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Background

- ***Department of Drug Administration (DDA) was established to implement the objectives and implement of Drug Act 2035.***
- ***One of department of MoHP***
- ***The Main objectives of Drug Act:***
  - ***To prevent misuse and abuse of drugs***
  - ***To prevent misleading information relating to use of drugs***
  - ***To regulate and control the production, marketing, distribution, sale, export-import, storage and use of drugs which are not safe, effective and of standard quality***

Major Activities

- Product Registrations
- Registration of Pharmacy
- Drug Information
- Pharmacovigillance Activities
- Post Marketing Surveillance
- Publication of Drug Bulletin, Essential Medicines and Formulary
- Inspection
  - Domestic Pharmaceutical Industries
  - Foreign Pharmaceutical Industries
  - Pharmacy (Wholesalers and retailer outlets)
  - Pharmaceutical Testing Laboratories
- Testing and Analysis of Medicines

Statistical Data

- No of Registered Pharmacy Outlets:
  Retailers: 12115 and Wholesalers: 2135
- Registered Pharmaceutical Industries:
  Foreign: 273 (modern), 27 (Vet), 32 (Herbal)
  Domestic: 37 (modern), 8 (Vet), 57 (Herbal)
- Domestic Indusries with WHO GMP Compliance: 34
- Products Registered:
  Foreign: 8238 and Domestic: 5826
- Sample Analysed: 601
  Compliance: 527
  Non-compliance: 74

Challenges and Problems

- Unregistered Nutraceutical, Food Supplements Products Cosmetic with some therapeutic Value also other health products
- Misuse of Pharmaceutical and Other Health Products
- Regular monitoring of Pharmaceutical Industries
- Regular monitoring of Pharmacy
- File case in the court
- Abuse of Narcotic and Psychotropic Drugs
- Weak in Pharmacovigillance Activities
- Post Marketing Surveillance of Marketed products
- Testing of medicines available in the market

Solution

- Revision of existing Drug Act and Regulation made thereunder
- Adequate Number of Technical Human Resources needed
- Financial Resources
- To be strengthen National Medicine Laboratory in terms of infrastructures, equipments, human resources

Revision of Drug Act: Process

- Study conducted by international consultant on need for amendment of the Drug Act, and recommendation presented for amendments.
- Drafting the Act in consultation with MoHP and DDA by national experts and dissemination to the stakeholders and getting feedback.
- Revision of the previous draft as per the comments and suggestions received
- Presentation and discussion at DDA and final revision of the draft.

Drug Act Revision: Major changes suggested

- Single authority to regulate all health-related products, in addition to medicine.
- More functional autonomy compared to ‘Department’ of Government of Nepal
- Semi-judiciary function to reduce the cases to be taken to the court.
- Pharmacovigilance under regulation.
- Management Committee (Health Secretary to Chair) for policy guidelines
- Director-General for all administrative work

Conclusion

Quality Assurance of Pharmaceutical is important in delivering health services thus needs strengthening of National Regulatory Authority (DDA) as well as National Quality Control Laboratory (NML)


THANK YOU