NPSA-NPSS Workshop
“Paradigm Shift in Pharmacy Profession”

Workshop Proceeding
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Nepal Pharmacy Students’ Society (NPSS)
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PHARMACY PROFESSION IN ACADEMICS

Prof. Sadhana Amatya

Pharmacist:
- Ultimate experts in medicines
- Discovering new active ingredients
- Formulating

Conventional role of Pharmacists in the context of Nepal
- Community pharmacist
- Hospital pharmacist
- Industrial pharmacist
- Regulatory pharmacist
- Academic pharmacy

Current Situation in Nepal
- Fresh graduates (with Masters degree) enrolled mostly in the teaching profession
- The relative ratio of pharmacists are lesser in the market; hence an individual having to take responsibilities of getting involved in many institutions.

Global Scenario
- Academic Pharmacy
- Community Pharmacy
- Consultant Pharmacy
- Hospital and Institutional Pharmacy
- Informatics
- Pharmaceutical services/ Industry
- Ambulatory Care Pharmacy
- Regulatory Pharmacy
- ...........
- ...........
- Veterinary Pharmacy

Industrial Pharmacy
- Gene Therapy
- Nano Medicine- Targeting key biological aspects of diseases with a very low side effect.
- Pharmacogenetics- Latest clinical interest is at the level of pharmacogenetics involving variation in genes, involved in drug metabolism with particular emphasis on drug safety.

Future Direction
- Change the degree status- The change in degree status and accompanying curriculum should be intended to produce graduates capable of delivering pharmaceutical care, overseeing the medication therapies of patients and also producing practitioners who are able to pursue a variety of practice option.

Challenges
- Recruitment
- Retention
- Development of Faculty members
Primary Care Pharmacists
  i. Prevent people from becoming ill
  ii. Encourage healthier lifestyles

Role for the Academicians
  - Teaching
  - Mentoring
  - Test Preparations
  - New publications
  - Grant Submission

Role of the Stakeholders
  - Primary Stakeholders - Various Universities.
  - Secondary Stakeholders - Affiliated Institutions
    - Create Environment
    - Provide Opportunities
    - Collaborate

Conclusion
  - The Academic Pharmacists bear huge burden but they do have certain advantages
    a. Freedom to be creative
    b. Develop an identity with a specialty and enhance career
    c. Ability to collaborate with other professionals
    d. Personal satisfaction

Recommendation
  - Primary Stake holders
  - Quality Assessment
  - In-service Training
  - Upgrading of Undergraduate Colleges
  - Elective
  - Academic and related fields
  - Retention
  - Monitory factor
  - Curriculum update-Molecular Biology
  - School of Pharmacy with different departments.
Community Pharmacy in Nepal
– Phr. Ganesh Maharjan

Community Pharmacy
• Community Pharmacy is a place where Pharmacist provides total pharmaceutical services with other allied services to their communities.
• Pharmacists can play an important role in the delivery of healthcare to the community acting as a bridge between the community and medicine.

Changing waves in Community pharmacy
• Avoiding medication-related problems with the use of a drug utilization review and patient counseling
• The present scenario of Community Pharmacy in Nepal is still like a creeping child, there is only a few Pharmacists working in community pharmacy.

Pharmacy Profession is least counted profession in community.
• Knowledge level on medicine is very low in Public.
• Antibiotic can be purchase without prescription
• From other profession they are taking benefit of this situation
• There are lots of counterfeit and adulterated medicines in market.
• Dangerous alarming of antibiotic resistance

Challenges in Community Pharmacy

Human Resources:
• Pharmacy profession mostly in education and Industry
• Pharmacist has lack of professional knowledge, business knowledge and marketing knowledge.
• Most of medicine importers and Distributors are non-pharmacy professionals.
• Pharmacy inspection.
• Mostly Hospital Pharmacies are run by non-pharmacy professionals.
• The number of diploma and B. Pharm coming out are not enough !!!!
• They are enough, but are not willing to work in retail pharmacy. [lack of motivation, knowledge and remuneration]
• Numbers of license granted are not used in proper way. [License business]
• There is an acute shortage of pharmacists who are willing to work in the community pharmacies.

Education
• A degree student is given no practical exposure in a community pharmacy
• Most of the teachers have no practical exposure to community pharmacy.
• There are no practical applications of community pharmacy, no case studies, no patient contact, no communication skills development and no psychological studies of patient.
There is a lot of difference between theory taught in the books and the real life situation in community pharmacy

**Political challenges**
- Error in definition of dispensing
- There is no charge on professional dispensing
- The health ministry, DDA, NCDA and other health professional organization in 2066/5/2 tried to push that a 3 months training to sales person and to give them license to practice independently.
- When pharmacy registered in DDA, a letter forwarded to NCDA [nongovernment and non-professional organization] but there is no information to the Professional organization NPA, And GPAN
- We do not see the political will and commitment to include the pharmacist as an equal partner in the National health care system

**Commercial Challenges**
- Unhealthy Competition
- Difficult for a pharmacy to honour every prescription without brand substitution
- Brands which have sound alike, look alike name, polypharmacy and doctors bad hand writing
- Patient does not by full prescription, need for strip cutting. Medicine return after incomplete course of administration after week, month later. [dose interruption]
- Expiry problem: Expired, near expiry
- Affordability to hire staff in Pharmacy
- To generate sales, pharmacies need to stock allied items
- Medicine Shortage
- Accounting software available but professional is not available for operating pharmacy

**Legal Challenges**
- Laws and regulations relating to community pharmacy: These were made when there is no community pharmacy, and very few number of Pharmacist and most of the dosage forms and drugs did not exist. There is a need to change with changing pharmacy environment.
- Presence of Pharmacist
- Sale of prescription medicines without a prescription
- Implementation of drug laws
- Unregistered pharmacy

**Entrepreneurship**
Pharmacy owners and staff have tough work of running pharmacy in spite of all the challenges. They often have to make big sacrifices.
- Long hours of work in high pressure including night.
- Neglect of family.
- Neglect of their own health
• No vacations.

Management in Community Pharmacy
1. Inventory Management
2. Expiry Management
3. Cold Chain Management
4. Waste Management
5. Human Resource Management
6. Cash Management
7. Vender Management
8. Taxation
9. Administrative Management

Professional Job in Community Pharmacy
1. Welcome Patient
2. Prescription Handling
3. Medicine Selection
4. Medication Billing
5. Medicine Interaction Checking
6. Medicine Allergy Checking
7. Labeling
8. Patient History taking
9. Medicine Counseling
10. Medicine Dispense

Activity Errors in Community Pharmacy
1. Prescription Error
2. Patient Error
3. Dispensing Error
4. Counseling Error
5. Labeling Error
6. Invoice Error
7. Medication Error

Special Care in Community Pharmacy
i. Diabetes Care
ii. Hypertension Care
iii. Gout / arthritis Care
iv. Asthmatic Care
v. Prostatic Care
vi. Gastritis Care
vii. Thyroid Care
viii. Psychiatric Care
ix. Epileptic Care
x. ECP Information
xi. Migraine Care
xii. Skin Care

**Advance Service in Community Pharmacy**

a. Blood Pressure Monitoring / Report  
b. Blood Sugar Monitoring / Report  
c. Cholesterol Monitoring / Report  
d. Immunization Planning / Report  
e. Health History Record / Report  
f. Patient Information leaflets  
g. Patient Education  
h. Patient Medication Record  
i. Diet Counseling

**Documentation in Community Pharmacy**

- Prescription Error  
- Patient Complain  
- Patient Medication Record  
- Patient Allergy Reaction Record  
- Medicine Delivery Record  
- Blood Pressure Monitoring  
- Blood Sugar Monitoring  
- Health History Record  
- Prescription Record  
- List of Patient  
- Medicine Information Leaflet  
- Diabetic Food Plan  
- Immunization Record / Card  
- Medicine Calendar  
- Medicine Purchase Specification  
- Medic Alert Card  
- List of Shortage Medicine  
- List of Narcotic and Psychotropic Drug  
- List of Band Drugs  
- All Staff Records  
- Patient Referral Form  
- Patient Counseling Records  
- Stock Order  
- Purchase Order  
- Stock Analysis  
- List of Unregistered Medicine  
- Refrigerator Temperature Monitor  
- Medicine Expiry Record  
- Medicine Disposal Record

**OTC Service in Community Pharmacy**

1. Symptom Analysis and Interaction with Patient before dispensing OTC Medicines  
2. Non-drug therapy  
3. Home remedies  
4. 1st line drug therapy  
5. Referral to Physician / Hospital  
6. Cosmetics Service  
7. Tetanus Injection  
8. Vaccination  
9. First Aid Medication  
10. Allergy Management  
11. Burn Management
Information Service in Community Pharmacy
1. Disease Information
2. Medicine Information
3. Poison Information
4. Antidote Information
5. Hospital Information
6. Ventilator Information
7. Ambulance Information
8. Pathology Lab Information
9. Medicine Importer Information
10. Vaccination Information
11. Pharmacy Information
12. Contraceptive ECP Information
13. International Hospital Information
14. Doctors Information
15. Oxygen Distributor Information.

Marketing in Community Pharmacy
1. Pharmacy Facilities Information
2. Health History Record Marketing
3. Vaccination Marketing
4. First Aid Kit Marketing
5. Blood Pressure Marketing
6. Blood Sugar Marketing
7. Medicine Delivery System Marketing
8. Community Pharmacy Membership Marketing
9. Trekking and Mountain Medicine Marketing
10. Web site Marketing ‘www.xenopharmacist.com’
11. Dispensing Label Marketing

Community Pharmacy and Social Welfare
1. Health Camps
   a. General
   b. Special [Diabetic / Hypertensive / Women Health]
2. Medicine Donation
3. Cash Donation
4. Volunteers
5. Drug Information
6. First Aid Treatment
7. Special Health Day [HIV Aids Day, Diabetic Day]
8. To open Community Pharmacy

CONCLUSION
• Pharmacy and chemist shop, majorly a trade rather than a profession
• The professional aspects of checking prescription.
So…..

• We need to change the actions in our pharmacies from drug selling to medicine dispensing.
• We need to change our pharmacists from businessman to health care professionals
• We need to change qualified pharmacist to a trained knowledgeable pharmacist.

**Ideal Pharmacist Candidate need….**

- Competent
- Motivated/Enthusiastic
- Teamwork spirit
- Good communication skills
- Responsible
- Problem solver
- Dedicated

**Development Issues**

There is no legal or regulatory impediment for a Pharmacist to establish a community pharmacy.

**Development Plans…**

What we need are –

1. Motivation of Pharmacists to get to community pharmacy
2. Training for development of skills
3. Investment
4. Social awareness

What we need are –

• These young pharmacists should be trained.
• Then the group should set up single or chain pharmacies at the commercially viable locations.
• There should be an organized campaign to generate social awareness on benefits that society as well as an individual may derive from the community pharmacies.

*The world is changing, time is changing unfortunately we are still in dark there is no sign of light until and unless there is revolutionary change in this profession*
“Hospital Pharmacy Practice in Nepal, Present Situation and Future Vision”

Phr. Raj Kumar Thapa
President, HosPAN
Senior Pharmacist/Chief, Patan Hospital

Mr Kiran Sunder Bajracharya
Secretary, Public Relation, HosPAN

Hospital Pharmacy Practice in Nepal, Present Situation and Future Vision

HOSPITAL PHARMACIST ASSOCIATION OF NEPAL (HosPAN)

Hospital Pharmacy

Hospital Pharmacy is the health care service, which comprises the art, practice, and profession of choosing, preparing, storing, compounding, and dispensing medicines and medical devices, advising healthcare professionals and patients on their safe, effective and efficient use.

Mission of Hospital Pharmacists

- To be part of the medication management in hospitals, which encompasses the entire way in which medicines are selected, procured, delivered, prescribed, administered and reviewed to optimize the contribution that medicines make to producing informed and desired outcomes.
- To enhance the safety and quality of all medicine related processes affecting patients of the hospital.
- To ensure the 7 “rights” are respected: right patient, right dose, right route, right time, right drug with the right information and documentation.

Paradigm Shift in Hospital Practice

Supply centered Services
- Pharmaceuticals
- Therapeutic devices
- Adherence Aids

Patient centered Services
- Medication Management Reviews
- Disease State Management
- Prescribing etc........

Hospital Pharmacy in Nepal

Introduced in Nepal by United Mission to Nepal at the Shanta Bhawan Hospital. (Present Patan Hospital) and subsequently at Tansen Hospital in 1954. Then hospital pharmacy service was followed by
- TUTH, Bir Hospital
- Dhulikhel Hospital, Shaid Gangal Lal hospital
- Manipal Medical College teaching Hospital, KIST Teaching Hospital
- Kathmandu Model Hospital, Manmohan Memorial Hospital and others.
- New hospitals like civil servants hospital, Kantipur Hospital
- Hospital Pharmacist Association of Nepal (HosPAN) –2008.

Where are We??
- Supply centered service than patient centered service.
- Treating the disease not the patients.
- Inventory management.
- Dispensing and counseling (not adequate).
- Information to hospital staffs.
- Unit dose dispensing in some hospitals.
- Compounding service (Patan, TUTH, Dulikhel)
- Pharmacovigilance service (rarely)
- DTC service and Infection Control service.
- Limited or no clinical service.

Regarding the Current issue and challenges of Pharmacy departments are below listed:

- Sustainability
- Enhancement of quality of care and quality control
- Human resource development
- Public relation
- Research
- International Relation
- Rural networking
- Improvement of patient care

Some improvements in Pharmacy services are suggested as below listed points.

- Improving communications
- Information leaflets
- Improving access to the patients from outside the valley
- Improve Emergency care
- Standard treatment guidelines
- Emergency Medical service
- Digitalization
- Ensure sustainability
- Ensure patients are not lost
- Openly and friendly approach optimal use of OT
- Optimal use of other recourses like lab and Pharmacy
- Attract patient from outside valley
- Improve the flow of private patients
- Develop a web site
- Developing a master plan for the infrastructure of the future

The future direction.

Counseling is a professional responsibility and not an option for the pharmacist. Every pharmacist must develop this skill in order to ensure GPP and rational drug use. Counseling is imperative for the following reasons.

- Patients need to be motivated to take their drugs.
- Many patients do not read instructions on labels.
- Advices on drugs are better appreciated if the drugs are before the patient, and this puts the pharmacist in a unique position to counsel since he has both the drug and the knowledge.
- Last but not the least “A Pharmacist who monitors drug therapy has multiple opportunities to work directly with patients, nurse, and physicians to provide Pharmaceutical care”.
• Legal Provision
No legal provision
Some commitment from the government
  ➢ Bed > 25 – Assistant Pharmacist.
  ➢ Bed > 100 – Pharmacist
Limited number of pharmacists in Hospitals.
  ➢ GP = 29(10)
Even Government hospitals are not running their own pharmacies.
Drug and therapeutic Committee not working properly in most hospitals.

The reason we are Behind
  ➢ No Policy/Wrong Policy.
  ➢ Doctor dominated health policy.
  ➢ Economic transaction in pharmaceutical services.
  ➢ No incorporation of pharmaceutical service in health services.
  ➢ Focus more on availability than service.
  ➢ Uncontrolled marketing strategy.
  ➢ Common standard of practice missing.
  ➢ Less number of competent pharmacists.
    • No training opportunities. (working as well as new).
    • No upgrading in knowledge and position.
    • No internship programme.
    • Curriculum not able to cater pharmaceutical care services.

Scope
  • Lots of opportunities in Hospital pharmacy.
  • International shift in pharmacy practice.
  • Government initiation towards establishing their own hospital pharmacy.
  • Hospital management more interested in hospital pharmacy service.
  • Lots of opportunities for upcoming pharmacists with competency and dedication.

For Upcoming Pharmacists
  • Competency, Stability and down to earth pharmacists.
  • Excellent communication skills.
  • Innovative attitude
  • Willingness to overcome barriers.
  • Confidence in knowledge base and role of pharmacist in medication management.
  • Good listener and learner.
  • Specialized knowledge eg. Geriatrics, pediatrics, asthma, diabetes, hypertension.

Pharmacist should be aware on the five important criteria for proper drug use,
  • Accurate diagnosis
  • Rational drug prescribing
  • Correct dispensing
  • suitable packing
  • Patient compliance.
What Next??

- Improvement in policy regarding pharmaceutical care.
- Curriculum reforms in the pharmacy schools.
- Government intervention and facilitation.
- Training to the upcoming pharmacist and continuing education to the practicing pharmacist. (HosPAN is taking the initiation).
Where is pharmacy profession moving on industrial pharmacy and expectations from fresh graduate pharmacists?

Mr. Jaya Bir Karmacharya

Content
- Introduction
- Current situation – Global vs. Nepal
- Future direction & challenges
- Role of stakeholders
- Conclusion
- Recommendation

Introduction
- Quality, efficacy and safety of drugs have always been a matter of concern for the public.
- Conventional pharmaceutical manufacturing is generally accomplished using batch processing with laboratory testing conducted on collected samples to evaluate quality.
- Today significant opportunities exist for improving pharmaceutical development, manufacturing, and quality assurance through innovation in product and process development, process analysis, and process control.
- It has been determined that testing of the final product alone is not sufficient to rely upon the quality of drugs as it depends on starting materials, manufacturing processes, building designs, equipment and personnel involved.

Quality cannot be tested into products; it should be built-in or should be by design.

Pharmaceutical Industry in Transition
Drug development and time-to-market remain vital to business success in the pharmaceutical and biotechnology industries, but manufacturing efficiency has become equally important to future success and competitive advantage.

Major business drivers
- Increasingly crowded therapeutic categories
- Powerful and increasing global competition
- Weak new product portfolios
- Increasing regulatory requirements that new pharmaceutical products be proven both safe and effective
- Increasing demand for more available and affordable drugs and new drug products
- Exponential advances in technology.

Current situation – Global vs. Nepal
- World-Wide Pharmaceutical Market
  - 2007: US$ 712 billion, an increase of 6.4%
  - 2008: US$ 785 billion, an increase of 4.5 to 5.5%,
  - 2009 the forecast should surpass US $ 820 billion.

World-Wide Pharmaceutical Market
### Geographic distribution:
- 41% USA
- 20% Europe 5 (1)
- 11% rest of Europe
- 11% Asia excluding Japan
- 09% Japan
- 06% Latin America
- 02% Canada

### Sales by Therapeutic Category in 2008:
- Oncology: +13.9%
- ACE inhibition: +13.7%
- Anti-diabetes: +8.5%
- Anti-psychotics: +10.6%
- Anti-epileptics: +13.4%
- Auto-immune agents: +19.6%

### Pharmaceutical Sector Increase in Sales:
- +6.4% for the global market in 2007 and +4.5 to +5.5% in 2008
- +4.1% for the USA in 2007, whilst the forecast for 2008 is +2%
- +4.8% for Europe 5 (1) in 2007
- +3.6% for Japan in 2007
- +14% for «Pharmerging markets (2) in 2007»

(1) Europe 5: France, Germany, Italy, United Kingdom, Spain
(2) Emerging Pharma markets (according to IMS Health report 2008): Brazil, Russia, India, China, Turkey, Mexico, South Korea

### Generic Sales Increase:
- 5 to 7% increase in the world in 2009.
- Generic medicines are 30 to 80% less expensive than the original brands.
- US$ 135 billion will be affected by generics between 2008 and 2012.

### New Chemical Entities and Market
- **Authorisation Application:** 17 NCEs FDA approved in 2008 as compared to 18 in 2007, 22 in 2006 and 20 in 2005.
- **Biotechnology Medicines:** (therapeutic proteins and vaccines) Also known as Biologics, this market represents US$ 75 billion and is dominated by the USA which holds 56%.
- **Biologics represent 11%** of the world-wide medicine market and **17%** annual growth.
  - The 2008 forecast follows the world-wide market, estimated at US$ 82 billion, an increase of only 10%. In 2007:
  - 42% of medicines in clinical trials are Biologics.
  - 134 Biologics have been on the market for about 15 years and 5 Biosimilars have already been authorised by the EMEA (European Medicinal Evaluation Agency) in Europe.
  - 22 out of 114 Biologics acquired «blockbuster» status.
    - 7 new Biologics authorised in 2007

### Breakdown of wholesale price of a drug
Nepalese Pharma Market

- In 1979, the import of drugs was estimated to be worth Rs.114.6 millions and there were only about 400 medical shops. According to another study conducted in 1988 the importation of drug was Rs.385 million. The consumption at sales price in subsequent periods are as follows
  - 1992: Rs. 1532.0 million
  - 1999/2000: Rs. 5900.6 million
  - 2004/2005: Rs.10659.0 million
  - 2005/2006: Rs. 9610.0 million and
  - Mid 2009: Rs. 12000.0 million
- The market share of Nepalese companies are as follows
  - 1979: 5%
  - 2000: 25.5%
  - 2005: 32%
  - 2006: 35.2%
  - 2009: 36%
- Investment made in the pharma industry is about Rs. 8000 million
- Total employment made about 6000 people
- Self sufficient in about 60 products.
- At present, there are about 42 pharmaceutical industries in operation in Nepal. Among them 16 industries obtained WHO GMP certificate.
- 22 companies are making good progress to achieve WHO GMP certification
- 6 companies are not in good progress on GMP and are termed as sick industries.

Nepalese Pharma Market

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<td>8</td>
<td>Ibuprofen+Paracetamol</td>
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Nepalese Industry Activities
- Chemi Drug Industry was established in 1971
- Until 1978 medicines are produced without any stringent regulation. (This had resulted in haphazard development of the pharmaceutical industry)
- Establishment of DDA in 1979, an environment has created for drug industry
- After 1983, private companies have sprung up rapidly
- At present 42 pharmaceutical companies are in operation and couple of industries are in stage of final project phase
- Present Capacity Utilization: About 40%

General Background of Regulatory Practices
- Drugs Act- 1978
- DDA establishment-1979
- Drug Registration Regulation 1981
- Code on Manufacture of Drugs-1984
- National Health Policy- 1991

Regulatory Process to Establish a Pharma Industry
- Letter of Recommendations
- Product License
- Letter of Recommendation for Material Import
- Market Authorization:
  - Once DDA give the marketing authorization for the product, the successive batches can be marketed based on the internal quality control analysis and release form own laboratory.

Nepalese Industry Activities
- Generic Pharmaceutical Companies: (Mainly formulating of active ingredients and packing into finished drugs in various solid oral dosage forms)
- Mainly Family Owned Business: (The board of directors are among family members that results in narrow vision)
- Manufacturer import materials from India and outside
- The products are supplied to the domestic market only.
- Subcontract manufacturing is not in practice

Product Marketing
- Push Selling’ is very popular. (It is reported there the pharmaceutical companies go overhead to make aggressive marketing of their products. Their medical representatives are rumored to be offering anything up to 50-60% cover commission on the prices of the drugs they put in the
market. They persuade the medical practitioners, the drug retailers to switch over to their drugs while prescribing or selling.

- There is no legal enforcement for punishment on prescription substitution. (In this process naturally drugs with lesser potency or even the spurious ones could be dispensed)

**Future direction & challenges**

- DDA had awarded WHO GMP certificate to 16 Nepalese Companies
- More Companies are striving for WHO GMP
- WHO GMP opens access to government supplies restricting supply from Non-GMP companies.
- Every company operating in Nepal needs to fulfill WHO GMP requirements once it is made mandatory by DDA as planned to do so in near future.

**Export Situation**

- Trying to enter the Indian and other market
- WHO GMP Certification: (opened their opportunity to be present in the international market).
- One needs to put strong effort (on enhancing own technical capabilities and on exploring market availability for the products and possible price benefit for feasible export to occur.)

**Future direction and challenges**

- Strengthening WHO GMP norms and practices in
  - Certified companies (to be strengthened)
  - Companies to be certified (to be developed)
- National Drug Policy was promulgated in 1995 with emphasis for the development of pharma industry to achieve self-sufficiency in drug production
- Development of National Medicine Policy 2010 considering pharmaceutical industry as priority sector and to consolidate its strength to be made itself as a strong member of WTO
- As member of WTO Nepalese pharma industries can make use of the flexibilities offered by WTO to the least developed countries (LDCs) in order to be global exporters. Nepal can export medicines to other LDCs and non WTO member countries including Laos, Russia and several African countries as we produce medicines at one of the most economical prices in the world.

**Some challenges**

- Manufacturing drugs with similar therapeutic effects.
- Transit and transportation Hassles
- Strikes, Agitations, Delayed government process and load shedding would also had negative impact on production output
- Unethical promotion of medicines and competition with unequivalent quality products from national and foreign manufacturers.
- High investment requirement for technological up gradation.
- A great variation and ways of development pattern
- Management commitment is another important factory for achieving GMP standard for the companies.
- Weak technical capabilities of existing manpower
- Continuous migration of technical experts outside the country due to economical and political insurgencies.

**Role of stakeholders**
• DDA with stringent regulatory norms and practices and also to develop new medicine policy
• APPON in consolidating required investment and exploration of business opportunities among the member companies
• Professional associations (GPAN, NPA, NMA, NCAD, APPON etc) in consolidating technical know how and developing suitable environment for technology transfer
• Academic institutions in developing academic programs in developing required manpower to meet future challenges.
• Strong Academia-Industry linkage in collaborative research and development work to develop innovative works for pharmaceutical development as a whole.
• All the political parties its all cadres and leaders to establish peace and build conducive environment for professional practices.

Scope for Investment and Development of Pharmaceutical Industry in Nepal
• Nepalese companies need to attain the right product-mix for sustained future growth. Core competencies will play an important role in determining the future of many Nepalese pharmaceutical companies.
• Nepalese companies in an effort to consolidate their position will have to increasingly look at merger and acquisition options of either companies or products. This would help them to offset loss of new product options, improve their R&D efforts and improve distribution to penetrate markets.
• The simplified regulatory norms for those who are coming up with all required concept would of one of biggest advantage for foreign investment. The DDA also allows manufacturing latest drug molecule if one can provide sufficient evidence of safety and better efficacy over the similar existing drug.
• Research and development has always taken the back seat amongst Nepalese pharmaceutical companies. In order to stay competitive in the future, Nepalese companies will have to refocus and invest heavily in R&D.
• The Nepalese pharmaceutical industry also needs to take advantage of the recent advances in biotechnology and information technology.

Expectation from Fresh Graduate Pharmacists
• Needs fresh graduates with strong dedication, skill, knowledge and sincerity.
• A fresh graduate is also expected to have good habit of continual development and up gradation of technical knowledge.
• One needs to have strong brain and skill along with equally good heart as well for overall development.

Conclusion
• With the existing production of 36% percent of national drug consumption by the national manufacturers, there remains a wide scope to gain market share from the imported products, which accounts to 64% of total consumption.
• This data is very much lucrative and justify the good scope for development of existing industries on one end and good scope for investment to establish new set up. However to gain
the share by replacing imported product one needs to develop own capability to competed with the product in terms of quality and price.

**Recommendation**

- Continuous improvement of the quality system is assured by having an effective quality planning process.
- Every one must take responsibility for the quality of their work. A critical but difficult process is communication.
- Management must provide the direction (top–down), listen (bottom–up), and encourage cross-functional cooperation. It is clear that quality depends on the leadership of the organization.
- Development of a national technical team with involvement of professionals from every sector including industry, academia, regulatory agencies, international communities, and professional associations to dedicate its activities for development and effective implementation of national policies, rules and regulations for development industrial pharmacy sector in Nepal.

"Thinking is the capital.
Enterprise is the way
Hard work is the solution."

"Look at the sky we are not alone.
The whole universe is friendly to us and
Conspires only to give the best to those
Who dream and work."
- Dr. A. P. J. Abdul Kalam
Former - President of India

*So let us dream and work hard for professional development*
Paradigm shift in pharmacy profession Health care, norms and ethics

- Phr. Balkrishna Khakurel

Content

- Pharmacy profession - Existing framework for health care, norms and ethics
- Paradigm shift - direction and challenges (elsewhere)
- Norms and ethics
- Role of stakeholders
- Conclusion and Recommendation

Existing Framework

- 1972 NDC and 45 private manufacturers
- 1972 NPA
- 1978 Drug Act
- 1979 DRA
- 1991 NHP, 1995 NDP
  - 1996 GPAN
- 2000 NPC Act, Regulation 2002
- 1994 onwards 4 Universities with pharmacy program, 13 under graduate and 21 diploma programs

- Manpower
  - 4 Universities, 14 Colleges/
    - B.Pharm/M. Pharm
    - CTEVT (Dip. Pharm)- 21
  - Pharmacists - 700
  - Pharmacy Assistants - 1200
  - Vyabasayi (Trained and Recognized ‘druggist’) -16000

- National Health Policy (NHP) - provision for drug policy (NDP)
- NDP1995 - pharmacy activities to be performed by pharmacy manpower
- MoHP’s Directives – 24 hours pharmacy with pharmacist/ assistant in health facilities with 50 or above beds
- Less than 20 pharmacist and 100 PA so far in hospital services in over 200 public and private hospitals
- NPC Act / Regulation prescribes professional code of conduct: no discrimination, work based on knowledge and skill obtained, no undue financial benefits from activities damaging the professional image, responsibility to be taken of professional work undertaken, name update.
• **Hospital Pharmacy**
  o Pharmacy service need to be available 24 hours in a hospital
  o Pharmacy assistant for a hospital of up to 25 beds
  o Supervision of a pharmacist for a hospital of up to 25-100 beds.
  o Pharmacists operate the pharmacy for hospitals with >100 beds within the concept and scope of D&TC of the hospital.
  o Temperature and relative humidity of room used for maintaining stock and sale-distribution has to be within prescribed range.
  o All medicines required to be maintained in specified low temperature should be stored in the refrigerator.
  o Narcotic drugs need to be securely stored in a locker
  o Expired medicines need to be disposed routinely following appropriate technique

• **Community Pharmacies (CP)**
  o CP should have a quality policy and commitment of the owner to service standard as per quality manual.
  o Staff of CP should be trained on quality manual
  o CP should be audited as per quality manual
  o Service manual is the basis of service of CP
  o Service manual implemented as per of quality manual
  o Legally recognized manpower for CP- pharmacists, pharmacy assistants, vyabasayi

**Existing Framework**
• No structure of pharmacy practice
• Hardly a few qualified pharmacy manpower engaged in pharmacy practice
• No provision of formal pharmaceutical care by pharmacist right from specialist, tertiary, regional / sub-regional, zonal, district level hospitals and primary care levels (PHC, HP and SHP) in the public sector and at all levels of private hospitals and using homes despite requirements of pharmacist's service in pharmacy as per the government’s standards

**Paradigm Shift**
• Fundamental change in theory, approach, practice framework or model or pattern
• The move from a product-centered to a cognitive services- Patient centered practice for pharmacy.

**Paradigm Shift (Elsewhere)**
• Product-centered distribution activity to a patient-centered system by which pharmacists are assuming new responsibilities, helping patients achieve healthy outcomes, and providing value previously unrecognized by the health care system.
• Pharmacy profession must establish new relationships with both patients and their health care providers to assure better outcomes. To accomplish this goal, the health care system needs to be refined to assure appropriate selection, use, and monitoring of pharmaceutical drug products.

Paradigm Shift
• Pharmaceutical care is patient-centered practice and evidence-based and is most effectively delivered in a well-functioning inter-professional team.
• The profession of pharmacy is the logical solution to meeting the challenge of controlling the effectiveness, minimizing the complexity, and managing the expense of pharmacotherapy in a new emerging health care system.
• Pharmaceutical care is becoming the accepted norm for pharmacy practice
• Patient’s right to informed consent (knowledge base upon which a patient may rationally choose or refuse treatment
• Strive to promote information to patient regarding professional services truthfully, accurately and fully.
• Society expects a profession to generate its statement of acceptable behaviour.
• Pharmacists can play an increasingly important role as part of the primary health care team, working with patients to ensure they are using medications appropriately and providing information to both physicians and patients about the effectiveness and appropriateness of certain drugs for certain conditions.
• This should allow pharmacists to consult with physicians and patients, monitor patients’ use of drugs and provide better information and communication on prescription drugs. In the future, there may also be a role for pharmacists who are not engaged in the retail sale of prescription drugs to prescribe certain drugs under specific, limited conditions.
• New roles for pharmacists will involve solving health care problems rather than selling drugs.
• Patient-centered clinical services should be offered to all patients, reflecting the highest practice standard attainable.
• The patient’s health-related quality of life has become an issue.
• Pharmacists’ effectiveness and the quality of their efforts will be closely monitored and measured, using performance indicators focused on treatment outcomes.
• The patient-centered paradigm combines the traditional distributive role of the pharmacist with new clinical obligations and responsibilities toward the patient.
• The pharmacist and patient are no longer passive in the process of health care delivery.

Pharmacy Profession – Norms and Ethics
• Pharmacy practice has not been based on previous research and evaluation.
• Content of the information and advice that pharmacist give
• The process by which the information is imparted
• A formulary for OTC medicines, documentation of recommended treatment, advice and referrals for both OTC and prescription medicines, mechanism for feedback from patient so that outcomes can be recorded.
• Self-regulation and self-discipline.
• Legal prerogatives given by society in return to accepting responsibility to maintain a standard of conduct.
• Ethics - control of profession from within
• 4 principles of health care ethics – autonomy, beneficence, non-maleficence and justice to be followed

Stakeholders’ Role
• Pharmacy is an inextricable part of the health care delivery system and will be influenced by—and hopefully will influence—events occurring within the health care system as a whole.
• Health care professionals, including pharmacists, must change their roles to better meet the health care needs of the people
  – positively influence treatment from pharmacy setting, monitor progress using dispensing process as the framework
  – Management of chronic conditions
  – Management of minor ailments
  – Promotion of healthy lifestyles
  – Advice to other health professionals
• Health care leaders and administrators recognize that specific attention must be focused on the design and process of medication use systems that can assure patient safety.
• Develop pharmacy practice standards
• Identify pharmacy practice model sites and facilitate / monitor / evaluate practice
• Undertake research on issues around key roles away from supply-oriented roles like management of prescribed medicines, chronic conditions, minor ailments, promotion of healthy life-styles, and advice to other health professionals
• Promote DTC concept in health facility, contract pharmacist and implement GPP.

Conclusion
• Pharmacy practice structures and process is very limited
• Stakeholders are not active towards creating pharmacy practice structures
• Evidences to support a range of pharmacist’s role is altogether lacking.
• Future agenda in the light of existing evidences for practitioners, researchers and those involved in service development is also lacking.

Recommendation
• Professional standards and ethics should be formulated and implemented
• Model pharmacy practice site and framework should be developed, monitored and evaluated.
• Research projects on all key roles (away from supply oriented roles) of pharmacy practices should be undertaken to generate evidences.
• Strategic action plan for the pharmacy profession as “fit for purpose” for the health care system of the future should be developed.
• Identify social and economic benefits of improved drug therapy.
• Identify structural, legislative, policy, program and funding requirements to support transitioning of the pharmacy profession.
• Preferred focus on future of pharmacy profession include: role change and pharmacy practice models; pharmacy human resources; pharmacy education and continuing professional development (CPD); information and communications technology (ICT); financial viability and sustainability; legislation, regulation and liability; and leadership for the profession.
• Pharmacists must match the pace of health care reform or risk losing parts of their role to other professions.
• The development of a more coordinated, collaborative and interdisciplinary team approach toward patient care would enable our health care system to attain improved outcomes and more cost-effective drug therapy.
• That there is a need for members of the pharmacy profession to become more literate about, and engaged with, value.
• The education and training of pharmacists needs further examination as the profession evolves towards “preferred future”.
• Current university curricula do not prepare new pharmacists to practice in a manner that is patient-focused, playing a key role on the health care team by actively managing drug therapy.
• Pharmacists who are in practice may need educational support (e.g., CPD) to maintain an up-to-date knowledge base in an area that is rapidly changing.
• Incorporating interdisciplinary education into the university curricula of all health professionals, including pharmacists, will be essential to build strong primary health care teams.
Harmonisation of undergraduate pharmacy curriculum: Is it necessary in Nepal?

Prof. Panna Thapa

Introduction
The profession of Pharmacy blends science, technical art and human relationships in a unique fashion.

Profession of Pharmacy (Situations and Issues)
Issue 1: In developed countries
Pharmacy Practice has been moving from its original "Product focus" to a "Patient focus"
Issue 2:
In many public policy circles, the role of the profession of Pharmacy and its contributions are too often unrecognized and even misunderstood.
Issue 3:
There is an increasing globalization of healthcare.
Issue 4:
There is a significant gap in healthcare services between developing and developed countries which needs to be addressed.

Profession of Pharmacy (What is our Mission?)
FIP’s mission statement is: to improve global health by advancing pharmacy practice and science to enable better discovery, development, access to and safe use of appropriate, cost-effective, quality medicine worldwide.
(Do we not share the similar mission at local setting??)

FIP's Policy on Good Pharmacy Education Practice
In a nutshell it states that the basic (first degree) course of education need to be designed to ensure:
Newly qualified pharmacist has the necessary knowledge and skills to commence practicing competently in a variety of settings including:
– Community
– Hospital
– Pharmaceutical industry
CPD must be a life long commitment for every practicing pharmacist.

There is no single, best model for the education and training of pharmacists on a worldwide basis but there are common concepts, principles and practices that should be employed by pharmacy education policy-makers to meet the needs of society locally, regionally and worldwide.
**Expanding Pharmacy's educational horizons**

- To move the profession in a new direction we should develop our future leaders to become change agents to transition the practice of pharmacy from its primary focus on drug distribution to a practice environment that places the patient and their safe and effective use of medications as its central focus.
- We need to have a Global alliance for Pharmacy Education for creating a contemporary vision of pharmacy practice & education (it is coming up through FIP!)

**We need to try to find answer for:**

- What will pharmacists do professionally in future say 2020 or 2030 in Nepal?
- Can medicine (physicians) alone address the primary care shortage?
- Can and should pharmacists be involved in meeting the primary care needs of our population?
- Do we need Inter-organizational collaboration with medicine, nursing and other discipline to advance inter-professional education?
  
  **“Interdependence”** is the major route on our roadmap to the future!

**Pharmacy Education Issues**

In order to prepare our pharmacy graduate for an undiscovered future:

Pharmacy Education should maintain:

- a dynamic (regular curricular reform)
- challenging and
- comprehensive curriculum
- Sciences relevant to Pharmacy Education are:
  - Natural Sciences
  - Applied Sciences
  - Clinical Science
  - Other Sciences such as behavioral and Communication Sciences

Ideal balance between the various sciences in Pharmacy education could be complex!

**Pharmacy Education (Harmonization Issues)**

Before talking about Harmonization of curriculum, we need to verify end points of pharmacy education by asking ourselves:

- What are pharmacists doing in Nepal?
- What are pharmacists doing that could be done by others?
- Are they doing it right, and if not, what are the constraints pharmacists face in Nepal?

Harmonization (clarification of term):

- It has been described using expressions such as ‘synchronization’, ‘coming together’, alignment’, or ‘similarity of outcomes’.
- It should not be understood as: “a common baseline” or an agreement “on commonality” or on transferability of students between pharmacy schools”

Curriculum: need to be seen as a “Broad Framework, including learning outcomes, assessment and teaching methods”
Why do we need Harmonization of Pharmacy Curriculum/Education?

- Is it for improving people's health by ensuring a minimum range of competencies for Pharmacists in Nepal?
- Does it enable us to share human, physical and financial resources?
- Is it for strengthening relationships with key stakeholders from Pharmacy Schools, Pharmacy Council and Drug Regulatory Authority?
- Do we need baseline data on education and training, roles of various bodies and regulatory information?

NPC Guidelines on standards and Criteria for Pharmacy degree programs

**NPC guidelines have 7 major sections:**

1. Mission and goals of the School or Department or College
2. General Characteristics of a basic degree course in Pharmacy
3. Academic/teaching staff
4. The educational program: course content, teaching learning approaches, student assessment and learning resources
5. Student affairs
6. Physical facilities and other resources
7. Management systems

NPC Guidelines on Accreditation of degree programs in pharmacy states:

“The NPC does not want the criteria and indicative detailed educational program (curriculum) to be overly constraining or too rigid that may stifle initiative, development and expansion in the field of pharmacy”.

“It has confidence in the commitment, expertise and innovation of academic staff in or working with higher education, including teacher-practitioners and visiting faculties”.

“These experts are allowed, indeed encouraged by NPC to produce diversity of content and approaches across Schools of Pharmacy in Nepal. Such diversity is strength”.

- Knowledge domain:
  - Practice of Pharmacy;
  - The source, isolation, characterization, analysis and properties of substances used in medicines.
  - Pharmaceutical Designs and manufacture.
  - The action and uses of pharmaceuticals and other products.

- Professional competencies

- Attitude domain etc.
Where do we stand in Profession and Pharmaceutical Education in Nepal?

- BPharm curriculum of Nepalese Universities is in line with the mission of Pharmacy Profession.
- Curriculum should not be prescriptive rather it must be dynamic.
- Duration of BPharm (how many years?) in order to produce 7 star Pharmacists.
- Is there harmonisation of pharmacy curriculum (education) in Nepal? To some extent answer is 'Yes'—see NPC’s accreditation guidelines. But we need to have more homework!

Areas of Harmonization of Pharmacy Curriculum/Education?

- Entry requirement for degree programs;
- Basic competencies (i.e. role of pharmacist in Nepal—Healthcare systems, industry etc);
- Duration of degree programs;
- Guidelines for incorporating Pharmacy assistants into degree programs.

Summary

- Harmonization need to be understood as 'comparability' but not as standardization or uniformity of program and degrees.
- Harmonization of pharmacy (first degree) curriculum need to be taken up as global agenda.
- We need to agree upon the areas of harmonization based on the role of Nepalese pharmacists in the Healthcare systems (community and Hospital) and pharma industry (core competency).
- Harmonization that encourages diversification is highly desirable.
- Curriculum: need to be seen as a "Broad Framework, including learning outcomes, assessment and teaching methods"
- But if we take harmonization issue as "common baseline" then arguably it kills innovation in curriculum development and takes away Academic Freedom!
- Pharmacy profession and education is at the cross-road in Nepal.

“A man would do nothing if he waited until he could do it so well that no one would find fault with what he has done” —Cardinal Newman
Need for PharmD Program in Nepal
- Prof. Balmukunda Regmi, MPharm, PhD

Status of Pharmacy and Pharmacists in Nepal

Pharmacy – a drug shop “no proper storage, no proper counseling, no drug information, no proper manpower”

Pharmacist – one who leases his license to the business firms “the pharmacist rarely deals with the business whether it is teaching, manufacturing, dispensing or drug information”

Pharmacist – who holds an advantageous position as an administrator, inspector, committee member “the pharmacist is not different otherwise”

Pharmacist – whose signature is mandatory if you want something done “others are not allowed to sign in his/her absence”

Change the Status of Pharmacy and Pharmacists in Nepal!

- Consumer to a retailer, “Mr. pharmacist, what should I do if I become pregnant within 3 days of taking this medicine?”
- Animal rightist to a pharmacy program coordinator, “Why do you need to carry out these LD50 experiments?”
- Hospital director to the pharmacist, “Compare these two brands of hepatitis B vaccine and recommend which one we should prefer.”
- Dermatologist to the dispenser, “Please dispense 50 grams of freshly prepared BIPP”
- General practitioner to a patient, “Find out the details of its possible interactions with food and precautions to be taken”
- A nurse to a pharmacist, “should I give it IV or IM? Can it be given with DNS?”
- A mother to a doctor, “The pharmacist says using cough syrups is irrational. Can you prescribe something else for my daughter?”
- A notice at the pharmacy, “Because the pharmacist is on leave, today’s services will be limited to those carried out by oriented vyavasayis. We apologize for inconveniences to our customers!”
- A pharmacist to her fellow pharmacist, “Can you advise me whether I can participate in the psoriasis trial planned by Nepal Herbal Industry Derma Division? I do not know what are the risks involved.”

Philosophy of Pharmaceutical Care

- Charges pharmacists with the responsibility for providing drug therapy that achieves defined outcomes and improves a patient’s quality of life.
- Pharmacists are expected to interact with patients and other health care providers to assure that the drug therapy prescribed is appropriate and achieving the desired outcomes.
Current Situation – Global Vs Nepal

Countries with the PharmD program as the required first degree - USA, The Netherlands, Iran, Pakistan.

Alternate entry level PharmD degree alongwith conventional BPharm program - Canada, India, Jordan, Lebanon, Nigeria, Thailand, Palestine, Philippines, Saudi Arabia

Post-graduate PharmD program - Egypt, New Zealand, Qatar and South Africa

Kuwait is in the process of implementing a post-BS PharmD (ACPE recommended that they pursue this option rather than changing their current BPharm degree to a PharmD).

Nigeria and Kenya are considering a move to all PharmD (entry-level).

Ghana is considering the PharmD (entry-level).

One school in UAE is considering changing its entry-level degree to the PharmD.

An entry-level PharmD is under development in Poland.

New Zealand is considering about possibly of discontinuing the PharmD.

Nepal: Kathmandu University is planning to introduce post-baccalaureate PharmD

Tribhuvan University is considering an entry-level PharmD program

Future Trends and Challenges

- Change our diploma, undergraduate and postgraduate education from knowledge-based to competency-based
- Pharmacy institutions will always have to answer the questions posed by the doctors, “In what way is pharmacist’s knowledge superior/equal/complementary in medical sciences to that of the doctors?”
- A 6-year curriculum in pharmacy education is likely to cause educational inequality and may ignite a struggle for power between pharmacists and physicians
- Industry-Institute interaction is extremely low, exposure of students to industry is virtually nil and teachers have little interest in work other than assigned. The linkages between institution and industry are too thin.
- Success of PharmD program in Nepal depends on our ability to convince policy makers such as the Ministry of Health, DDA, DHS, health-related professional councils, and the public in general of the role qualified pharmacists can play in the better healthcare of people.
- The first few batches of PharmD graduates will play a decisive role in the acceptance of the pharmacists by other members of the health care team and the patients and the public in general. We should not let the degree just prove a tag.
- There is a danger of clinical pharmacy and PharmD programs being promoted as isolated single entity and not related to a stable population-based pharmaceutical system which we should avoid.
Role of Stakeholders

- Nepal Pharmacy Council
- MoH Department of Health Services and Department of Drug Administration
- Pharmacy-related Professional Organizations
- Universities
- Nepal Medical Council
- Nepal Medical Association
- Global market

Conclusions

- Era of globalization - we cannot remain unresponsive to the global trend and deny our fellow citizens of the quality pharmacy service they deserve
- Primarily it should be the pharmacists’ concern to introduce more competent PharmD program in Nepal.
- We should try our best to convince all the stakeholders for this genuine cause.
- Time it may take, introduction of PharmD program is inevitable in Nepal.
Pharmacy Research and Information in Nepal
Phr. Uttam Budhathoki

Introduction
- **Research**: "Search for knowledge or any systematic investigation to establish facts."
- **R&D**: "Creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications."

The Global R&D Challenge
- **Must Be Globally Safe and Efficacious**
  - Across Racial and Ethnic Groups
  - Across Age, Weight, and Sex Differences
- **Must Appeal to Global Markets**
  - Different Cultures, Healthcare systems, Distribution systems
- **Pass Global Regulatory Review**
  - MOST Regulated Industry in the World
  - Must meet regulatory requirements in EVERY country
The Long Road to a New Medicine

**Pharmaceutical R & D – A Multi-Disciplinary Team**


Over 100 Different Disciplines Working Together
Research based products and its partners

Universities

RESEARCH BASED PHARMACEUTICALS PRODUCTS/INNOVATION

PHARMACEUTICAL RESEARCH CENTRES
(Govt. & Non-govt)
A Research-Based Health Care Company

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2000 Total R&D Spending ($ Billions)

R&D in US

Research and Development Continues to Grow

Mean Approval Times for New Therapeutics*, 1998 – 2008**
America's pharmaceutical research and biotechnology companies invested a record $65.2 billion in new research and development projects. PhRMA member companies alone invested an estimated $50.3 billion in pharmaceutical and biotechnology.
INDUSTRY-ACADEMIA LINKAGE

- 16 August 2005: To begin and booster academia and private sector collaboration for technological development of the nation.
- Bioavailability and Bioequivalence Study of Ciprofloxacin (Proxin USP 500mg tablets) - Completed
- Proate-200 SR tablets - Understudy.
- 24 December 2007: Shimadzu KU Education Centre for Pharma Professionals @ Dept of Pharmacy, KU.
- GC and HPLC training/Research purpose

RESEARCH GRANTS

- Nepal Academy of Science and Technology (NAST)
- University Grant Commission (UGC)
- Nepal Health Research Council (NHRC)
- International Science Programme (ISP)
- International Foundation for Science (IFS)
• Nepalese Pharmaceutical Industries

**Nepalese Journal**
- JNHRC
- Nepal Journal of Science and Technology
- Journal of Nepal Chemical Society
- JNMA
- Journal of Institute of Medicine
- KUSET
- Himalayan Journal of Sciences
- Kathmandu University Medical Journal

**International Journal**
- Elsevier
- Springer
- Hinari
- Wiley Inter Science
- Asian Journal of Pharmaceutics
- The AAPS Journal
- Pubmed

**National and International Pharmaceutical Organisation**
- FIP
- IPSF
- GPAN
- NPA
- AAPS
- APPON
- Federation of Asian Pharmaceuticals

**Drug Information System in Nepal**
1. Drug Information Network of Nepal (DINoN)
   Five centres
   • DDA (focal point), Kathmandu.
   • Drug Information Unit (DIU), TUTH, IoM.
   • NCDA), Kathmandu
   • Resource Center for Primary Health Care (RECPHEC), Katmandu.
   • Nepal Health Research Center (NHRC), Katmandu
2. Bangladesh, Bhutan, India and Nepal (BBIN)
   • To share the information on the control and management of few selected infectious diseases that is common to these countries.
   • The common diseases are Malaria, Kala azar and Japanese Encephalitis.
   • Research in the field of insecticide resistance of the vectors and drug resistance of the parasites

3. Nepal Poison Information Center (NPIC)
   • Part of United Hands to Nepal and affiliated to the Central Ohio Poison Center in North America.
   • Provides information on poisoning, adverse drug reactions and insects’ stings including snakebites.
     Publish a quarterly newsletter: Access

4. Nepal Centre for Telecommunication (NCT)
   • Joint venture between Nepal and Manipal group
   • Provides distant education program in India and South East Asia including Nepal.
     Provides teleconference between doctors in Nepal and the doctors in Ohio State University on special topics like Neonatology and Therapeutic drug monitoring

Conclusion
1. Research grant & its output.
2. Infrastructure continuity.
4. Companies’ sales & R&D.
5. Govt policy and support in research.
6. Political stability and security.

Recommendation
2. Universities & Research centers towards innovation.
3. Logical flow of Research funds and their utilization.
5. R&D fund: sales of industries to be focused.
6. Skill development and Infrastructure.
7. Govt policy and political stability.
8. Concept of Centre of Excellence (like NIPER, India).
Rational use of medicines and role of pharmacist

- WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that only half of all patients take them correctly.
- The overuse, under use, or misuse of medicines results in wastage of scarce resources and widespread health hazards.
- The rational use of medicines (RUM) contributes to high-quality health care while irrational use leads to health hazards and wastage of resources that are already insufficient in the majority of health care systems.

6 rights for RUM:
- Right drugs
- Right dose
- Right route
- Right duration
- Right price
- Right information

Some common problems of medicine use:
- Self-medication
- Misuse of antibiotics
- Over use/demand of injections
- Use of irrational drug combinations
- Use of herbal medicines and supplementary medicines
- Aggressive pharmaceutical promotion
- Use of needless luxurious drugs such as lifestyle drugs

Scope for RUM at hospitals:
- Medicine and therapeutics committee (MTC)
- Medicine information center
- Pharmacovigilance center
- Medication counseling center
- Hospital pharmacy
- Pharmaceutical care and pharmacy practice

Medication counseling center:
- Deals with providing information, advice and assistance about medication and therapy either orally or in written form to the patients or to their representatives.
- Leads to better compliance
- Depending upon the demand services
- Omnibus Budget Reconciliation Act 1990 (OBRA-90) recommendations
  - Name and description, dosage, route, duration, special direction for administration, common adverse reactions, drug interactions, contraindications, techniques of self monitoring, storage, refill information, action to be taken in case of missed dose
- Vaginal pessaries, dry powder and metered dose inhalers, insulin pen

**Pharmacovigilance activities:**
- ADR reporting form designing
- Placement at wards and OPDs
- Regional pharmacovigilance center
- ‘Vigiflow’
- Orientation programme for various levels of staff
- Community pharmacovigilance initiatives

**Involvement in MTC activities:**
- Hospital medicine list
- Generic medicines
- OTC drug list
- Developing own hospital formulary
- Academic detailing
  - Unbiased information
  - FDCs, ORS

**Hospital formulary:**
- Restriction of brands
- Formulation of objective criteria for selecting medicines
- Creation of a hospital medicines list
- Regulation of access of medical representatives to prescribers

**Monitoring drug use:**
- Drug utilization studies
- Prescribing indicators
  - Average no. of drugs per encounter
  - Total no. of drugs prescribed by generic name
  - Percentage of encounters with an antibiotic prescribed
  - Percentage of encounters with an injection prescribed
  - Percentage of drugs prescribed from EDL

**Patient care indicators:**
- Average consultation time
- Average dispensing time
- Percentage of drugs actually dispensed
• Percentage of drugs adequately labeled
• Patient’s knowledge of correct dosage

**Medicine information services:**
• The information about medicines as provided by the company representatives to the prescribers - biased
• May not be current or evidence-based
• Access to unbiased information
• Objective information about medicine and therapeutics
• Reduction/prevention of drug related complications (DRCs)
• Documentation
  o Designing of forms

**Antimicrobial management team:**
• Formation of infection control committee
  o Members of MTC
• Selection of antibiotics for various infectious disease
• Framing guidelines
  o SIGN guidelines for SAP
  o Evidence based recommendations to reduce inappropriate prophylactic antibiotic prescribing
    • Scottish Intercollegiate Guidelines Network

**Teaching students to use medicines rationally:**
• PBL sessions
• Activity based sessions
  o Pharmaceutical promotion, social issues in medicine
• Guide to good prescribing

**Training of pharmacy staffs:**
• Training related to pharmacy practice
• Orientation for pharmaceutical care services
• Motivation for future works

**Conclusion:**
• In the present scenario, the pharmacist is a coordination centre between different members of healthcare team and the patients.
• Hence, proper role and involvement of a pharmacist in safe use of medicines and overall healthcare programme becomes very crucial.
What fresh graduate Pharmacist can Do?
Phr. Prajwal Jung Pandey

**Drug expert:**
The drugs & pharma industry is a multibillion-dollar business. In the rapidly changing global scenario the pharmaceutical industry and professionals will play a vital role in shaping up our national economy. This new decade is thus, bound to have an ever growing demand of pharmacy professionals not only in the country, but even worldwide. Anticipating this demand the government has to taken special steps to boost this unique discipline having a blend of both technology, as well as, health-sciences.

**Career Opportunities:**
A career in pharmacy, unfolds a vista full of opportunities leading to a golden future for a young career aspirant. The job opportunities, working conditions, job satisfaction and monetary benefits are getting better day by day.

**Opportunities so far:**
- Production & Manufacturing
- Hospitals and Other Institutional
- Analysis & Testing
- Research & Development
- Regulatory Affairs
- Academic Pharmacy
- Community Pharmacy
- Marketing

**PHARMACY ABROAD:**
- Golden opportunities galore for qualified Pharmacy professionals in various countries including the U.S.A., Canada, European Countries like U.K., France, Germany, African Countries like S. Africa, Nigeria, Yemen, Gulf Countries like Saudi Arabia, Kuwait, South East Asian Countries like Singapore, Korea, Japan, etc. and the Australian Continent including New Zealand.
- There are plenty of higher education and research opportunities in the developed western countries along with excellent job openings. The pharmaceutical career is one of the highest rewarding careers in these countries.
- The monetary job benefits abroad are highly exciting, job profiles in African Countries like, and Nigeria, Yemen & Gulf Countries like Saudi Arabia, Kuwait mainly as pharmacists in drug stores and hospitals.
Current scenario of pharmaceutical Industry in India:

- Indian Pharma profession has grown tremendously and has become self-sufficient industry known for producing quality medicine at economic price worldwide. Indian Pharma industry, which has registered a spectacular progress today, ranks 4th in volume and 13th in value in the global pharmaceutical market with exports worth USD 2.6 billion besides domestic sales amounting to over USD 4 million.
- There are 26,000 pharmaceutical companies in India and out of them 300 are organized sector. Today 40 % of the world’s bulk drugs requirement is met by India. 15% Scientists working in drug discovery laboratories in USA are Indians. The manufacturing units within the country are meeting about 80% of the country’s drug requirements. The drug production sector is equipped with technology and researched knowledge base. The industry produces drugs worth rupees 18000 crores and is growing at 9 per cent every year.
- India is emerging as a global source of vaccines Increasing number of hospitals, nursing homes and pharma-companies all over the country is a clear indication of the growing scope in this area. Thus to meet the ever demanding needs of pharmaceutical industry in the country and abroad too, the well-qualified pharmacists are needed. Pharmacy offers reasonably good career opportunities both by way of jobs as well as in terms of starting own business.

![Fig1: New products fuel growth](image1)

![Fig2: Indian Companies Growing Faster Than MNC](image2)

![Fig3: Chronic Therapy Areas Growing Faster Than Acute Therapies](image3)
Current scenario of pharmaceutical Nepal:
- Emerging field
- Scope of pharmacy profession is gearing up day by day
- New field has being identified
- Pharmacist are not job less

Emerging scope of pharmacy:
- Hospital
- Community
- Academics
- Marketing
- Public health

New opportunities:
- Pharmacy Practice
- Sales and marketing
- Public health
- Consultancy

Pharmacy Practice:
- The expanding scope of practice for licensed pharmacist has resulted in increased educational requirements for students and increased responsibilities for practitioners.
- Pharmacists participate actively in drug monitoring and disease management, multidisciplinary clinical care, and patient education.
- Pharmacist expertise is to advise patients and prescribers with regard to potential drug/drug, drug/food and drug/disease interactions and the changes in management of chronic and acute illnesses

Sales and Marketing:
- The Pharma. Sales & Marketing is a highly technical field & offers excellent opportunities for the pharmacy graduates. Additional qualification like M.B.A. adds to their arsenal.

Public health:
- NGO’s
- INGO: (UN, UNDP, PSI, FHI, PLAN, NFHP, RED CROSS, PSI)
- Government agencies related to Public health

Consultancy:
- This is an ideal opportunity for highly technical and experienced pharmacy professionals to earn handsomely as self-employed entrepreneurs, even after the age of retirement such as;
- Documentation
- Approvals
- Manufacturing Processes
- Analytical Series
- Research
- Market Surveys & Sales Promotion
- Information Retrieval
- Data Management
- Turn Key Projects, etc.

**Challenges that can turn to Opportunities:**
- Most drug retailers with little pharmacy knowledge in Nepal
- Government health system and policy
- Less crowd of pharmacist population
- Inadequate professional highlighting exercises

**Unexplored area:**
- Pharmacist as a clinician can work in
  - Nuclear Pharmacy
  - Nutrition Support Pharmacy
  - Oncology Pharmacy
  - Psychiatric Pharmacy
  - Forensic Pharmacy
  - Poison Control
  - Pharmaco Therapy
  - Geriatric / Pediatric Pharmacy

**Conclusion/recommendation:**
- Gone are the days, when medicine and engineering was the subject of choice for the rankers. The pharmacy profession has strived hard to attract the young talent and in the country like Nepal, it will become one of the best professional courses. Pharmacy offers the resources, opportunities and flexibility needed to balance a successful healthcare career with a satisfying personal life.
- Pharmacy graduates can expect to get on the fast track in one of the most dynamic industries in health care. Pharmacists enjoy a prestigious job in a field that increasingly relies upon their skills and expertise.
- Pharmacy graduates are offered many opportunities and learn wide variety of things, but educating patients about their medication therapy is always the most important.
- Pharmacist should be an integral part in Country’s health care system
Appendix 1

Recommendation /Conclusion/Summary

Pharmacy Profession In Academics – Prof. Sadhana Amatya

- Change the degree status- The change in degree status and accompanying curriculum should be intended to produce graduates capable of delivering pharmaceutical care, overseeing the medication therapies of patients and also producing practitioners who are able to pursue a variety of practice option.
- Quality Assessment
- In-service Training
- Upgrading of Undergraduate Colleges
- Elective
- Retention
- Monitory factor
- Curriculum update-Molecular Biology
- School of Pharmacy with different departments.

Community Pharmacy in Nepal – Phr. Ganesh Maharjan

- Pharmacy and chemist shop, majorly a trade rather than a profession
- The professional aspects of checking prescription.
  So……
- We need to change the actions in our pharmacies from drug selling to medicine dispensing.
- We need to change our pharmacists from businessman to health care professionals
- We need to change qualified pharmacist to a trained knowledgeable pharmacist.

Ideal Pharmacist Candidate need….

- Competent
- Motivated/Enthusiastic
- Teamwork spirit
- Good communication skills
- Responsible
- Problem solver
- Dedicated

Development Issues

There is no legal or regulatory impediment for a Pharmacist to establish a community pharmacy.

Development Plans…

What we need are –

5. Motivation of Pharmacists to get to community pharmacy
6. Training for development of skills  
7. Investment  
8. Social awareness  

What we need are –  
• These young pharmacists should be trained.  
• Then the group should set up single or chain pharmacies at the commercially viable locations.  
• There should be an organized campaign to generate social awareness on benefits that society as well as an individual may derive from the community pharmacies.

“Hospital Pharmacy Practice in Nepal, Present Situation and Future Vision”  
– Phr. Raj Kumar Thapa/ Phr. Kiran Sunder Bajracharya  
• Counseling is a professional responsibility and not an option for the pharmacist. Every pharmacist must develop this skill in order to ensure GPP and rational drug use.  
• Improvement in policy regarding pharmaceutical care.  
• Curriculum reforms in the pharmacy schools.  
• Government intervention and facilitation.  
• Training to the upcoming pharmacist and continuing education to the practicing pharmacist. (HosPAN is taking the initiation).  
• Pharmacovigilance, DTC services, and implementation of existing legal provision.

Where is pharmacy profession moving on industrial pharmacy and expectations from fresh graduate pharmacists?  
– Phr. Jaya Bir Karmacharya  
- Strengthening WHO GMP norms and practices in  
  o Certified companies (to be strengthened)  
  o Companies to be certified (to be developed)  
• DDA with stringent regulatory norms and practices and also to develop new medicine policy  
• APPON in consolidating required investment and exploration of business opportunities among the member companies  
• Professional associations (GPAN, NPA, NMA, NCAD, APPON etc) in consolidating technical know how and developing suitable environment for technology transfer  
• Academic institutions in developing academic programs in developing required manpower to meet future challenges.  
• Strong Academia-Industry linkage in collaborative research and development work to develop innovative works for pharmaceutical development as a whole.  
• All the political parties its all cadres and leaders to establish peace and build conducive environment for professional practices.  
• Development of a national technical team with involvement of professionals form every sector including industry, academia, regulatory agencies, international communities, and
professional associations to dedicate its activities for development and effective implementation of national policies, rules and regulations for development industrial pharmacy sector in Nepal

Stakeholders’ Role

- Pharmacy is an inextricable part of the health care delivery system and will be influenced by—and hopefully will influence—events occurring within the health care system as a whole.
- Health care professionals, including pharmacists, must change their roles to better meet the health care needs of the people
  - positively influence treatment from pharmacy setting, monitor progress using dispensing process as the framework
  - Management of chronic conditions
  - Management of minor ailments
  - Promotion of healthy lifestyles
  - Advice to other health professionals
- Health care leaders and administrators recognize that specific attention must be focused on the design and process of medication use systems that can assure patient safety.
- Develop pharmacy practice standards
- Identify pharmacy practice model sites and facilitate / monitor / evaluate practice
- Undertake research on issues around key roles away from supply-oriented roles like management of prescribed medicines, chronic conditions, minor ailments, promotion of healthy life-styles, and advice to other health professionals
- Promote DTC concept in health facility, contract pharmacist and implement GPP.

Paradigm shift in pharmacy profession Health care, norms and ethics

- Phr. Balkrishna Khakurel

Conclusion

- Pharmacy practice structures and process is very limited
- Stakeholders are not active towards creating pharmacy practice structures
- Evidences to support a range of pharmacist’s role is altogether lacking.
- Future agenda in the light of existing evidences for practitioners, researchers and those involved in service development is also lacking.

Recommendation

- Professional standards and ethics should be formulated and implemented
- Model pharmacy practice site and framework should be developed, monitored and evaluated.
• Research projects on all key roles (away from supply oriented roles) of pharmacy practices should be undertaken to generate evidences
• strategic action plan for the pharmacy profession as “fit for purpose” for the health care system of the future should be developed.
• Identify social and economic benefits of improved drug therapy
• identify structural, legislative, policy, program and funding requirements to support transitioning of the pharmacy profession
• Preferred focus on future of pharmacy profession include: role change and pharmacy practice models; pharmacy human resources; pharmacy education and continuing professional development (CPD); information and communications technology (ICT); financial viability and sustainability; legislation, regulation and liability; and leadership for the profession.
• Pharmacists must match the pace of health care reform or risk losing parts of their role to other professions.
• The development of a more coordinated, collaborative and interdisciplinary team approach toward patient care would enable our health care system to attain improved outcomes and more cost-effective drug therapy.
• that there is a need for members of the pharmacy profession to become more literate about, and engaged with, value
• The education and training of pharmacists needs further examination as the profession evolves towards “preferred future”.
• Current university curricula do not prepare new pharmacists to practice in a manner that is patient-focused, playing a key role on the health care team by actively managing drug therapy
• Pharmacists who are in practice may need educational support (e.g., CPD) to maintain an up-to-date knowledge base in an area that is rapidly changing.
• Incorporating interdisciplinary education into the university curricula of all health professionals, including pharmacists, will be essential to build strong primary health care teams.

Harmonisation of undergraduate pharmacy curriculum: Is it necessary in Nepal?
Prof. Panna Thapa, MPharm PhD

Areas of Harmonization of Pharmacy Curriculum/Education?
• Entry requirement for degree programs;
• Basic competencies (i.e. role of pharmacist in Nepal- Healthcare systems, industry etc);
• Duration of degree programs;
• Guidelines for incorporating Pharmacy assistants into degree programs.
Summary

- Harmonization need to be understood as ‘comparability’ but not as standardization or uniformity of program and degrees.
- Harmonization of pharmacy (first degree) curriculum need to be taken up as global agenda.
- We need to agree upon the areas of harmonization based on the role of Nepalese pharmacists in the Healthcare systems (community and Hospital) and pharma industry (core competency).
- Harmonization that encourages diversification is highly desirable.
- Curriculum: need to be seen as a “Broad Framework, including learning outcomes, assessment and teaching methods”
- But if we take harmonization issue as “common baseline” then arguably it kills innovation in curriculum development and takes away Academic Freedom!

Need for PharmD Program in Nepal  - Prof. Balmukunda Regmi, MPharm, PhD

- Change our diploma, undergraduate and postgraduate education from knowledge-based to competency-based
- Pharmacy institutions will always have to answer the questions posed by the doctors, “In what way is pharmacist’s knowledge superior/equal/complementary in medical sciences to that of the doctors?”
- A 6-year curriculum in pharmacy education is likely to cause educational inequality and may ignite a struggle for power between pharmacists and physicians
- Industry-Institute interaction is extremely low, exposure of students to industry is virtually nil and teachers have little interest in work other than assigned. The linkages between institution and industry are too thin.
- Success of PharmD program in Nepal depends on our ability to convince policy makers such as the Ministry of Health, DDA, DHS, health-related professional councils, and the public in general of the role qualified pharmacists can play in the better healthcare of people.
- The first few batches of PharmD graduates will play a decisive role in the acceptance of the pharmacists by other members of the health care team and the patients and the public in general. We should not let the degree just prove a tag.
- There is a danger of clinical pharmacy and PharmD programs being promoted as isolated single entity and not related to a stable population-based pharmaceutical system which we should avoid.

Role of Stakeholders

- Nepal Pharmacy Council
- MoH Department of Health Services and Department of Drug Administration
- Pharmacy-related Professional Organizations
- Universities
- Nepal Medical Council
- Nepal Medical Association
• Global market

Conclusions
• Era of globalization - we cannot remain unresponsive to the global trend and deny our fellow citizens of the quality pharmacy service they deserve
• Primarily it should be the pharmacists’ concern to introduce more competent PharmD program in Nepal.
• We should try our best to convince all the stakeholders for this genuine cause.
• Time it may take, introduction of PharmD program is inevitable in Nepal.

Pharmacy Research and Information in Nepal - Phr. Uttam Budhathoki
• Universities & Research centers towards innovation.
• Logical flow of Research funds and their utilization.
• Academia – Industries Linkages.
• R&D fund: sales of industries to be focused.
• Skill development and Infrastructure.
• Govt policy and political stability.
• Concept of Centre of Excellence (like NIPER, India).

Rational use of medicines and role of pharmacist - Phr. Nisha Jha
• Promoting Pharmacovigilance activities;
• Involvement in MTC activities;
• Effective Hospital formulary;
• Monitoring drug use;
• Medicine information services;
• Antimicrobial management team;
• Teaching students to use medicines rationally;
• Training of pharmacy staffs;
• In the present scenario, the pharmacist is a coordination centre between different members of healthcare team and the patients.
• Hence, proper role and involvement of a pharmacist in safe use of medicines and overall healthcare programme becomes very crucial.

What fresh Graduate Pharmacist can Do? - Phr. Prajwal Jung Pandey
Opportunities so far:
• Production & Manufacturing
• Hospitals and Other Institutional
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• Regulatory Affairs
• Academic Pharmacy
• Community Pharmacy
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• Consultancy

• Pharmacy graduates are offered many opportunities and learn wide variety of things, but educating patients about their medication therapy is always the most important.
• Pharmacist should be an integral part in Country’s health care system

Appendix II

Chairpersons’ and Co-Chairpersons’ Introduction

Phr. Radha Raman Prasad  
Director, Department of Drug Administration (DDA)

Phr. Asfaq Sheak  
Ex. DDA Director  
Chief, Lomus Herbenaria

Phr. Shiba Bahadur Karkee  
Ex. NPC Chairperson  
Head, CIST College

Phr. Dharma Prasad Khanal  
General Manager, Lomus Pharmaceutical  
Visiting Faculty, KU

Phr. Tirtha Ratna Shakya  
Chief, National Medicines Laboratory

Phr. Shobha Basnet  
MD, Jestha Laboratories  
Technical Consultant, SR Drug Laboratories  
Visiting Faculty, Institute of Medicine

Speakers’ Introduction

Prof. Sadhana Amatya  
Head, Department of Pharmacy  
Maharajgunj Medical Campus, IOM, Nepal
Prof. Panna Thapa, MPharm PhD
Dean, KU School of Science
Kathmandu University, Dhulikhel, Nepal.
Chairperson, Nepal Pharmacy Council

Prof. Bal Mukunda Regmi PhD
Professor, Department of Pharmacy
Coordinator, BPharm Program
Institute of Medicine Maharajgunj Campus

Phr. Balkrishna Khakurel
Drug Administrator, DDA
Registrar, Nepal Pharmacy Council
Visiting Faculty, IOM

Phr. Jaya Bir Karmacharya
Chief, Factory Operation
Omnica Laboratories Private Limited, Bhaktapur.

Phr. Uttam Budhathoki
Assistant Professor and Coordinator
Department of Pharmacy, Kathmandu University, Nepal.

Phr. Raj Kumar Thapa
Senior Pharmacist/Chief, Patan Hospital

Phr. Nisha Jha
Assistant Professor
Department of Clinical Pharmacology and Therapeutics,
KIST Medical College, Lalitpur.

Phr. Ganesh Maharjan
Pharmacist & Managing Director- XENO Pharmacy Pvt. Ltd.
Norvic Hospital [DTC- Member Secretary]
Civil Services Hospital [SISH FX-99 Hospital software consultant]

Phr. Prajwal Jung Pandey
Program Head (NMCAL),
Head, Lomus pharmaceuticalsPvt.ltd
Visiting Faculty, IOM