National Joint Annual Review, 2078/79

Government of Nepal

Ministry of Health and Population

Department of Drug Administration

Bharat Bhattarai

Director General

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To ensure Safety, Quality and Efficacy of medicines

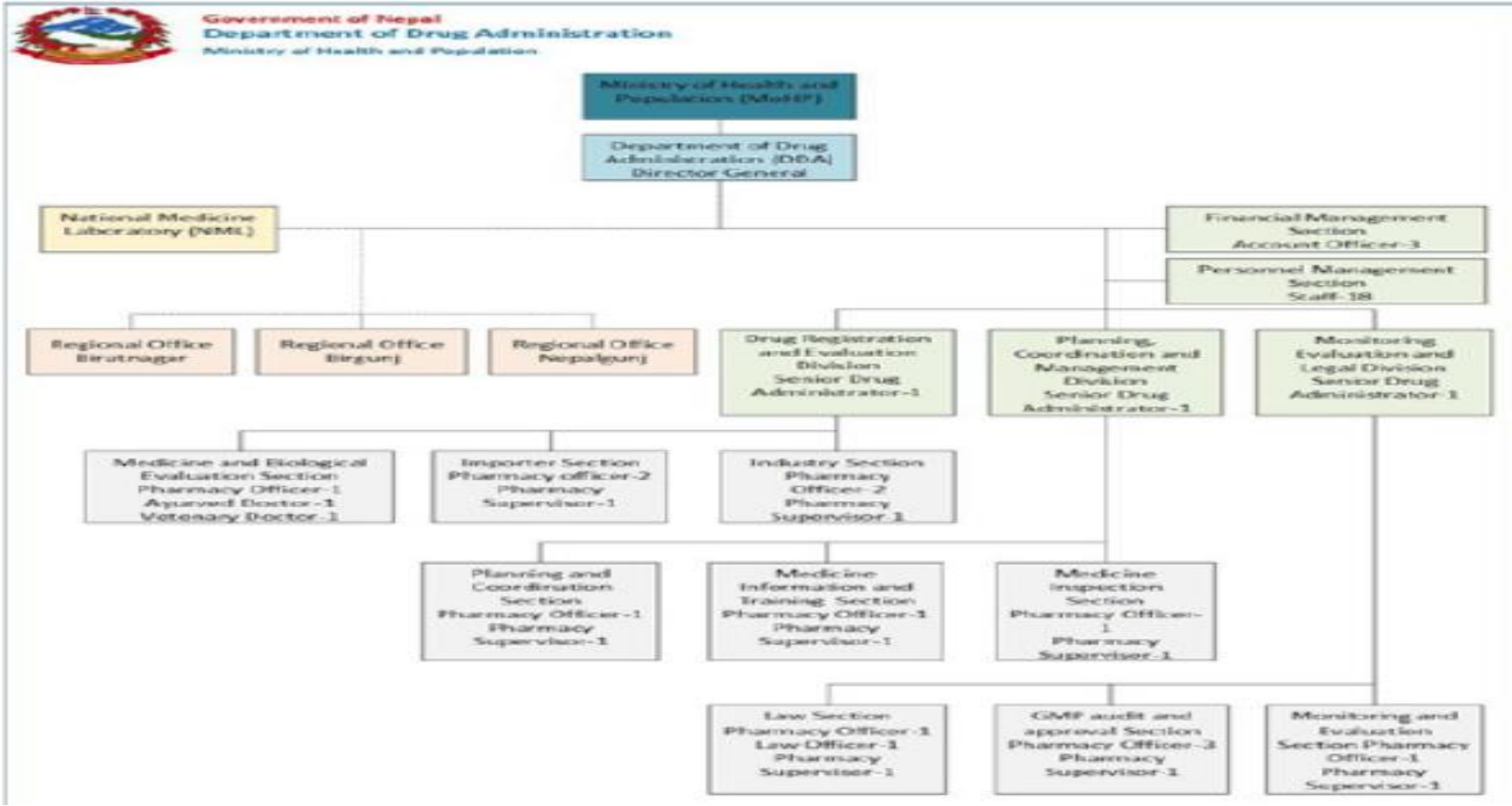
Introduction

- A National Medicine Regulatory Authority established in 2036 through Drug Act, 2035
- Four regulations and two codes under the act
- Three Branch Offices (Biratnagar/Birgunj/Nepalgunj) and National Medicine Laboratory as National Control Laboratory.

Regulatory Functions	Service Functions
• Licensing/registration of pharmaceutical industries, market authorization, pharmacy and clinical trial and their renewal • Inspection, investigation, prosecution and filing of cases	• Preparation of EML list, STG • Training and refresher for pharmacies • Drug information • AMR containment and RUM • Drug availability • Promotion of domestic manufacturers (GMP/GLP) • Nepal National Formulary

Organogram

Ministry of Health and Population
Department of Drug Administration
Organization Structure



Regulated Pharmaceutical Areas

SN	Activities	Registered Number	Total Marketed
1	Domestic pharmaceutical industries including veterinary (3)	122 (-83 in operation	5761 brands
2	Ayurvedic/alt industries	196 (56 in operation)	5971 brands
3	Foreign companies	350	6806 brands
4	Pharmaceutical retails (Pharmacies)	23712	
5	Pharmaceutical wholesalers	4208	
6	Pharmaceutical importers	169	

Regulated Pharmaceutical areas Cont..

- Testing of Post marketed/Suspected Spurious and falsified during inspection/premarketing/samples as per the request from other institutions Samples.
- Good Laboratory Practice Audit
- Analytical Method Validation
- Lot release of Vaccine
- Participation on Proficiency testing.
- Preparation for ISO 17025:2015 accreditation.

Human Resource

Offices	Technical		Admin		Vacant Technical (Admin)	Remarks
	Sanctioned	Filled	Sanctioned	Filled		
DDA Central	34	30	15	9	88.23% (60%)	3 Scholarships + 1 Contract 2 Computer Operator
NML	33	22	7	2	66.67% (28.57%)	
Branch offices						
Biratnagar	5	2	4	2	40% (50%)	
Birgunj	5	4	4	3	80% (75%)	
Nepalgunj	4	4	4	4	100% (100%)	
Total	**81**	**62**	**34**	**20**	**76.54% (58.82%)**	

Total staffs at the time of establishment in 2036=49 current HR=49

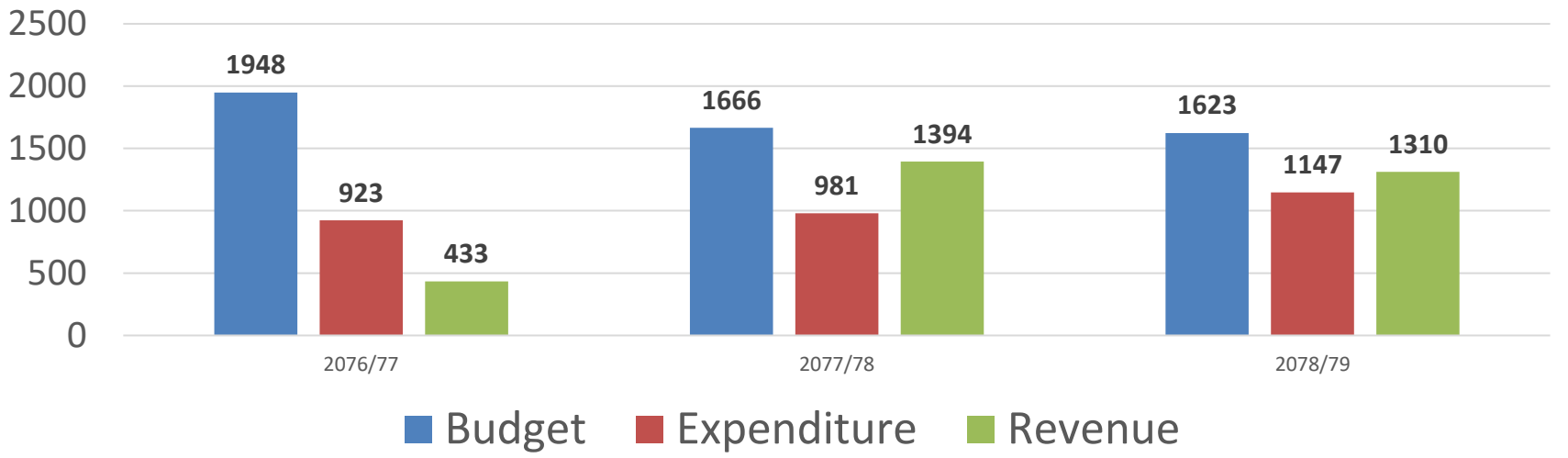
Budget Allocation

In millions (NRP)

FY	DDA Budget	% Share of MOHP
2075/76	167.6	0.57
2076/77	190.6	0.48
2077/78	165.0	0.27
2078/79	171.7	0.14

Budget/Expd. And Revenue

Rs. In Lakhs



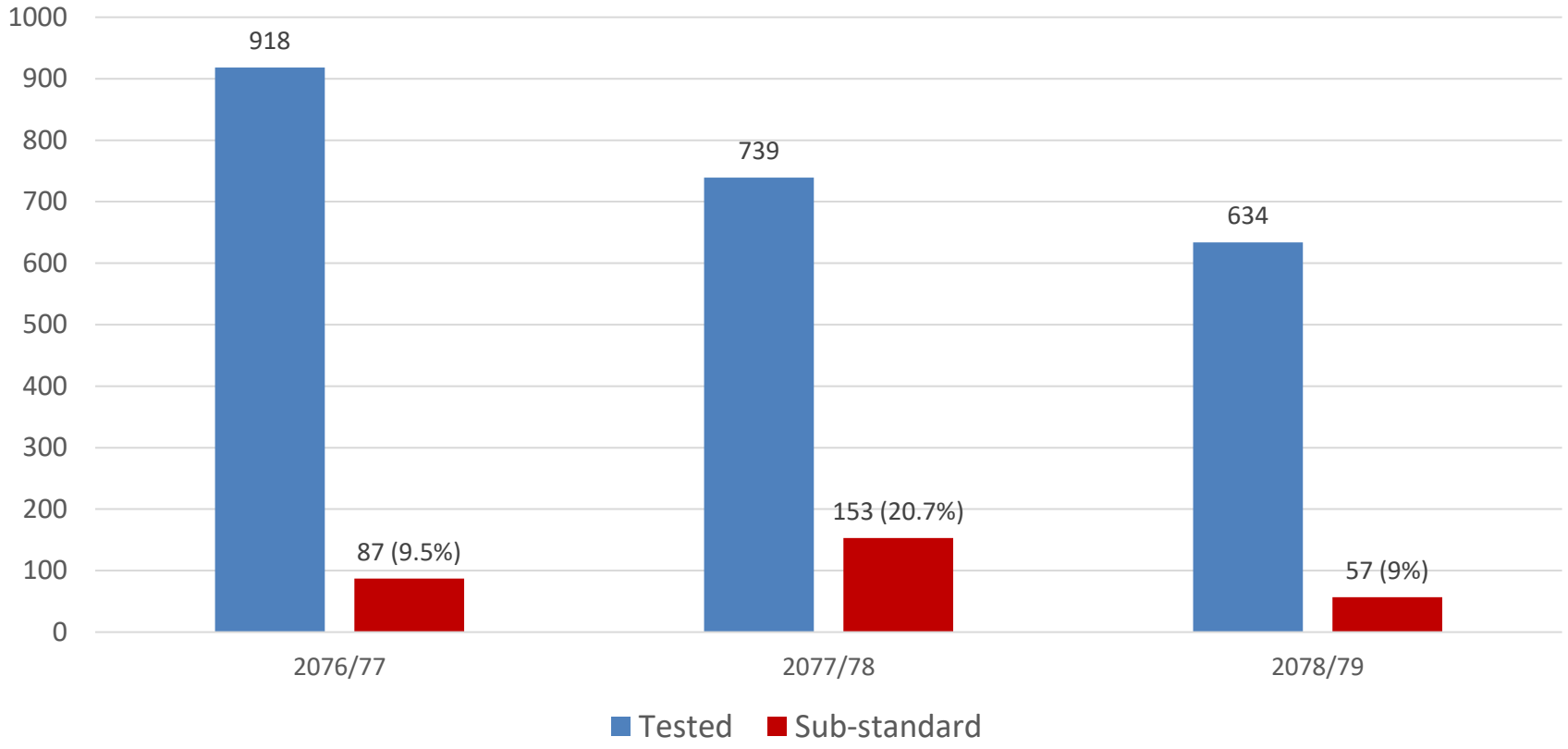
Office	Total Budget (Lakh)	Expenditure (Lakh)	Percentage (%)
DDA	118.36	47.86	40.43 %
Laboratory	73.14	27.07	37.01 %

Beruju Rs 287500 (Samparikshan-125000:162500)

Highlights of AWPB FY 2078/79

Category	Target	Achievement(%)
Pharmacy Inspection	3300	3663 (110 %)
Industry Inspection (Domestic)	92	88 (95.65 %)
Sample Analysis by NML including PMS	900	634 (70.44 %)
Substandard Medicines reported by NML	NA	58 (in 634) – 9.14 %
Laboratory Inspection for GLP	30	32 (106.66 %)
Information dissemination	45	61 (135.5 %)
Publication of Drug Bulletin of Nepal	3	3 (100 %)
Cases Filed	NA	64
Action taken against Manufacturers	NA	5
Pharmacy License Suspension	NA	231
WHO GMP Compliance Audit (Foreign Companies)	NA	63

Comparison of Sample Test Results



- About 10% Substandard medicine
- Sanitizer

Key Interventions (FY 2078/79)

- New Drug Act covering medicine, HTP, Nutraceutical and cosmetics drafted and forwarded.
- Drafted New National Medicine Policy 2079.
- 6th NLEM 2021 revised and released.
- Approval of National Life saving emergency drug list and orphan drug list
- Drafted Ayurveda GMP guideline
- Focal Point for Antimicrobial Consumption (AMC) and data submitted to WHO GLASS AMC (2016-2021)
- DDA as participating member of WHO Collaborative Registration Procedure.
- Special permission of Medicines including vaccines granted for availability as per Special Permission Guidelines 2078.

Key Interventions (FY 2078/79) cont..

- Drafted quality manual for ISO 9001:2015 certification.
- Drafted GPP and GSDP guidelines
- Drafted RB PMS Guidelines and Pilot Study on Risk Based Post Marketing Surveillance
- Active member of SEARN (South East Asia Regulatory Network), Nepal.
- MoU with Department of customs for NNSW.
- Support for BA/BE Laboratory at TUTH
- Regulatory Gap Analysis using WHO Global Benchmarking Tool (WHO GBT) followed by IDP/Maturity Level 1.
- Stepwise Assessment Tools Towards Accreditation (SATTA). Level 1

External Development Partners

WHO	MTaPS	PQM+
National List of Essential Medicine Revised	Revision of National Medicine Policy and Drug Act	Protocol Development and Pilot Study on Risk Based Post Marketing Surveillance
National Life Saving Emergency drug list and orphan drug List	QMS implementation targeting ISO 9001:2017	Risk Based GMP Inspection
Ayurveda GMP Guidelines	GDP/GSDP Guidelines	Stepwise Assessment Tool Towards Accreditation
Partner WHO collaborative Registration Procedure		
AMC reporting to GLASS		

EDP Partners Support

Ongoing Activities	Partners
Regulatory System Strengthening (ML 3 by 2025)	MTaPS/TQM/WHO
National Medicine Policy revision	USAID MTaPS/WHO
Drug Act revision	USAID MTaPS/WHO
Quality Manual and SOPs	USAID MTaPS
GPP/GSDP guideline	USAID MTaPS
Risk Based Post Marketing Surveillance	PQM+/WHO
Software Development	USAID MTaPS
Antimicrobial Consumption Studies	FHI/WHO
Pharmacovigilance activities	USAID MTaPS/WHO
Capacity Building	MTaPS/TQM/WHO

DDA on Self Assessment on WHO Global Benchmark Tool

S. no.	Function	Implementation Percentage	Maturity Level
01	National Regulatory System (RS)	57.0%	1
02	Registration and Marketing Authorization (MA)	49.0%	1
03	Vigilance (VL)	30.0%	1
04	Market Surveillance and Control (MC)	35.0%	1
05	Licensing Establishment (LI)	66.0%	1
06	Regulatory Inspection (RI)	78.0%	1
07	Laboratory Testing (LT)	56.0%	1
08	Clinical Trail's Oversight (CT)	43.0%	1

Target for Maturity level 3 by 2025 provided regulatory framework and resources are in place.

Key Issues and Challenges

- Legal framework as per international best practices and international harmonization.
- New O & M as per the federal provision.
- Regulation of HTP, Nutraceuticals and cosmetics.
- Open Cross border issues.
- Old and insufficient infrastructure, HR and other resources of DDA & NML.
- Effective and efficient Market Surveillance and Control.
- Effective and dynamic price control mechanism with reference to international prices. (including price adjustment).
- Online Pharmacy and advertisement of Medicines.
- Interdepartmental co-ordination and communication.
- Clinical Trial oversight including GCP.
- Laboratory functions for Vaccines and BABE.
- Inventory Management

Way Forward

Way Forward	
• Digital DDA • New O & M as per federal provision. • Competence (NML accreditation ISO 17025, 2015 • Maturity level 3 by 2025 • Accreditation • Quality Management System. • DDA and NML ISO certification under process • DDA-MIS under development • HTP/Nutraceuticals regulation • PV strengthening • Clinical trail	• Ayurvedic GMP • Self Sufficiency • Dynamic price regulation mechanism • Collaborative registration procedure with good reliance practice. • Pharmaceutical Waste Management • New provision for import of medicines. • Risk based inspection, Post Marketing Surveillance, Risk based dossier evaluation. • NHSSP 2022-30 • Ethical Drug promotion guidelines

Thank you