

# **BUSINESS PLAN**

**Department of Drug Administration  
Fiscal Year 2019/2020**

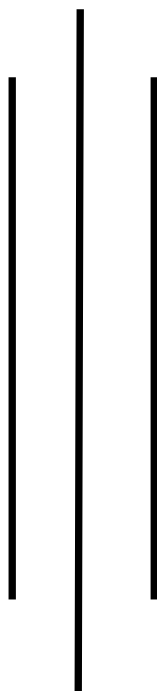


**Government of Nepal  
Ministry of Health and Population  
Department of Drug Administration**

**November 2019**



# **Business Plan: Department of Drug Administration Fiscal Year 2019/2020**



**Government of Nepal  
Ministry of Health and Population  
Department of Drug Administration**

November 2019





नेपाल सरकार

# स्वास्थ्य तथा जनसंख्या मन्त्रालय

(..... शाखा)



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प्राप्त पत्र संख्या :-

पत्र संख्या

चलानी नं. :-

रामशाहपथ,

काठमाडौं, नेपाल ।

मिति :- २०७६।१०।१३

विषय :-

प्राक्कथन

राज्यको पुनः संरचना अनुसार सङ्घ, प्रदेश र स्थानीय तहले प्रदान गर्ने स्वास्थ्य सेवाका सम्बन्धमा गरेको व्यवस्था अनुसार सबै नागरिकका निम्ति सहज र गुणस्तरीय सेवाको पहुँच अपरिहार्य रहेको छ । यस सन्दर्भमा सङ्घीय सरकार, स्वास्थ्य तथा जनसङ्ख्या मन्त्रालय मातहतको औषधि व्यवस्था विभागले सम्पादन गर्नुपर्ने कार्यलाई व्यवस्थित गर्न व्यावसायिक योजना (Business Plan) तर्जुमा गरी लागू गरेकामा अत्यन्तै खुसी लागेको छ । स्वास्थ्य नीति, २०७६ ले अंगिकार गरे अनुरूप सहज रूपमा गुणस्तरीय सेवा प्रदान गर्न आवश्यक स्रोतको आँकलन समेत गरेको हुँदा मन्त्रालय र मातहतका निकायको वार्षिक योजना तथा कार्यक्रम तर्जुमा गर्दा कार्यक्रमहरूको प्राथमिकीकरण गरी आवश्यक स्रोत जुटाउन यो व्यावसायिक योजनाले मद्दत पुऱ्याउँछ भन्ने विश्वास लिएको छु ।

यो व्यावसायिक योजना तर्जुमा गर्न प्राविधिक सहयोग प्रदान गर्ने USAID/Public Financial Management Strengthening Project लगायत यस Business Plan तर्जुमा कार्यमा सम्बद्ध सबैलाई धन्यवाद दिन चाहन्छु ।

खगराज बराल

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## List of Acronyms

DBN	Drug Bulletin of Nepal
DDA	Department of Drug Administration
DoAAM	Department of Ayurveda and Alternative Medicine
DOHS	Department of Health Services
EDP	External Development Partners
E4D	Evidence for Development
FY	Fiscal Year
GMP	Good Manufacturing Practice
GoN	Government of Nepal
LG	Local Government
LBG	Louise Berger Group
MoF	Ministry of Finance
MOHP	Ministry of Health and Population
MTEF	Medium-term Expenditure Framework
NLEM	National List of Essential Medicine
NPL	Nepal Pharmacy Council
NPR	Nepalese Rupee
PFMSP	Public Financial Management Support Program
PG	Provincial Government
PPMD	Policy Planning and Monitoring Division
PMS	Post Marketing Surveillance
SoE	Statement of Expenditure
USAID	United States Agency for International Development
WHO	World Health Organization



# Chapter 1: Introduction, Objectives and Methodology

## 1.1 Introduction

Department of Drug Administration (DDA) was established in 1979 AD to implement the provisions of the Drug Act 2035 (1978 AD). Under this Act, various regulations and codes have been formulated, including:

- Drug Consultative Council and Drug Advisory Committee rules, (2037 BS).
- Drug Registration Rules, (2038 BS).
- Drug Standard Rules, (2043 BS).
- Enquiry and Inspection Rules, (2040 BS).
- Codes on Sale and Distribution of Drugs, (2071 BS).
- Codes on Drug Production, (2072 BS)
- Drug Donation guidelines

National Drug Policy was formulated in 1995 to guide the medicinal provision in the country. DDA is supported by one National Medicine Laboratory (NML) and three branch offices located at Biratnagar, Birgunj and Nepalgunj. The branch offices have the responsibility of inspection, pharmacy registration and renewal. The NML carries out testing and analyzing the quality of drugs. Besides, it also issues lot release certificate for vaccines and audits pharmaceutical laboratories in Nepal. DDA has five spending units. Detailed information on DDA can be obtained from the following website: [www.dda.gov.np](http://www.dda.gov.np).

## 1.2 Objectives, roles and responsibility

### 1.2.1 Objective

The main objective of DDA is to regulate all functions relating to modern, veterinary and traditional medicines, like misuse and abuse of medicines and its raw materials, to stop false and misleading advertisements and make available safe, efficacious and quality medicines to the general public by controlling the production, marketing, distribution, sale, export-import, storage and use of medicines.

### 1.2.2 Roles and responsibility

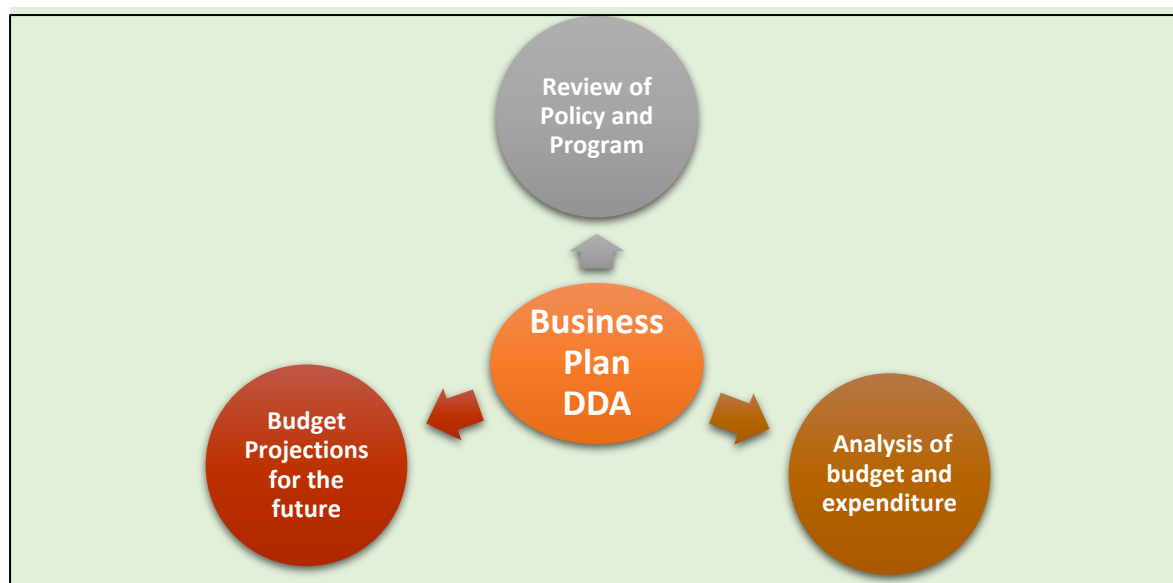
- Ensuring safety, quality and efficacy of medicines.
- Promotion of Rational use of medicines and health technology products.
- Ensuring access to medicines and health care technology products.

- Enforce provisions of drug law for regulatory compliances.
- Institutional development including HR.

### 1.3 Methodology

This Business Plan is prepared based on the analysis of the Redbook, Ministry of Health and Population (MOHP) annual work plan and budget, DDA AWPB, MTEF and TABUCS. We have also reviewed relevant policy frameworks that have guided having budgets for the future. The details of the policy frameworks included in the MOHP’s business plan.

**Figure 1: Approaches Utilized**



This is a first comprehensive Business Plan of the DDA. Thus, series of consultative meetings and consultative workshops were organized with the section chiefs and the program planners to validate the figures, forecasting and target setting for future years. Since this is an official document of DDA we have used the reference from the existing documents including AWPM, MTEF, Red Book, TABUCS, Audit observation report and LMBIS. Every public sector business plan needs to be consistent with existing budgetary framework, thus, independent technical approaches/methods were not used while projecting the budget for the future. We have utilized data from the MTEF to capture budget for the fiscal year FY 2020/21 and FY 2021/22. The complete expenditure data up to the fiscal year 2017/18, is available thus, is utilized in this analysis.

## Chapter 2: Business Plan

### 2.1 Structure of the DDA

Department of Drug Administration (DDA) is one of the three departments of the Ministry of Health and Population (MOHP). The office of DDA is situated in Bijuli Bazar, Kathmandu. It has three divisions, namely the Registration Division, Management Division and Inspection Division. National Medicines Laboratory (NML) is also under the DDA. DDA has three branch offices located in Biratnagar, Birgunj and Nepalgunj. The structure of DDA includes:

- Drug Evaluation and Registration Division
- Drug and Biological Evaluation Section
- Import Section
- Industrial Section
- Planning, Cooperation and Management Division
- Planning and Cooperation Section
- Drug Information and Training Section
- Drug Monitoring Section
- Monitoring, Evaluation and Law Implementation Division
- Law Section
- Good Manufacturing Practice (GMP) Audit and Certification Section
- Monitoring and Evaluation Section
- Administration Section
- Personnel Administration
- Finance Section

### 2.2 Financial and Physical progress in FY 2017/18

Following subheadings provide an update on the financial progress of DDA for FY2017/18. Since the complete expenditure cannot be captured for FY 2018/19, expenditure data of FY 2017/18 has been analyzed which gives an analysis of budget allocation, expenditure and DDA's capacity in spending.

### 2.2.1 MOHP and DDA budget and expenditure

DDA receives the federal conditional grants from MOHP. Table 1 shows that DDA has lower absorptive capacity than that of MOHP in FY 2017/18.

**Table 1: MOHP and DDA adjusted budget and expenditure (NPR in thousands)**

S.N.	Budget Entity	Budget (NPR)	Expenditure (NPR)	% Exp
1	MOHP	32,954,405	27,053,339	82.0
2	DDA	128,391	101,141	79.0

Source: FMR 2017/18, MOHP

This indicates that a proper planning needs to be carried out by DDA. However, there could be other reasons beyond the control of DDA.

### 2.2.2 DDA budget and expenditure by capital and recurrent

Table 2 shows that DDA spent 93% of the capital budget. However was able to spend only 75% of the recurrent budget.

**Table 2: DDA capital and recurrent adjusted budget and expenditure (NPR in thousands)**

SN	Program	Budget (NPR)	Expenditure (NPR)	% Exp
1	Capital	27,116	25,260	93.0
2	Recurrent	101,275	75,881	75.0
	<b>Total</b>	<b>128,391</b>	<b>101,141</b>	<b>79.0</b>

Source: FMR 2017/18, MOHP

This table indicates that DDA needs to improve the spending in recurrent budget.

### 2.2.3 DDA budget and expenditure by GoN and EDP

**Table 3: DDA adjusted budget and expenditure by GoN and EDP (NPR in thousands)**

SN	Program	Budget (NPR)	Expenditure (NPR)	% Exp
1	GoN	128,391	101,141	79.0
2	EDP	0	0	0
	<b>Total</b>	<b>128,391</b>	<b>101,141</b>	<b>79.0</b>

Source: FMR 2017/18, MOHP

Table 3 shows that DDA has not received any funding from external development partners. The table suggests that a business planning process would help DDA in getting engaged with the EDPs. It is important to note that DDA may need technical support to improve its overall functions. The EDPs can help in providing the technical expertise in drug management and in the administration sector.

## 2.2.4 Budget and Expenditure by indicators

The total budget allocated to DDA is spent on various activities. Table 4 shows the budget allocation and expenditure of DDA in the last fiscal year by indicators.

**Table 4: Major activity allocation and expenditure (NPR thousands)**

SN	Major program activities	Allocation	Expenditure
1.	Consumption and operation cost	51,950	48,803
2.	Monitoring of medical shops and medicine industries	2,175	1,798
3.	Inspection of Foreign industries	3,900	3,225
4.	Quality measurement	10,400	8,599
5.	Monitoring of rational use of medicines	1,800	1,788
6.	Training and orientation	2,000	1,654
7.	Review and workshops	150	150
8.	Procurement of machinery for NML	40,416	21,524
9.	Procurement of Vehicle	15,600	13,600
	<b>Total</b>	<b>128,391</b>	<b>101,141</b>

Source: FMR 2017/18, MOHP

As shown in the table above, various indicators have been compared according to the number of units, allocated budget and the expenditure in the previous fiscal year 2017/18.

## 2.2.5 Physical progress in FY 2017/18

Table 5 summarizes the overall physical progress by the DDA for FY 2017/18.

**Table 5: Physical progress of fiscal (NPR thousands)**

SN	Output indicators	Unit	Target	Achievement	Percentage Achieved
1	Medicines information to the public by different media	Number	30	32	107
2	Publication of Drug Bulletin of Nepal	Issues	3	3	100
3	Conducting examination of veterinary drug sellers' training	Number	2	2	100
4	Inspection of domestic Pharmaceutical Industries	Number	100	90	90
5	Inspection to drug retailers & wholesalers	Number	2900	3691	127
6	Drug sample Analysis	Number	1000	1004	100
7	Audit of Pharmaceutical Analytical Laboratories	Number	30	32	107
8	Inspection of Foreign Companies	Times	5	8	160

Source: Annual Report 2017/18, Department of Health Services

## 2.3 Budget allocation pattern in FY 2018/19 and 2019/20

The table 6 presents DDA's budget in FY 2018/19 and FY 2019/20. It is important to note that DDA received increased budget in FY 2019/20.

**Table 6: Budget allocation for FY 2018/19 and 2019/20 in different categories (NPR thousands)**

SN	Group	Fiscal Year 2018/19		Fiscal Year 2019/20		Budget Change %
		NPR	Share %	NPR	Share %	
<b>Budget by National, Health Sector, Federal, Province, Local</b>						
1	National Budget	1,315,161,700		1,532,967,100		16.6
2	Health Sector Budget	65,343,200	5.0	78,404,400	5.1	20.0
3	Ministry of Health and Population	56,419,700	4.3	68,779,100	4.5	21.9
4	Federal Budget (MOHP)	34,082,300	60.4	42,670,900	62.0	25.2
3	Department of Drug Administration	167,600	0.5	190,600	0.4	13.7
<b>Budget by Capital and Recurrent</b>						
1	Capital	72,500	43.3	51,400	27.0	-29.1
2	Recurrent	95,100	56.7	139,200	73.0	46.4
<b>Total</b>		<b>167,600</b>	<b>100.0</b>	<b>190,600</b>	<b>100.0</b>	<b>13.7</b>
<b>Budget by Government of Nepal and Donor</b>						
1	GoN	160,800	95.9	185,900	97.5	15.6
2	EDP's	6,800	4.1	4,700	2.5	-30.9
<b>Total</b>		<b>167,600</b>	<b>100.0</b>	<b>190,600</b>	<b>100.0</b>	<b>13.7</b>

Source: Redbook 2019/20, MoF and TABUCS, MOHP

DDA is receiving only 0.24% of total health sector budget, and 0.45% of Federal MOHP budget. However, volume of DDA budget is increasing (13.7% more than last year's budget). Majority of the budget for FY2019/20 is allocated in recurrent cost (Consumption cost, office operation and monitoring cost NPR139.2Million). There is only a small amount of funds provided by WHO as an external donor partner which is provided as on budget, off treasury assistance.

### a) DDA's budget for FY 2018/19 and 2019/20 by different major program activities

As a federal unit of the MOHP, the DDA receives a major chunk of funding from the Government of Nepal (GON). Table 7 shows the DDA's budget for FY 2018/19 and FY 2019/20 by major activities. It shows that consumption, operation and maintenance cost are the major activities followed by quality measurement and procurement of machinery and furniture activities.

**Table 7: Budget allocation for FY 2018/19 and 2019/20 by major activities (NPR thousands)**

SN	Major program activities	Fiscal Year 2018/19	Fiscal Year 2019/20
1.	Consumption, operation and maintenance cost	87,900	105,000
2.	Monitoring of medical shops and medicine industries	3,500	3,685
3.	Inspection of Foreign industries	1,500	2,115
4.	Quality measurement	26,800	28,400
5.	Monitoring of rational use of medicines	1,900	1,800
6.	Training and orientation and other program cost	3,500	7,900
7.	Review and workshops	600	1,500
8.	Procurement of machinery and Furniture	41,900	40,200
9.	Procurement of Vehicle	0	0
	<b>Total</b>	<b>167,600</b>	<b>190,600</b>

Source: Redbook and LMBIS 2018/19 and 2019/20

## 2.4 Indicators and targets

The functions of DDA as a regulatory authority of government, are planning, monitoring, resource allocation, reporting and evaluation of pharmacy related services and activities. The indicators and progress are measured through the services provided by various units under DDA. As per the Annual Report of DOHS, the following Targets have been mentioned and taken as indicators as well. Table 8 shows the comparison between targets and achievements for eight different indicators related to service delivery along with the target set for each indicator for next three fiscal years.

**Table 8: Indicators and Targets**

SN	Indicators	Unit	Last year's Achievement (%) (2074/75)	Target FY 2076/77	Target FY 2077/78	Target FY 2078/79
1	Drug information to the public by different media	Number (20)	107%	35	40	45
2	Publication of Drug Bulletin of Nepal	Issues (3)	100%	3	3	3
3	Conducting examination of veterinary drug sellers' training	Number (1)	100%	2	2	2
4	Inspection of domestic Pharmaceutical Industries	Number (100)	90%	100	150	200

SN	Indicators	Unit	Last year's Achievement (%) (2074/75)	Target FY 2076/77	Target FY 2077/78	Target FY 2078/79
5	Inspection to pharmacies (retailers & wholesalers)	Number (2900)	127%	3200	3500	4000
6	Medicine sample Analysis	Number (1000)	100%	1500	2000	2500
7	Audit of Pharmaceutical Analytic Laboratories	Number (30)	107%	35	40	45
8	Inspection of Foreign Pharmaceutical industries	Times (8)	100	10	12	15

## 2.5 Three years budget forecast for major activities

Table 9 shows the actual budget allocation by activities and projections for FY 2020/21 and FY 2021/22. These figures are tentative and may fluctuate depending on fiscal and political scenarios.

**Table-9: Budget projection for three consecutive fiscal years (NPR in thousands)**

SN	Major program activities	FY 2019/20	FY 2020/21	FY 2021/22
1.	Consumption, operation and maintenance cost	105,000	109,242	113,649
2.	Monitoring of medical shops and medicine industries	3,685	3,834	3,989
3.	Inspection of Foreign industries	2,115	2,200	2,289
4.	Quality measurement	28,400	29,547	30,739
5.	Monitoring of rational use of medicines	1,800	1,873	1,948
6.	Training and orientation and other program cost	7,900	8,219	8,551
7.	Review and workshops	1,500	1,561	1,624
8.	Procurement of machinery and Furniture	40,200	41,824	43,511
9.	Procurement of Vehicle	0	0	0
	Total	190,600	198,300	206,300

Source: MoF, Redbook, LMBIS 2019/20 and MTEF 2020/21-2021/22

Despite the changes that have occurred as a result of the federalism, the budgeting of DDA has not been perceived to be changed over the years.

## 2.6 Three years budget forecast by category

Table 10 summarizes the budget projection for the next three fiscal years by source and category.



**Table 10: Budget allocation for the year by source (NPR thousand)**

SN	Source of Funding	FY 2019/20	FY 2020/21	FY 2021/22
1	Government of Nepal			
1.1	Recurrent	139,200	144,824	150,666
1.2	Capital	51,400	53,476	55,634
2	Other sources			
2.1	Not included in the budget			
	<b>Total</b>	<b>190,600</b>	<b>198,300</b>	<b>206,300</b>

Source: MoF, Redbook, LMBIS 2019/20 and MTEF 2020/21-2021/22

The table shows the allocated budget for FY 2019/20 and estimated budget from different sources for two consecutive fiscal years, which has been projected to increase steadily in forth coming fiscal years.

## 2.7 Procurement

Procurement of laboratory reagents and office materials are regularly carried out by the department. Besides, procurement of services and payment for human resources (on contract) are foreseen to be necessary. Table 11 summarizes the estimated cost over next three fiscal years.

**Table 11: Estimated Procurement and cost for next three fiscal years (NPR in thousands)**

SN	Procurement item	FY 2019/20		FY 2020/21		FY 2021/22	
		Quantity	Allocated cost	Quantity	Estimated cost	Quantity	Estimated cost
1	Procurement of goods						
1.1	Medicine		8,700		10,005		11,206
1.2	Medical equipment		29,100		33,465		37,481
1.3	Office materials		3,000		3,450		3,864
1.4	Vehicle		0				
1.5	Furniture		11,100		12,765		14,297
2	Construction						
2.1	Building		0		0		0
2.2	Other construction		0		0		0
3	Procurement of Services		1,000		1,150		1,288
4	Contract						
4.1	Human resource for Health		12,400		14,260		15,971
4.2	Other services		0		0		0
	<b>Total</b>		<b>65,300</b>	<b>0</b>	<b>75,095</b>	<b>0</b>	<b>84,106</b>

Source: MoF, Redbook, LMBIS 2019/20 and MTEF 2020/21-2021/22

The table shows the allocated budget for FY 2019/20 and estimated cost for various procurement items for next two fiscal years. The total cost of the items are projected to increase steadily for the next three years.

## 2.8 Human Resource

Altogether 46 human resources are currently employed by DDA. Table 11 shows the mix of various categories of health workers under the DDA and the human resource need of DDA for three consecutive years on the basis of position, type and existing (sanctioned or fulfilled post).

**Table-11: Human Resource Need (Position, type, sanctioned and fulfilled HR)**

SN	Position	Types (Permanent, Contract, Deputation)	Existing		FY 2019/20	FY 2020/21	FY 2021/22
			Sanctioned	Fulfilled	Number	Number	Number
1	Director General (11)	Permanent	1	1	1	1	1
2	Senior Pharmacy Officer (9/10)	Permanent	3	3	3	3	3
3	Senior/ Pharmacist (7/8)	Permanent	13	13	13	13	13
4	Section Officer	Permanent	1	1	1	1	1
5	Account Officer	Permanent	1	1	1	1	1
6	Law Officer	Permanent	1	0	1	1	1
7	Veterinary Doctor	Permanent	1	1	1	1	1
8	Ayurveda Doctor	Permanent	1	1	1	1	1
9	Computer Officer	Permanent	1	1	1	1	1
10	Pharmacy Supervisor (5/6)	Permanent	8	5	8	8	8
11	Nayab Subba	Permanent	5	3	5	5	5
12	Accountant	Permanent	1	1	1	1	1
13	Computer Operator	Permanent	2	2	2	2	2
14	Sub Accountant	Permanent	1	1	1	1	1
15	Kharidar	Permanent	1	1	1	1	1
16	Driver	Permanent	4	4	4	4	4
17	Office Assistant	Permanent	4	4	4	4	4
	Total		49	46	49	49	49

Source: Approved Organization Chart with Sanction Post and Fulfill post from DDA

Note: Deputation includes HWs deputed by MOHP/DOHS, deputed by autonomous agency, and international agency

## 2.9 Financial Management

The DDA is an independent department and has its own financial management procedures to spend the received budget as per the regulations of GON. A finance officer is responsible for overseeing the finance related activities. There are no audit observations under DDA.

## Chapter 3: Challenges and way forward

### 3.1 Challenges and way forward

The major challenges for DDA include the lack to strong legal authority to regulate the pharmaceutical sector in a holistic way, lack of adequate human resources, limited financial resources and frequent transfer of human resources. The major challenges, way forward are provided in the following table.

SN	Challenges	Way forward	Responsibility
1	Clear Organizational Structure for federal, provincial and local government	Organization structure should be expanded or facilitated to open provincial drug administration office under each province	MOHP
2	Lack of mechanism (legal and organizational for regulation of HTP)	Amend the existing legal provisions	MOHP
3	Information Management, Transparency and lack of dynamic and Responsive Information system	Develop and implement a digital information system and	DDA/MOHP
4	Illegal import of medicines due to open border and SSFFCs regulation and control	Amend the existing legal provisions	GoN/MOHP
5	Lack of resources (human and Technology)	Increase resources and recruit HR	DDA/MOHP
6	Provincial harmonization and uniformity, MRH and SRA collaboration	A national framework or a national 'Medicine Assembly'	DDA/MOHP
7	Pharmacovigilance, post marketing surveillance	Develop the system, train the people and implement it	DDA/MOHP
8	Limited financial resources	Increase the budget ceiling	DDA/MOHP
9	Medicine Shortages issues	Improve the planning	DDA
10	Lack of organization structure for price monitoring	Conduct O&M survey	DDA/MOHP

### **3.2 Recording, Reporting and Monitoring**

DDA keeps a list of pharmaceutical companies operating inside the country. Similarly, it also keeps list of companies who supply medicines to Nepal. List of hospital and private pharmacies operating inside the country is also available at DDA. Recording of services is done at the service delivery facilities. Monitoring of the pharmaceutical companies and pharmacies is done from DOA as per need. For quality control of medicines the National Medical Laboratory performs various tests. If any errors are found, it directs the pharmaceutical company for improvement or takes regulatory measures.

### **3.3 Dissemination**

DDA publishes a Drug Bulletin of Nepal three times a year to inform about drug policy, act, regulation, and other guidance, news about drug management. It disseminates the achievements through the Annual Report of DOHS. There is a section allotted to DDA in the DOHS's annual report. Major activities and achievements are shown in the report. Besides, it informs the public about medicines through different media as necessary. The department maintains its own website. For more detailed information please visit: [www.dda.gov.np](http://www.dda.gov.np)

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