Progress and Challenges, Priorities and Perspectives

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Outline of the presentation

- Objectives of Drug Act 2035
- Regulatory system
- Progress
- Challenges
- Priorities
- Perspectives

Drug regulation Objectives

- To control misuse and abuse of drugs and allied materials
- To prevent false and misleading information relating to use of drugs and other allied materials
- To control drugs and other allied materials which are not safe, effective and of standard quality

Regulatory System(1)

Comprise of:

- NHP 2071 and NMP 1995: Regulation and delivery of pharmaceutical Care
- Drug Act 2035
- Drug Consultative Council and Drug Advisory Committee 2037
- Drug Registration Regulation 2038
- Drugs Inspection and Inquiry Regulation 2040
- Standards on Drugs 2043

Regulatory System(2)

OTHERS

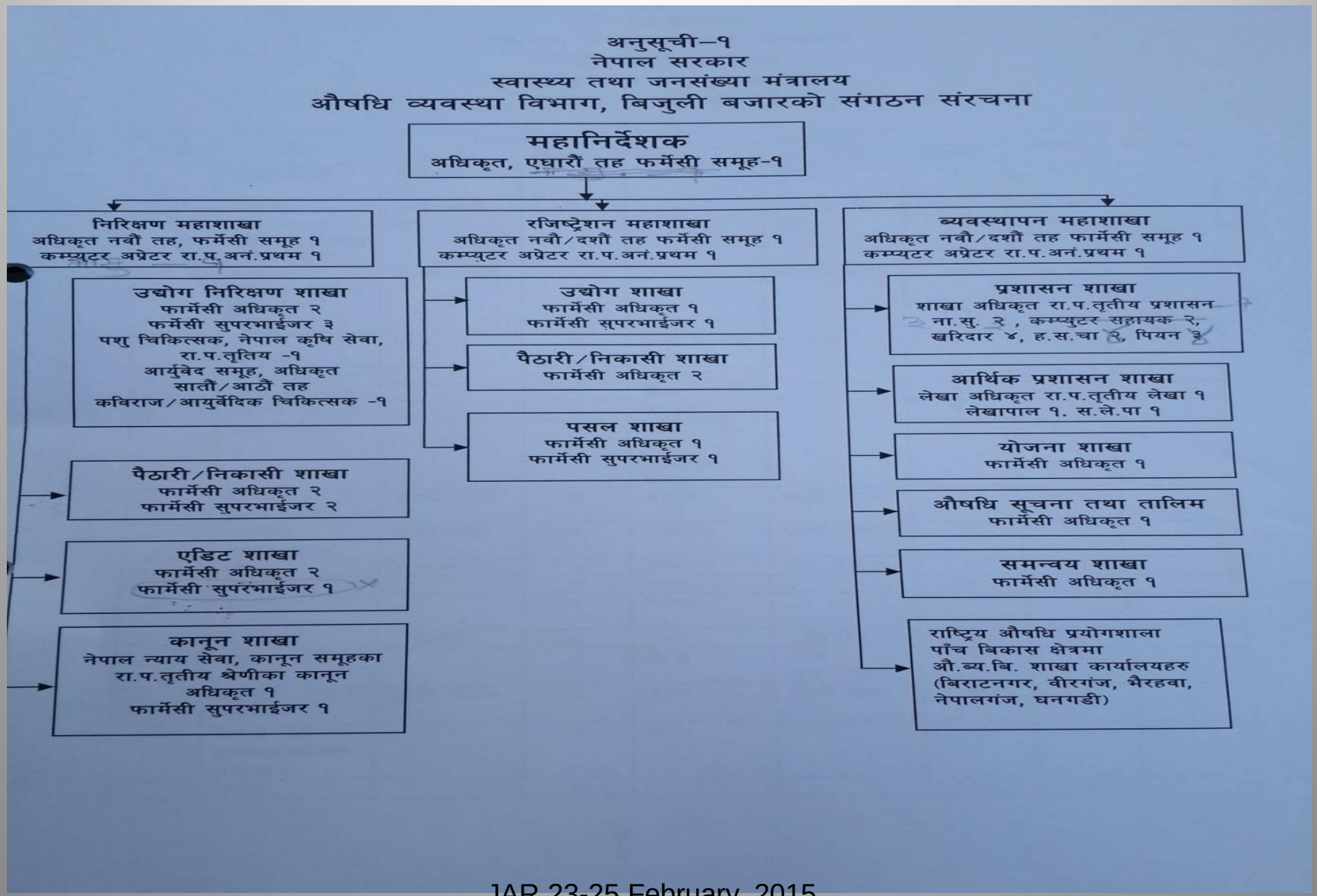
- Drug Donation Guidelines 2060
- Codes on Drug manufacturing 2041
- Guidance on standards of establishment, update and operation of health care institutions 2070
- Hospital Pharmacy Guidelines 2070
- Codes on Drugs Sale and Distribution 2071
- Medicine Importation Guidance 2071

Regulatory System (3)

Stakeholders include:

- DDA as implementing agency
- Consultative council and advisory committee, evaluation committee
- National medicines laboratory
- Nepal Pharmacy Council for HR Registration
- Pharmaceutical QA Section, PHAM&E, MOHP
- APPON and NCDA
- Global Regulatory Authorities, EDPs

Regulatory Structure(1)



Regulatory Structure(2)

Total Sanctioned Posts- 115

Organization	No of sanctioned post
DDA(centre)	49
NML	40
DDA(brt)	9
DDA(bir)	9
DDA(npj)	8

Regulatory functions

1. Medicine evaluation and registration
2. Licensing of medicinal Product, Vyabasayi and facilities (Manufacturing, sales and distribution)
3. Marketing authorization of medicinal products
4. Post marketing surveillance / Inspection (facility, professional conduct including foreign industries, medicine PV)
5. Administrative direction, legal action, and sanctions
6. Advocacy, actions, advisories, E-regulation, etc.
7. Promotion of rational use of medicines
   - Developing national essential medicines list, Issuing of drug bulletin
   - Organizing training, workshops, seminars in drug use, misuse issues
8. Training and organizational development

Regulatory Facts and Figures

No of Registered Pharmacy Outlets:19338

Retailers: 16640

Wholesalers: 2698

Registered Pharmaceutical Industries:445

- Domestic 120
- Foreign:325

Domestic Industries with WHO GMP Compliance: 37

- Products Registered:15247

  Foreign: 8831

  Domestic: 6416

- Sample Analyzed: 687
- Non-compliance:99

Progress

Safety and efficacy

- Regular Publishing of drug Buletin
- Public notice / awareness:
- ADR reporting/pharmacovigilance
- Technical committee -Evaluation and Registration
- Improved registration procedures
  - Bioequivalence bioavailablity study as requirement for registration
  - Expedited registration for SRA approved, UN PQed products

progress

Quality

- WHO-GMP, CPP
- Stability Study
- Laboratory Testing and pharmacopoeial status
- Manufacturing License
- Drug testing /Analysis / MoA / Spec., etc
- GMP certification
- Drug industry inspection
- Foreign GMP inspection
- Pharamcy inspection

inspection and violationsFY207071.pptx

Progress

Access

- EML 2011
- Price transparency
- Ethical promotion code
- Collaboration with manufacturers, imported

Progress

Rational Use

- Antibiotic policy
- EML
- Standard drug treatment protocols
- Regular advocacy/information communication
- DTC at hospitals
- Codes on sales and distribution

Notable Achievements

- New import provision
- Codes on sales and distribution 2071
- 7 more posts of pharmacist fulfilled
- Good distribution Practices
- Online registration on the making
- Drug Advisory commiteee meeting held 1 time
- Drug price monitoring committee meeting

Challenges(1)

- Regulatory framework
- Regulatory science, culture, performance, hearing and reporting
- Regulatory base to address demographic changes
- Good governance - accountability

Challenges(2)

- Market practice and intelligence
- Legal proceeding
- Cross border issues
- Regulatory Harmonization
- Presence at district and below
- Indicator based regulatory interventions(safety, efficacy, quality, access and rational use

Priorities(1)

- Broaden Regulatory capacity and Scope
  - Health Technology Assessment
  - District level presence
  - QA products distributed in public sector
  - Evaluation of SEQ of HTP
  - Registration Centre - first time HTP
  - Registration and Licensing of HTP at the regional level
  - Price monitoring and transparency
  - Monitoring of market promotion

Priorities(2)

- GRP: advocacy, transparency and communication (flexibility and empowerment), online registration and dynamic webpage hosting for disseminating regulatory decisions
- Regulatory compliance overall
- Update in regulatory instruments.
- Medicine safety and efficacy - REMS, PV and PMS
- Medicine quality - Risk-based GMP Audit, inspection and more

Perspectives

- Pharma sector in NHP 2014 and New O&M for
  Universal health coverage
  Promotion and protection of public health
- Pharmaceutical care as integral component of HCT - rational use, treatment protocol, generic products, evidence-based medicines, access to HTP.
- Integation of *pharma sector indicators to NHIS*

Thank you for your kind attention