pharmacies to be considered, implying that more than 4250 drug inspectors are required to manage the retail pharmacy segment [35].

CDSCO and SDRA have different roles.

Pre-manufacturing is the process of preparing a product for manufacture.

Expert panels help the Central Drugs Standard Control Organization (CDSCO) to regulate premanufacturing. The following is their primary role in dealing with the two major criteria:

- Clinical studies (clinical trial registry, GCP, inspections, ethics committee, and significant adverse events)
- Import and marketing license approvals for new drugs [36].

#### 8.4 Industrial production

The State Drug Regulatory Authority (SDRA) oversees regulating drug product manufacturing in the states, while CDSCO oversees union territories. In some circumstances, the CDSCO and SDRAs undertake joint inspections [37]. The terms listed below are required for the manufacture of pharmaceutical products.

- Permit (generic and marketing license)
- GMP (good manufacturing practices) inspection
- Drug testing and noncompliance penalties [31].

# 8.5 Sales and distribution

The SDRAs oversee regulating the distribution and sale of drugs in the states, while the CDSCO oversees the union territories. The terms listed below are required for the distribution and sale of pharmaceutical items.

- Permit (sale and distribution practices)
- Good Distribution Practices Inspection (GDP)
- Drug testing and noncompliance penalties [38].

# 8.6 Situation now

The current state of pharmacy education, authority functions, and future difficulties of pharmacists in all aspects was discussed, particularly considering the COVID-19 epidemic. During the development phase, it must overcome numerous obstacles, including regulations, duration, process controls, legal stumbling blocks, and situational flaws [39]. **Table 3** summarized the educational updates.

# 8.7 The government's initiative

From June 2, 2020, the PLI Scheme will be open for 4 months, allowing investors to propose the construction of Greenfield facilities for any of the 53 important drug intermediates and bulk pharmaceuticals that are now barely made in India [40]. The list contains important chemicals found in regularly given medications such as paracetamol, aspirin, metformin, atorvastatin, and others. The whole planned incentive package is worth Rs. 13,760 Crore, which is divided between bulk medicines and medical devices as shown in **Figure 1**.

COVID-19 PPs

- Millions of people around the world are affected
- Insight into no cure
- Online (digital) education

Pharmacy program	Number of institutions	Annual intake
D Pharm	3022	180,770
B Pharm	1961	125,524
Pharm D	267	8010
M Pharm	792	24,465
Ph. D. in Pharmacy	31	1240

Table 3.

Statistics of pharmacy education program in India.

- Evaluate Indian strategy and tactics.
- India's pharmaceutical industry's expectations in terms of global visibility
- Opportunities with challenges

### 8.8 Regulatory hurdles

Across the several layers of regulatory and enforcement procedures, this industry suffers from knowledge asymmetry. Because each state has its own regulations, there is a lot of variation in the quality of drug regulation across the country [41]. India's drug inspectors, who are crucial players in drug regulation, should be highly qualified and adequately compensated to reflect the dignity that comes with such a large duty. The agency has a budget limit when it comes to implementing innovative methods of regulatory monitoring [39].

### 8.9 Future challenges for the pharmaceutical industry

There is a great deal of anticipation, price pressure, and caution in the development of vaccines, particularly (Covaxin, Covishield, or Sputnik) for the treatment of COVID-19, which is still in Phase I and II clinical trials in India. There is a potential that poor data will emerge in a Phase III study, as several countries have done in the past, leading to vaccine development and outcome failure [42]. Nowadays, one of the most pressing issues in the management of process controls during the formulation of pharmaceuticals is the formation of impurities in the form of genotoxic and carcinogenic impurities, which are extremely toxic and harmful to patients taking medication for diabetes, gastric ulcers, and psychosis [43]. There is also a compensation challenge in India due to the loss of fixed-dose combination (FDC) drugs, as many of the 344 drugs in this category were banned and withdrawn because they were therapeutically irrational and caused toxicity in patients when used to treat chronic diseases like tuberculosis and HIV. As a result, there are still hopes of bringing FDCs to market for patient benefit with assurances of safety and efficacy [44]. If the financial expenditure is not increased, the quality of research, drug discovery, and development will suffer.

#### 8.10 Online education

According to Holon IQ global education intelligence, the current \$6 trillion education market will grow to \$10 trillion by 2030. Digital platforms account for only 3% of worldwide education spending, and by 2025, they will account for \$325 billion, or less than 5% of total spending [45, 46]. Although this will go a long way toward solving the country's educational challenges, the government's present worries include guaranteeing smooth delivery of education on the post-Covid road of digital education [47]. The UGC is now working on a game-changing regulation that will allow universities with a high "NAAC" score in the top 100 NIRF rankings to offer online programs. This will be a game-changer since educational jurisdiction will become worldwide, and only equipped universities will survive [48].

#### 8.11 Observations and recommendations

The following recommendations were implemented for the PPs based on the unique circumstance faced by each country because of COVID-19:

- The pharmaceutical business must shift its focus away from COVID-19 and onto the needs of the country, as well as ideas for overcoming governmental and regulatory obstacles.
- The government should provide adequate funds to PPs researchers for the development of novel drugs and the conduct of clinical trials.
- To achieve the required results, the pharmaceutical business should learn to invest in quality staff and move its attention from the product to the patient [49].

• Application of state and federal norms to protect public health and disease prevention.

- Strengthening the regulations governing healthcare administration and professionals, requiring them to adhere to severe state-based rules.
- There should not be a large reliance on API procurement from China; instead, actions should be done to ensure API supply from within the country.
- Enabling workflow changes in principles while dealing with emergencies
- To raise awareness and develop educational training programs to protect people's physical and mental health during the pandemic.
- To combat COVID-19 as a naturopathy-based treatment, the pharmacognosy and phytopharmacy department should focus on herbal and ayurvedic formulation development.
- Positive, credible, and evidence-based marketing to be made by PPs on the conventional way of using AYUSH-based drugs to combat COVID-19.
- The general public should consume "Kapasura kudineer," which is widely available in retail pharmacies, particularly in south India, and contains many combinations of herbs that can combat the coronavirus and other microorganisms. This has shown promising results, as many people have been benefited and relieved from COVID-19 in asymptomatic reported positive cases.
- Steps to be done for e-learning/webinar programs in order to receive additional updates from the WHO and the health advisory council for pharmaceutical development and public health protection.
- In the event of an emergency, the use of PPs as second-line healers or physicians to diagnose the patient's ailment [50].
- During the COVID-19 epidemic, enabling e-prescriptions and home delivery of medicines to self-isolated individuals and older people by guaranteeing preventive steps and safety.
- Advocacy with policymakers and stakeholders must be strengthened in order to create the optimal regulatory framework for the pharmaceutical industry to thrive.

# 9. Unethical practices in healthcare and pharmaceuticals during COVID 19 in India

The devastating second wave of the COVID-19 outbreak has brought strangers together offline and online to assist one another in any way they can. Even terrible stories of death and loss have not deterred some people from engaging in unethical and immoral actions including black-marketing medical life-saving medicines, hoarding, and defrauding in the name of COVID-19 medical supplies, and charging exorbitant prices for ambulance service. The Delhi Police recently raided a finedining restaurant in Lodhi Colony and seized 419 oxygen concentrators. These were being sold at an astronomical price of 69,999, complete with bogus MRP labels. About 96 oxygen concentrators were seized from Khan Chacha, owner of a famous food joint in Khan Market. When Delhi-NCR is in the midst of the biggest crisis in its history, notable figures in the city urge tough punishments for anyone who engages in such unlawful and inhumane activities. In connection with a Rs 450 crore medical equipment maintenance scam, Andhra Pradesh's Crime Investigation Department (CID) has filed a complaint against Bengaluru-based TBS India Telematic & Biomedical Services Private Limited, private individuals, and health department employees. The case was filed under the sections of the Indian Penal Code dealing with cheating, criminal conspiracy, and criminal breach of trust. Price increases, inflated bills for nonexisting equipment, and increased invoices for equipment in government hospitals in AP are among the irregularities. Over 300 doses of anti-COVID vaccination were taken from a hospital in Jaipur during a spike in coronavirus illness, forcing authorities to file a criminal complaint. According to agency reports citing a Centre RTI response, Tamil Nadu recorded 12.10% vaccine wastage, followed by Haryana (9.74%), Punjab (8.12%), Manipur (7.80%), and Telangana (7.80%) (7.55%). Vaccine wastage in Tamil Nadu is up to 13% for Covaxin and 9% for Covishield, according to data from the state directorate of public health, which distributes vaccines and regulates its use. Between January 16 and April 17, 7.14 lakh doses of Covaxin and 44.80 lakh doses of Covishield were sent to drug retailers, according to state authorities. A vial must be used within 4 h of being opened and stored at a temperature between 2 and 8°C. The state has used 47.05 lakh dosages by April 17, including 40.5 lakh Covishield. Health staff was under pressure to vaccinate as many individuals as possible. Even though there were not enough individuals, they opened bottles of 20 and 10 dosages. We will now be able to expand immunizations due to an increase in cases and stock. On Friday, as a new day dawned over Delhi, a somber narrative surfaced from Sir Ganga Ram Hospital, one of the capital's most prestigious institutions. In the last 24 h, at least 25 COVID-19 patients had perished there. Physical ventilationoccasional6manual compression of a gas-filled reservoir bag to drive the gas into a patient's lungs-has been used on occasion to ensure that patients on ventilator assistance survive. The burning question is how to treat patients when key supplies are not available. As per specialist doctors without oxygen, a patient who requires ventilator assistance can die in minutes. Many other hospitals were in a similar situation. The hospitals then devised a plan to have two patients share a cylinder by using connectors. But also, according to doctors, those on a ventilator can die in minutes if their oxygen supply is cut off. Doctors face a significant hurdle because of this. Despite government pledges and rules, the black market for Remdesivir, a crucial COVID-19 medicine, is thriving in Chennai, with many pharma dealers asking up to Rs 14,000 per 100-mg vial. Even though the Tamil Nadu government has promised to assist them in obtaining the drug, many private hospitals have thrown in the towel, leaving numerous COVID-19 patients in their care without treatment. A private COVID panel hospital has been charged with overbilling by the

#### Bioethical Issues in Healthcare

Kanpur district administration. On Monday, the complainant filed a complaint alleging that he was overcharged by Rs 3.50 lakh in the previous 7 days, and on Tuesday, the district administration issued a notice to the hospital's management after completing a preliminary investigation. The charges were confirmed to be accurate after a preliminary investigation by the extra city magistrate and a government doctor. When the hospital's management failed to respond satisfactorily, district magistrate Alok Tiwari issued an order to register an FIR against it on Tuesday. The administration has appointed static magistrates and sector magistrates to investigate overbilling issues in private panel hospitals, according to the district magistrate. Furthermore, the government has already circulated cell phone numbers for the public to use to report any overbilling complaints. Despite threats of severe consequences for overbilling, private panel hospitals are seizing every opportunity to overcharge patients. Prices of oxygen concentrators, oximeters, and nebulizers have risen by 50-100% in the last 10 days, owing to a massive demandsupply mismatch as the coronavirus epidemic enters its second wave. Even as the organized medical device sector, legal entities, and consumers pressed for enforcing pricing control over these products, e-commerce giant Amazon stated it has begun removing listings of accounts selling these products beyond MRP. Over the last 7 days, the price of oxygen concentrators, which generate oxygen from the air, has nearly doubled, while the price of oximeters has increased by Rs 1000-2000. Prices have risen in both physical businesses and online marketplaces such as Amazon and Flipkart. The government set a price cap on certain products last year, but some vendors, companies, and importers are not following it. A spokesman for Amazon India stated the business is taking urgent action to stop the surge pricing. Hundreds of tweets from customers have gone viral, claiming that they had to pay more than Rs 1 lakh for oxygen concentrators that would normally cost Rs 45,000. The device's monthly rentals have also increased from Rs 5000 to Rs 10,000–20,000. Many sellers and importers have boosted costs of COVID-essential medical supplies by two to four times in just a week, even on online markets like Amazon and Flipkart. The problem is large with imported products by opportunistic dealers who import these products at low costs and then continuously raise prices to profit from the scenario while blaming it on their suppliers.

# 10. Essential commodities (control of unethical practices in marketing of drugs), 2017

Since the pharmaceutical industry's exponential rise, there has been a need to regulate the interaction between pharmaceutical firms and medical practitioners. The Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, as revised until February 1, 2016, ("MCI Regulations") were enacted with this in mind. The MCI Regulations, Regulation 6 (Unethical Acts), establishes a code of conduct for medical practitioners in their interactions with the pharmaceutical and allied healthcare industries. The MCI Regulations, on the other hand, apply only to medical practitioners. As a result, on December 12, 2014, the Department of Pharmaceuticals ("DoP") declared the Uniform Code of Pharmaceuticals Marketing Practices ("UCPMP") effective on January 1, 2015, for a 6-month period of voluntary adoption. When the DoP announced UCPMP, it stated that it was a voluntary code for the Indian pharmaceutical industry, but warned that if it is discovered that the pharma associations/companies have not implemented it successfully, the government may consider making it a statutory code. The DoP then extended UCPMP until further orders on August 30, 2016. Despite the fact that the UCPMP was the first of its kind and contained substantial regulations, the DoP

attempted to replace the voluntary code with mandatory recommendations since it was optional. As a result, the DoP transmitted the draught Essential Commodities (Control of Unethical Practices in Drug Marketing) Order, 2017 ("Order") to the Law Ministry in July 2017 for final approval. The Law Ministry, on the other hand, is concerned about the Order, which is now being sought to be issued under the Essential Commodities Act, 1955. It is worth noting that the Order is beyond the scope of the Vital Commodities Act of 1955 ("Act"), whose goals are to control the manufacture, supply, and distribution of essential commodities rather than to oversee medication marketing. In 2015, the UCPMP was expanded to include the medical devices business, which is worth more than Rs 25,000 crore annually. The Order indicates that it will not apply to medical devices because the DoP is in the process of creating and releasing a separate code of marketing practices for the medical device industry (which would be voluntary for 6 months). The Order, like the UCPMP, prohibits pharmaceutical corporations from presenting cash, gifts, or sponsorship to doctors, chemists, or pharmacists, as well as giving travel facilities or paid vacations. Any pharmaceutical firm or its representatives are prohibited from giving presents, cash cards, hampers, or any other item that may produce monetary benefit or allow profits in kind to a medical practitioner, a retail chemist, or pharmacists, or their "family members" under paragraph 3 of the Order. It does, however, allow for the financing of academic conferences organized by medical groups, as well as the organization of screening camps or awareness campaigns in government-owned healthcare institutions, with the caveat that these cannot be used as surrogate advertising. A pharmaceutical business or its agent is also prohibited from providing free samples to any medical practitioner under the terms of the Order. Allowing pharmaceutical companies to distribute free samples up to a full course of medicines for a maximum of three patients has created an exemption to this norm. Three, on the other hand, is a modest amount for any medical professional to comprehend and analyze the effects of a new drug on patients. It is important to note that the term "Agent" is defined very broadly in paragraph 2(b) of the Order, and includes any person, company, society, nongovernmental organization, or other institution who has been hired or authorized by a third party to call on any healthcare facility to promote a pharmaceutical company's drugs. The Order further states that a company's MD or CEO is accountable for ensuring that the Order is followed. All complaints involving violations of the Order shall be investigated by an Ethics Compliance Officer (ECO) designated by the Government of India, who shall not be below the rank of a Joint Secretary to the Government of India, according to paragraph 5 of the Order. It should be noted that a firm or its agent who fails to comply with the terms of subparagraphs (a) (b) (c) or (d) of paragraph 3 of the Order will face a penalty under paragraph 4 of the Order. Furthermore, paragraph 5(4) of the Order lays out the mechanism for imposing a penalty by prohibiting the breaching corporation from marketing its best-selling product for the previous 12 months for a period of three to one year. The Order also states that corporations can pay a penalty ranging from Rs 5 lakh to Rs 10 lakh to have the marketing prohibition lifted. According to the Order, the DoP Secretary will be the appellate authority, and appeals from the Appellate authority's orders will be handled by the court.

# 11. The way forward

There is an utmost necessity to relook and re-establish the standards of pharmacy practice in healthcare setups available in each and every corner of the country in line with guidelines provided by the World Health Organization (WHO) and International Pharmaceutical Federation (FIP). For that, the dependency and responsibilities are very high on healthcare professionals, particularly in this pandemic situation. The pharmacy zone is adaptable, evolving, and increasingly diverse, offering a wide range of work and management opportunities to execute [27]. PPs are human service professionals whose responsibilities include safeguarding individuals by dispensing medications based on prescriptions [28]. Representing the world's third-largest medicinal services with active gathering, and in India, there are over 1,000,000 (1 million) enrolled PPs employed in various capacities and readily contributing to the country's well-being [51]. Pharmacy practice, which includes clinical, community, and hospital pharmacy, is referred to as total healthcare in its true sense. Through adaptation and implementation of GPP in healthcare setup, PPs form an essential link between physicians, nurses, and patients in the social community group, with an ultimate emphasis on patient well-being and protection [30].

There should be country-wise GPP training programs are specifically aimed to gain rapid insights from World Health Organization (WHO) and International Pharmaceutical Federation (FIP) joint guidelines for advancing pharmacy practice worldwide and especially in India. In the view of current COVID-19 crisis, this initiative should be the first of its kind training program being offered in India. This training program mainly focuses on experiential training while promoting the GPP concept among healthcare professionals in India. This course will help the participants to get easy access to the guidelines, provides opportunities for peer discussions, and eventually be influential in improving pharmacy practices.

There should be a very focused approach for the same as follows

- 1. To understand the roles of pharmacists, national pharmaceutical organizations, and healthcare systems in developing GPP standards.
- 2. To understand the role of the pharmacist as a part of healthcare and the requirements of this role.
- 3. To understand the methodology and principles of quality management.
- 4. Be able to set standards, measure the quality and use the principle of continual improvement in one's own working environment.
- 5. This course mainly explores and discusses the WHO/FIP GPP guidelines, the model of GPP in the hospital setting, and aseptic preparations.
- 6. Additionally, focus on WHO, MoH & FW, ICMR & NCDC guidelines for handling, treatment, and disposal of biomedical waste at healthcare facilities.

Across the globe, pharmacy is one of the most important, dynamic, and versatile segments of the healthcare industry. The pharmacy zone has become adaptable, evolving, increasingly diverse, adhering to the quality standards. However, the importance of ensuring appropriate quality to every patient has taken a center stage in this pandemic, especially in India. In such time, it is important to understand and execute the methodology and principles of quality management and set standards, for continual improvement in one's own working environment, while realizing the emerging roles of pharmacists, national pharmaceutical organizations, and healthcare systems in developing good pharmacy practice (GPP) standards in this pandemic era.

The International Pharmaceutical Federation and World Health Organization define good pharmacy practice (GPP) as practices that meet the personal needs of

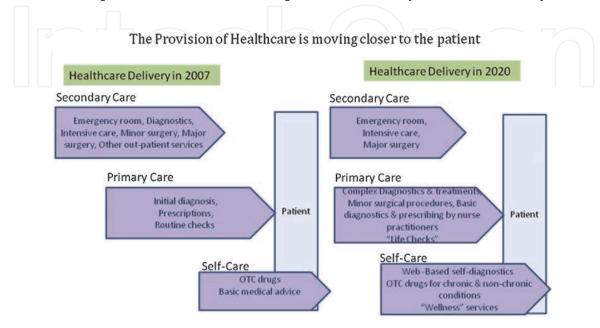
patients or those using pharmacy services by offering appropriate evidence-based care. In developed countries, pharmaceutical assistance is defined as a pharmaceutical practice model that involves attitudes, ethical values, behaviors, skills, appointments, and co-responsibility to prevent diseases, promote and recovery health in an integrated manner as part of the healthcare process, highlighting, among other, the requirement that the institution fully adopts the GPP. The program should be designed to take care of the Indian healthcare system and its context of adoption of "new normal" due to the unprecedented event of COVID 19 and the importance of GPP for the healthcare professionals in same.

This kind of training program should be opened to

- Health, Health IT, Hospital & Pharma Management Students & Professionals.
- Medical, Dental, Physiotherapy, Nursing, Pharma, Paramedical Students.
- Any Graduate student/Professional who wants to pursue a career in healthcare.

Today, the forms of care are shifting from secondary care providers to primary care providers to patients (**Figure 2**). This trend has already started in developed countries, such as the behind-the-counter drug option in European countries that was already endorsed by the FDA. The FDA showed positive signs toward boosting the numbers of nonprescription drug statuses to over-the-counter statuses. The healthcare delivery system is coming closer to the patient due to knowledge and understanding, as well as better diagnostic tools and monitoring devices [52] (**Figure 2**).

The use of simulation and related technology in healthcare education will continue to grow in the next years, and this methodology has a collective role within the pharmacy curriculum. It is expected that increasing the quantity of simulation in pharmacy curricula will have a good impact on pharmacy student education and training, resulting in favorable outcomes for patients and the healthcare team. The obvious goal of incorporating simulation techniques into the pharmacy student training curriculum is to increase pharmacist education and training with the ultimate goal of enhancing patient care and safety. Simulation experiences will never be able to replace real-world clinical experiences, but they do have the ability to



#### Figure 2. The healthcare delivery status of 2007 and 2020. Source: PricewaterhouseCoopers.

### Bioethical Issues in Healthcare

supplement clinical education and serve as a tool for developing the skills necessary for a successful pharmacist. Simulation approaches have been utilized in pharmacy education to address broad cognitive and social skills, particularly communication, decision-making, ethical dilemmas, prioritization, and teamwork, in addition to the development of technical skills such as procedural and clinical abilities. Simulated learning environments could provide a more systematic approach to both clinical skill training and pharmacy programs that aim to provide an opportunity for theoretical knowledge to be applied to a real clinical situation. Basic sciences, dispensing, and drug supply all benefit from simulation's constant, predictable experience. In an ideal world, simulation training would be integrated into all levels of pharmacy education and training.

Types of simulation technology used in healthcare education [53, 54].

- 1. High-fidelity patient simulator or mannequin—able to mimic human actions and physiology and respond to physiologic and pharmacologic interventions
- 2. Task trainer —designed to help learners practice, specific skills and do not have the extensive programming capabilities of high-fidelity models. It can be considered as *low-fidelity simulators or moderate-fidelity* simulators depending on the sophistication of the model
- 3. Standardized patients—live people who are coached to portray patients, usually referred to as simulated patients
- 4. Virtual reality simulator—in which a computer display simulates the physical world and user interactions are with the computer within that simulated (virtual) world
- 5. Full environment simulation—it involves the incorporation of high-fidelity mannequins, standardized patients, healthcare professionals, and ancillary equipment to recreate a real-life clinical environment

# 11.1 Key components should be included in hospital & community pharmacy practice: automation & technology

- Serves to increase efficiency and accuracy of dispensing
- Re-direct staff time away from routine technical tasks and toward more direct patient care activities
- Featured Systems: ADC, place medications much closer to the user, but still allow electronic verification
- Pharmacy Robot: Reduced preparation and check time for medications, minimizations of potential contamination in sterile product preparation
- Bar coded medication administration
- Computerized prescriber order entry systems (CPOE)
- Smart pumps
- Clinical decision support system (CDSS)
- Predictive population risk stratification
- Patient self-management tools

Mr. B. Hajee Bahadoor	Dr. Radhika Sanjay Hatolkar	
BSc., PGDBM Health	Bachelor of Physiotherapy, PGDBM Health	
Dr. Chandolu Teja Venkata Narayana	Ms. Ranjitha Roy	
Bachelor of Physiotherapy, PGDBM Health	Bachelor of Nursing, PGDBM Health	
Dr. Chandwani Mayuri Mukeshkumar	Mr. S. Neeraj Naga Santosh	
Bachelor of Dental Surgery, PGDBM Health	B.Tech, PGDBM Health & Hospital Management, IIHMR Bangalore	
Dr. Geetanjali Bhaskar	Dr. S. Siri Charan	
Bachelor of Dental Surgery, PGDBM Health  ් Hospital Management, IIHMR Bangalore	Bachelor of Dental Surgery, PGDBM Health	
Ms. Goyal Anshita Jitendra	Dr. Sanem Pavani Mayusha	
BCom., PGDBM Health	Bachelor of Homoeopathic Medicine	
Ms. Iffat Naz	Dr. Saniya Suleman Ahmed	
BCom., PGDBM Health	•	
Dr. Kanakam Viswa Praneeth	Mr. Seelambuttagalla Bharath	
Bachelor of Dental Surgery, PGDBM Health & Hospital Management, IIHMR Bangalore	BA, PGDBM Health	
Ms. Madhushree	Dr. Shreya Shresth	
Bachelor of Hospital Management, PGDBM Health	Bachelor of Medicine	
Dr. Mansi Trakroo	Mr. Sidharth Samantaray	
Bachelor of Dental Surgery, PGDBM Health	B.Tech Computer Science & Engineering, PGDBM Health & Hospital Management, IIHMR Bangalore	
Ms. Mridula Pandey	Ms. Sweta Kumari	
BSc., PGDBM Health	BBA, PGDBM Health & Hospital Management, IIHMR Bangalore	
Dr. Apoorva Uday Munagekar	Dr. Sweta Sharma	
Bachelor of Physiotherapy, PGDBM Health ජං Hospital Management, IIHMR Bangalore	Bachelor of Medicine	
Mr. Nilesh Sharma	Ms. Anjali Deb	
BSc. Biotechnology, PGDBM Health	BA, PGDBM Health	
Dr. Nunna Krishna Madhuvani	Dr. Prajwal Ramesh	
Bachelor of Physiotherapy, PGDBM Health  ජං Hospital Management, IIHMR Bangalore	Bachelor of Dental Surgery, PGDBM Health & Hospital Management, IIHMR Bangalore	
Ms. Pallavi Kushwaha	Dr. Shaila Sharma	
BBA, PGDBM Health	Bachelor of Dental Surgery, PGDBM Health	
Dr. Parul Phulera	Dr. Shradha Saran	
<b>Dr. Parul Phulera</b> Bachelor of Dental Surgery, PGDBM Health	<b>Dr. Shradha Saran</b> Bachelor of Dental Surgery, PGDBM Health ඒ Hospital Management, IIHMR Bangalore	

Dr. Poosarla Sree Harsha	Brig. Sandeep B Singh	
Bachelor of Dental Surgery, PGDBM Health	B.Tech Electronics, PGDBM Health & Hospital Management, IIHMR Bangalore	
Ms. Preetha S.	Ms. Radha Virendra Deosthalee	
BSc. Perfusion Technology, PGDBM Health లీ Hospital Management, IIHMR Bangalore	Bachelor of Hospital Management, PGDBM Health	
Ms. Priyanka Saha	Dr. Ramesetty Lavanya	
B.Tech Civil Engineering, PGDBM Health	Bachelor of Dental Surgery, PGDBM Health	
Lt. Col. Eswar Chandar	Mr. Peeyush Srivastava	
B.Sc. (National Defence Academy), PGDBM Health	BSc., PGDBM Health	
Ms. Shipra Mishra	Ms. Kesari Sai Sowjanya	
Bachelor of Hospital Management, PGDBM Health	BSc. Clinical Nutrition	
Mr. Yohan Deepak		



# Author details

Mrinmoy Roy Indian Institute of Health Management and Research, Bangalore, India

\*Address all correspondence to: mroy2612@gmail.com

# IntechOpen

© 2021 The Author(s). Licensee IntechOpen. This chapter is distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/3.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

# References

[1] Death of Covid patients due to nonsupply of oxygen not less than genocide: Allahabad HC—Coronavirus Outbreak News (indiatoday.in)

[2] The National Portal of India, New Delhi. Know India-states and Union Territories. 2009. Available from: http:// india.gov.in/knowindia/state\_uts.php [Accessed: November 01, 2014]

[3] Visaria P. Demographics of ageing in 12 India. Economic and Political Weekly. 2001;**36**(22):1967-1975

[4] Rana RD. Pharmacy in ancient India.Indian Journal of History of Science.1987;22(2):119-121

[5] Saha D, Paul S. Glimpse of pharmaceutical education in India: History to advances. International Journal of Pharmacy Teaching and Practices. 2012;**3**(4):387-404

[6] Report of the Steering Committee on Health for the 12th Five Year Plan.
Yojana Bhavan, New Delhi: Health Division, Planning Commission; 2012.
p. 7. Available from: http:// planningcommission.nic.in/aboutus/ committee/strgrp12/str\_health0203.pdfc

[7] Health Infrastructure, National Health Profile. 2011. Available from: http://cbhidghs.nic.in/writereaddata/ mainlinkFil e/11%20%20Health%20Inf rastructure%202011.pdf [Retrieved: February 20, 2015].

[8] Sreelalitha N, Vigneshwaran E, Reddy GNYP, Reddy MR. Review of pharmaceutical care services provided by pharmacists. IRJP. 2012;**3**(4):78-79

[9] Nand P, Khar RK. Hospital and Clinical Pharmacy. 5th ed. Delhi: Birla Publications Pvt Ltd; 2008

[10] Nahata MC. Hospital pharmacy practice in India. Drug Intelligence & Clinical Pharmacy. 1984;**18**(6):523-524 [11] Annual Report 2011–12, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. Government of India. http://pharmaceuticals.gov.in/annualre port2012.pdf [Accessed: March 1, 2015]

[12] Desale P. An overview about pharmacy education in India. Indian Journal of Research in Pharmacy and Biotechnology. 2013;1(3):329-330

[13] Sachan A, Sachan AK, Gangwar SS.
Pharmacy education in India and its neighbouring countries. International Current Pharmaceutical Journal. 2012; 1(9):294-301

[14] Goyal R, Pareek P. A review article on prescription behaviour of doctors, influenced by the medical representative in Rajasthan, India.
IOSR Journal of Business and Management. 2013;8(1):56-60.
Available from: http://www.iosrjourna ls.org/ ccount/click.php?id=5229
[Accessed: December 15, 2014]

[15] The Order of MOH of Ukraine of 30.05.2013 № 455. On approval of the guidelines good pharmacy practice: Quality standards pharmacy services. Weekly Pharma. 2013;**27**:18-20

[16] Vetutneva NO, editor. Modern Concept of Quality Assurance of Medicinal Products. Vinnitsa: Nilan LTD.; 2018. pp. 69-75

[17] General Pharmaceutical Council of Spain. Good Pharmacy Practice in Spanish Community Pharmacy. Madrid: General Pharmaceutical Council of Spain; 2013. p. 15

[18] Good Pharmacy Practice (GPP) in developing Countries.Recommendations for Step-WiseImplementation: FIP. 1998:16

[19] Joint FIP/WHO guidelines on good pharmacy practice: Standards for

quality of pharmacy services. Fortyfifth report of the WHO expert committee on specifications for pharmaceutical preparations. WHO Technical Report Series. 2011;**961**: 310-323

[20] The Patient in Focus: A Strategy for Pharmaceutical Sector Reform in Newly Independent States//EUR/ICP/ QCPH062202WHO/DAP/98/8. 1998. p. 38

[21] Good Pharmacy Practice in the Newly Independent States. Guide the Development and Implementation of Standards. Provisor; 2002. p. 17: 3-8, 18: 3-13, 21: 8-14

[22] FIP Reference Guide on Good
Pharmacy Practice in Community and
Hospital Settings. First edition 2009/
Approved by FIP Council in Istanbul in
September 2009. The Hague,
Netherlands, International
Pharmaceutical Federation
Internationale Pharmaceutique; 2009.
p. 62

[23] Forty-fifth Report of the WNO Expert COMMITTEE on Specifications for Pharmaceutical Preparations (WHO Technical Report Series; No 961). 2011. pp. 310-23

[24] Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. Working Document QAS/10.352/. Vol. 1. 2010. p. 19

[25] Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services from the WHO Technical Report Series, No. 961, 45th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations © World Health Organization; 2011. p. 20

[26] Kasthuri A. Challenges to healthcare in India-the five A's. Indian Journal of Community Medicine. 2018;**43**:141-143 [27] Basak SC, Sathyanarayan D. Community pharmacy practice in India: Past, present and future. Southern Med Review. 2009;**2**(1):11

[28] Rotta I, Salgado TM. Ensuring consistent reporting of clinical pharmacy services to enhance reproducibility in practice: An improved version of DEPICT. Journal of Evaluation in Clinical Practice. 2015;21: 584-590

[29] Mohanan M, Hay K, Mor N. Quality of health care in India: Challenges, priorities, and the road ahead. Health Affairs. 2016;**35**:1753-1758

[30] MoHFW. Home; 2020. Available from: https://www.mohfw.gov.in/ [Accessed: August 05, 2020]

[31] Lakshminarayanan S. Role of government in public health: Current scenario in India and future scope. Journal of Family and Community Medicine. 2016;**18**:26-30

[32] Kalaiselvan V, Srivastava S, Singh A. Pharmacovigilance in India: Present scenario and future challenges. Drug Safety. 2019;**42**:339-346

[33] Palsokar G, Tajne M. Postgraduate research in pharmaceutical sciences in India: A survey of select pharmacy professionals. International Journal of Current Pharmaceutical Research. 2017; **9**:161-164

[34] Jose J, Rafeek N. R pharmacovigilance in India in comparison with the USA and European Union: Challenges and perspectives. Therapeutic Innovation & Regulatory Science. 2019;**53**:781-786

[35] Supreme court of India, Union of India vs. M. V. Mohanan Nair. 2020. Available from: https://indiankanoon. org/doc/55062525/ [Accessed: August 05, 2020]

[36] Kishore J. Legislation and health promotion in India. Review of Global Medicine and Healthcare Research. 2012;**37**:75-87

[37] Peraman R, Dugga HHT. Need for the refinement of licensing procedure for pharmacists in India. Journal of Young Pharmacists. 2016;**8**:293

[38] Roderick P, Mahajan R. India should introduce a new drugs act. Lancet. 2014; **383**:203-206

[39] Bennett D, Yin W. The market for high-quality medicine: Retail chain entry and drug quality in India. Review of Economics and Statistics. 2019;**101**:76-90

[40] Thaker Z, Jethva K, Bhatt D,
Zaveri M, Deshpande S. Orphan drugs:
Overview and regulatory review
process. International Journal of
Pharmaceutical Sciences and Research.
2019;10:505-518

[41] Praveen A, Deepak B, Abdul R.Drug approval procedure in India (CDSCO). Research & Reviews:A Journal of Drug Design & Discovery.2015;2:20-26

[42] Pravat KJ. Impact of pandemic COVID-19 on education in India. International Journal of Current Research. 2020;**12**:12582-12586

[43] World Health Organization. Coronavirus Disease (COVID-19) Outbreak Situation. 2020. Available from: https://www.who.int/emergencie s/diseases/novel-coronavirus-2019 [Accessed: August 10, 2020]

[44] Hedima EW, Adeyemi MS, Ikunaiye NY. Community pharmacists: On the frontline of health service against COVID-19 in LMICs. Research in Social and Administrative Pharmacy. 2020;**19**:30381-30388

[45] Ung COL. Community pharmacist in public health emergencies: Quick to

action against the coronavirus 2019nCoV outbreak. Research in Social and Administrative Pharmacy. 2020;**16**: 583-586

[46] Mukattash TL, Jarab AS. Pharmacists' perception of their role during COVID-19: A qualitative content analysis of posts on facebook pharmacy groups in Jordan. Pharmacy Practice. 2020;**18**:1900

[47] Shrimali, Gireesh, Retna Kumar, Aravind. Battery Storage Manufacturing in India: A Strategic Perspective. 2020. Available from: https://ssrn.com/abstrac t=3616404 [Accessed: August 10, 2020]

[48] Usha Sharma. Pharma cos should develop strategies to develop APIs and making India self-reliant: Dr Eswara Reddy. Express Pharma; 2020. Available from: https://www. expresspharma. in/latest-updates/pharma-cos-shoulddevelop-strategies-to-develop-apis-andmaking-india-self-reliant-dr-eswarareddy/ [Accessed: August 10, 2020]

[49] Department of Pharmaceuticals.
PLI Scheme for Pharmaceuticals and Medical Devices; 2020. Available from: https://pharmaceuticals.gov.in/scheme s#:~:text=Download%20(1.6%20MB)-, Production%20Linked%20Incentive% 20(PLI)%20Scheme%20for%
20promotion%20of%20domestic%
20manufacturing,Promotion%20of%
20Bulk%20Drug%20Parks [Accessed: August 10, 2020]

[50] Mandaviya M. Covid-19: Centre Chalks Out Four Schemes to Boost Production of Bulk Drugs and Medical Devices; 2020. Available from: https:// economictimes.indiatimes.com/news/ economy/policy/covid-19-centre-chalksout-four-schemes-to-boost-productionof-bulk-drugs-and-medical-devices/ articleshow/74867468.cms?from=mdr [Accessed: August 10, 2020]

[51] Manoharan V, Ganesh K. Pharmacy professions in India during COVID-19

pandemic: Present status, future challenges and a way forward. International Journal of Applied Pharmaceutics. 2021:32, 10.22159/ ijap.2021v13i1.39688-35

[52] Pharma 2020: challenging business. 2007. Available from: http://www.pwc. com/gx/en/pharma-life-sciences/ pharma-2020-business-models/index. jhtml

[53] Lin K, Travlos DV, Wadelin JW, Vlasses PH. Simulation and introductory pharmacy practice experiences. American Journal of Pharmaceutical Education. 2015;**75**:209

[54] Vyas D, Bray BS, Wilson MN.Use of simulation-based teaching methodologies in US colleges and schools of pharmacy. AmericanJournal of Pharmaceutical Education.2013;77:53

