# Chapter V: Procurement of drugs and quality inspection

#### **Audit objective:**

#### To assess whether:

- System of selection of vendors was geared to provide economy and quality in procurement;
- System of indenting, provisioning and supply for central procurement of medicines was managed efficiently and effectively;
- The supply chain promptly responded to user's demands to their satisfaction;
- System of local procurements of medicines by hospitals was well managed so as to ensure both economy and quality in supply; and
- Quality assurance procedures and infrastructure were in place.

# 5.1 Types of stores

Stores which are consumable in nature or which cannot be used repeatedly are termed 'expendable' e.g. drugs, dressings, chemicals, blades, needles, etc. Items which do not have life beyond one year due to fair wear and tear are also termed as 'expendable'. Expendables with shelf life up to two years such as all medical stores, medical gases, transfusion sets, X-ray films, etc are classified as 'short life' having and those with shelf life of more than two years are categorized 'long-life'. Stores which can be used again and again with fair wear and tear are termed as 'non-expendable' such as forceps, operating tables, apparatuses, equipment, etc.



The stores in service use are listed in 'Priced Vocabulary of Medical Stores' (PVMS) consisting of 29 sections. Each drug is codified in six digits where the first two digits denote PVMS section; the next two indicate the sub-section and the last two digits the particular drug. The PVMS indicates the accounting

unit, the specification, the life and the rate per unit. Drugs and other items not listed in the PVMS are categorized as 'Not in Vocabulary' (NIV). Certain drugs are categorised as 'Proprietary Article Certificate' (PAC) items which are manufactured and supplied only by a specific firm.

DGAFMS reviews PVMS periodically through a 'Drug Review Committee' (DRC). The recommendations of the DRC, on its acceptance by the DGAFMS, are

incorporated under an 'Amendment list' (AL) issued by the DGAFMS containing drugs newly introduced, deleted (i.e. obsolete) and 'obsolescent'.

The procurement of medical stores is governed by provisions of Defence Procurement Manual (as amended from time to time) and instructions issued by the DGAFMS.

# 5.2 Sources of supply and procurement agencies

The main sources of supply of medical stores are Trade, Import and Pharma Central Public Sector Enterprises (CPSE). Major agencies involved in the procurement of medical stores are:-

**DGAFMS:** The DGAFMS enters into rate contracts with manufactures/suppliers for supply to various consignees, where the annual consumption of store is over ₹ 20 lakh. All procurements under these rate contracts are booked under CP allotments.

**AFMSDs:** The AFMSDs (Mumbai, Delhi and Lucknow) are the central procurement agencies mandated to supply medical stores to the non Direct Demanding Officer (DDO) hospitals, AMSDs and FMSDs under their jurisdictions based on indents raised on them. AFMSDs book their expenditure both under CP and LP whereas the DDO hospitals book their expenditure under local purchase allotments.

**Hospitals:** Seven hospitals viz Command hospitals SC, WC, EC, CC, AH (R&R), CH (AF) and INHS Ashwini, declared as DDOs are independent of the AFMSDs to meet their requirement of drugs, kits and consumables.

The remaining hospitals, declared as non-DDOs, are dependent on AFMSDs for their requirement. These hospitals are also empowered to make emergent local purchases of drugs up to the limits laid down in delegation of financial powers issued by the Ministry in July 2006 against the non-availability intimated by the AFMSDs. All such procurements are booked under LP allotments.

**AMSDs/FMSDs:** FMSDs and AMSDs are operational units at the levels of Corps and theatre of operations, respectively. They are tasked to store and supply medical stores to units located in forward areas where it is not possible for these units to collect the stores directly from AFMSDs. In addition to supply from AFMSDs they are also empowered like non-DDO hospitals to make emergent local purchases. All procurements by FMSDs and AMSDs are booked under LP allotments.

# 5.3 Quality inspection of drugs

Pursuant to DPM -2005, the Ministry issued additional guidelines in July 2006 to DGAFMS governing procurement and inspection of Medical Stores/equipment. The

procedure for inspection stipulated therein stated that "DGQA will carry out inspection of all drugs of 'central purchase' which exceed ₹ 1.5 lakh. The inspection will be carried out strictly in accordance with the terms of AT¹8/Supply Orders. Alternatively, the firm may also submit test certificate from laboratories accredited by "National Accreditation Board for Testing and Calibration Laboratories (NABL)". This was elaborated further by the DGAFMS in August 2006 for purchases by Direct Demanding Officers (DDOs) stipulating that for purchases within limit of ₹ 1.5 lakh the inspection will be carried out by a Board of Officers in the hospital (including one specialist). Inspection will, however, be as per procedure prescribed for central purchase i.e. by DGQA, for purchases exceeding ₹ 1.5 lakh by DDOs.

For inspection of drugs procured locally by non-DDOs the quality inspection was not entrusted to any inspecting authority. This has serious implications when viewed in the context of increasing trend of local procurements done by hospitals.

# 5.4 Vendor registration

For ensuring qualities in procurement of goods, the DPM-2005 had laid down broad guidelines for selection and registration of firms. It envisages a thorough scrutiny of credentials of a firm, financial status, manufacturing and quality control facilities, business ethics, and market standing before registering it as an approved source of supply.

In July 2006, the Ministry laid down that drugs will be purchased from the firms which met the following criteria:



DGQA registration or holding GMP (Good manufacturing practice) certificate issued for the plant by State or Central authorities, duly supported by a valid manufacturing licence along with annual turnover of pharmaceutical products alone of more than ₹ 20 crore for the last three consecutive years or

original inventor of molecule and manufacturing and marketing certificate.

As per the instructions of DGAFMS issued in August 2006, the registration of firms is to be done by a Board of Officers, duly approved by the Commandant of the hospital. Past performance of the firm is also to be taken into account when registering a firm.

Scrutiny of the system of registration during the last three years revealed that the hospitals registered even those firms which had made false declaration, did not even possess valid drug licence at the time of registration nor had prescribed turnover, etc. as narrated in the paragraphs below.

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<sup>&</sup>lt;sup>18</sup> Accepted Tender

# Registration of firms not holding Valid Drug Licence/Good Manufacturing Practice/Dealer Licence

The Ministry's instructions cited above stipulated that procurement is to be made from the manufacturers/dealers only and not from any other source. While registering manufacturers it is to be ensured that they possessed certificate of Good Manufacturing Practice (GMP). Holding of GMP certificate ensures reliance on quality.

We observed that vendors other than manufacturers/dealers were also registered by the Hospitals. Out of 19 Hospitals/Depots where Board Proceedings were made available, we noticed that only six units, namely, CH SC, MH Kirkee, Amritsar, AFMSD Lucknow, Pune and Mumbai had considered GMP as one of the criteria for registration of manufacturers. The remaining 14 hospitals/depot<sup>19</sup> did not consider GMP as the criterion, which was in violation of the instructions issued by the DGAFMS and the Ministry.

#### **Dealership** certificate

Dealership certificate is given by a manufacturer to its licenced dealer for marketing its products in a given area.

Three hospitals viz. INHS Ashwini, INHS Jeevanthi and MH Deolali did not insist on submission of dealership certificate for registering the firms. AFMSD Lucknow registered 122 drug vendors and 30 non-drug vendors though only approved dealers of the manufacturers were to be registered.

#### **Drug licence**

Any dealer who intends to sell medicines should possess a valid drug licence issued by the Food and Drugs Authority. The hospitals/depots who register the firms are to ensure that the firms hold drug licence which is valid for the entire period of registration. At nine hospitals/depots we noticed that in the registration of vendors during 2007-08 to 2010-11, 95 firms did not possess valid drug licences at the time of registration. Four of these hospitals viz MH Agra, MH CTC, CH NC and CH SC purchased drugs valuing ₹7.76 crore from 27 firms which did not possess valid drug licences.

A few cases of serious irregularities in registration of firms not having valid drug licence are indicated below:

At CH SC six firms not having valid drug licences were registered and orders valuing ₹2.13 crore were also placed on these firms during 2010-11.

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<sup>&</sup>lt;sup>19</sup> CH WC, CHAF, AHR&R, MHCTC, INHS Ashwini, Jeewanthi, BH DC, 166 MH, MH Jabalpur, 6 AF, MH Deolali, 170 MH, MH Ambala and AFMSD Delhi

92 BH registered three vendors who had not produced valid drug licences, yet during 2007-08 to 2009-10 orders were placed on them. Further scrutiny revealed that one firm had been issued licence by the licencing authority only in April 2011 effective for the period January 2008 to December 2012 and had received supply order valuing ₹ 6.61 lakh in June 2009.

The drug licence of M/s. Y Enterprise had expired in December 2006; yet seven orders valuing ₹ 12.93 lakh had been placed on it by 92 BH in 2008-09 and 2009-10. In respect of M/s Z and Sons drug licence was issued by the licencing authority on 10.4.2007 valid from 1.4.2007 to December 2007. Yet, eight orders valuing ₹ 15.30 lakh had been placed by 92 BH during 2007-08 to 2009-10. The above cases show that the process of verification of licences was not working effectively.

At MH CTC we noticed that seven firms were registered wherein the drug licence certificate furnished by the firms at the time of registration was not in the name of the firm being registered. The hospital stated that the Board of Officers only verifies whether the drug licence issued by the competent authority is in the name of the same vendor or firm. It is not clear how the Board of Officers recommended the name of the vendor who did not possess drug licence in its name. Such registration carries risk of spurious vendors gaining entry in supply of drugs & medicines.

MH CTC had registered a Pune based firm and procured allopathic medicines from the vendor for ₹ 11.6 lakh. We noticed that the drug licence granted to the firm in October 1994 was renewed by the Food and Drug Administration authorities in Pune in February 2008 for the period January 2007 to December 2011 to stock or exhibit (or offer)/sale or distribute homoeopathic medicines in their premises. Therefore the purchase by MH CTC of allopathic medicines from the vendor, who was not authorised to sell such medicines, was incorrect.

We also noticed that MH CTC had registered two firms operating from one and the same location and with the same telephone and fax. During 2010-11, the hospital had placed 13 orders valuing ₹ 12.31 lakh on these vendors.

#### Recommendation No 7

We recommend that the DGAFMS should strengthen their internal processes for procurement of quality medicines by ensuring strict adherence to the laid down procedures. Periodic checks of the registration process may be conducted to identify, investigate and effectively discourage deviations.

The Ministry agreed with the recommendation that there cannot be any deviations from the laid down procedures but did not offer any comments on the specific deviations pointed out.

# 5.5 Central procurements through rate contracts

DGAFMS and AFMSDs as the central procurement agencies in AFMS have the mandate to procure the entire requirement for an item on the basis of indents arising from a planned provisioning process. A Rate Contract (RC) is a tool for procuring items in bulk at a fixed rate over a period of time while minimising the order processing and inventory carrying costs. RC system supports supply chain management, economies of scale and efficient transactions for both the purchaser and the supplier. Further, all central procurements, valuing in excess of ₹ 1.5 lakh, are required to be certified for quality by DGQA on the basis of test inspection or by an NABL accredited laboratory.



Drugs in the PVMS/NIV, having annual turnover in excess of ₹ 20 lakh, are also procured through RC which is normally concluded for a period of two to three years. Any extensions of the existing RC or conclusion of an RC for a period exceeding three years is required to be approved by the Ministry of Defence.

As per delegation of financial powers framed in July 2006, the DGAFMS has been delegated financial power up to ₹ 5 crore for entering into RC in consultation with the IFA.

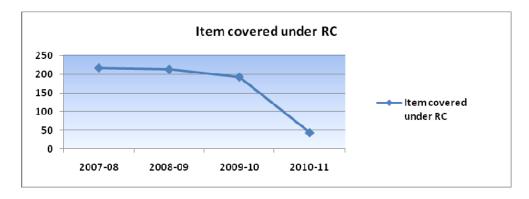
## Inadequate coverage of items under RCs

There are around 8000 expendable items listed under PVMS. Of these, 102 drugs are under PPP<sup>20</sup> and 261 under DGS&D RCs numbering 473 in all. On the basis of information available with DGAFMS, 722 items have an annual consumption of ₹20 lakh and above. RCs were thus required to be concluded in respect of at least 722 items of the PVMS. The coverage was however found to be dismal. As of March 2011, RCs were in force only in respect of 44 items (6 *per cent*). The number of RCs in operation for the last four years was as under:

From private sources Year From CPSEs **Total RCs RCs** Items **RCs** Items **Items** 2007-08 3 3 213 210 216 213 2008-09 10 16 202 202 212 218 2009-10 224 26 58 166 166 192 2010-11 52 20 24 24 44 76

Table- 41: Details of RCs in force

<sup>&</sup>lt;sup>20</sup> Purchase Preference Policy i.e. items procured from the CPSEs



The number of RCs had decreased sharply over the last four years. In respect of procurements from private sources, the RCs in force in 2010-11 (24) had declined by 89 *per cent* compared to 2007-08 (210). Consequently, as pointed out in Chapter II on Financial Management, the share of Central procurements by DGAFMS and AFMSDs which constituted 62 *per cent* of total procurements in 2006-07, had gradually declined to 44 *per cent* in 2010-11.

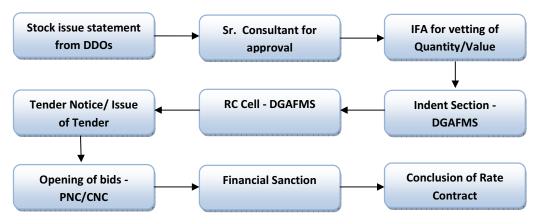
The decline in centralised purchases has implications on the price of drugs and, more importantly, for ensuring the quality of drugs supplied. As already pointed out, local procurements are not subjected to any quality inspection and hence the possibility of substandard drugs getting into the supply chain is high.

#### Low conversion from indents to rate contracts



For conclusion of RCs, as a first step, the quantity required is arrived at based on the annual stock/issue statements of the ten DDOs. This is vetted and approved by the senior consultant in DGAFMS. The vetted quantity is then forwarded to the Integrated Financial Adviser (IFA) before according Acceptance of Necessity (AON) to the proposal. Once AON is

approved, an indent is prepared by the Indent Section which forwards it to the RC Cell in DGAFMS for conclusion of RC.



The indents processed and converted into RCs during 2008-11 were as under:

Table-42: Details of indents converted into RCs

Year	No. of Indents forwarded to RC Cell	No. of RC concluded	Cases under process	Indents closed
2008	126	108	02	16
2009	62	39	12	11
2010	158	17	118	23
2011	102	Nil	99	3
Total	448	164	231	53

It can be seen from the above table that the RCs concluded sharply decreased from 108 in 2008 to 17 in 2010. No RC was concluded as of 01 January 2012 against 99 indents of 2011 and 118 indents of 2010. These were under various stages of examination by the DGAFMS as shown below:

Table- 43: Stages of indents under process for RC

Reasons	2010	2011
Re tender	2	
Advertised	96	19
Advertisement under process	Nil	23
Under approval from DGAFMS	1	29
RC under process	10	14
Other reasons	9	14

Ninety six indents of 2010 were not processed beyond the advertisement stage which should not have taken more than 10 weeks as stipulated in DPM.

#### Extra expenditure due to non-conclusion of RC

As discussed above, an indent is raised where the estimated value of the annual demand is ₹ 20 lakh and above. A Tender Enquiry (TE) is then issued to obtain the lowest rate for determining the feasibility of RC. However, when the anticipated annual procurement based on lowest rate obtained during the tendering process is lower than the said limit such cases are closed.

DGAFMS closed 30 indents during 2008-09 to 2010-11, whose estimated annual consumption was found to be less than the limit of ₹ 20 lakh with reference to the lowest rate obtained against TEs issued for concluding RC. We independently compared the local procurement rates in seven DDOs and found that the actual rates of local procurement were much higher than the L1 rate of the TE causing loss to the exchequer. This will be evident from the following table.

Table- 44: Extra expenditure due to non conclusion of RC

PVMS No.	DDO	Qty of LP	Period of LP	1	Range of LP Rate	L1 Rate of TE	Extra expendit ure (in ₹)
010110	CH(WC), CHAF	3400	09/09 3/11	to	44.44 - 149.50	44.42	98827
010847	CH(SC), CH(WC), CHAF, AH (R&R)	3320	7/09 3/11	to	400 - 1480	377.52	479407
011609	CH (SC), CHAF, AFMSD Delhi & Lknw	64998	7/09 3/11	to	20.79-68.58	18.80	729783
013294	AFMSD Delhi, Lknw, CH (WC), CH (SC) and CHAF	298604	9/09 2/11	to	7.15 – 17.33	6.75	658262
011151	CH(SC), CH (WC), CHAF & AFMSD Lknw	1777000	7/09 3/11	to	0.24 -1.16	0.10	689520
012206	CH(SC), CHAF & AH (R&R)	23625	2/10 2/11	to	10.90 -19.47	9.98	82995
013233	AFMSD Delhi	123000	2/10 3/11	to	19.85-54	14.43	901712
013235	AFMSD Mumbai, Lknw & CHAF	165750	4/10 11/10	to	10 – 18.69	9.33	310350
013239	AFMSD Delhi, Lknw, Mumbai & CHAF	39360	2/10 3/11	to	43.47 – 59.90	30.83	667744
013242	AFMSD Delhi, Lknw, Mumbai, CH (WC), CH (SC), CHAF & AH R&R	292395	8/09 2/11	to	3.75 – 32.75	2.95	798316
013280	CH(SC), CH (WC), CHAF, AFMSD Lknw, & AH R&R	506800	4/10 3/11	to	0.61 – 5.15	0.54	177997
011253	AFMSD Delhi & CH (WC)	35000	2/10 12/10	to	16 -28.35	13.12	400755
011778	AFMSD Delhi, CH (SC), CH (WC), CHAF & AH R&R	24700	2/10 3/11	to	28.08 - 40.08	27.90	204316
012708	CHAF, AH R&R, CH (WC) & AFMSD Lknw	5118330	7/08 2/11	to	0.18 - 0.38	0.17	193049
170156	AFMSD, Mumbai, Lknw, Delhi and CHAF	5938	1/09 3/11	to	567 – 1209	545.13	1042201
Total ex	tra expenditure						7435234

Source: Data compiled from supply order details furnished by DDOs



Equally alarming was the fact that the DDOs procured drugs at widely varying rates which were much higher than the L1 rate obtained in the TEs closed by DGAFMS. During the above period, the extra expenditure in local procurement of 15 drugs alone was ₹74.35 lakh. We are

of the view that such practices need to be investigated by DGAFMS to curb price manipulation in collusion with the suppliers.

#### Abnormal delays in conclusion of rate contracts

Test check of 34 RCs concluded during 2008-11 indicated considerable time taken to finalise these contracts. In 28 cases (82 *per cent*) the delay ranged from six weeks to 107 weeks. Nine illustrative cases in seven DDOs examined in audit revealed that due

to local procurement in the intervening period, extra expenditure was incurred as compared to the RC rate, as shown below:

Table- 45: Extra expenditure due to delay in concluding rate contracts

PVMS No.	DDO	Quantity of LP	Period	Range of LP rate (₹)	RC rate (₹)	Extra expenditure (₹)
011343	AFMSD Delhi	1830009	9/07 to 2/09	12.97 - 16.44		1138250
	AFMSD Mumbai	54000	3/08 to 5/09	12.36 - 14.03	8.51	247980
	AFMSD Lucknow	51500	5/08 to 2/09	9.36 - 13.20	0.51	91775
	CHAF	2900	6/09	12.4 – 12.5		11331
011971	AFMSD Delhi	75950	2/08 to 4/09	21.06 - 29.99		637633
	AFMSD Mumbai	15000	3/08	27.59	16.78	162150
	AFMSD Lucknow	2100	6/08	25.50	10.76	18312
	CH (WC)	1430	4/08	69.90		75962
	AH RR	20750	12/08 to 5/09	21.40 – 64		127815
	CH SC	13300	7/08 to 1/09	19.50 - 25.50		61976
011979	AFMSD Delhi	5500	7/09	11.06		16940
	AH (RR)	58010	5/09 to 1/10	11 - 16.60	7.98	255650
	AFMSD Lucknow	1440	5/09	16.60	7.98	12413
	CH(SC)	3000	11/09	13.52		16620
	CH(WC)	35080(incl ECHS) 10/09 to 3/10 15.40 - 15.50			263154	
	CHAF	12800	6/09 to 2/10	9.84 - 12.90		37504
013258	AFMSD Mumbai	3400	3/09	124.80		100300
	AH(RR)	13000	6/08 to 5/09	101.90 - 134	05.20	226800
	AFMSD Lucknow	20650	11/08 to 8/09	101.9 - 145.64	95.30	228230
	CH(WC)	620	8/08	160		40114
280606	AH(RR)	30	6/08	29120	23400	171600
011021	CH(SC)	56	1/10 to 2/10	3159 - 3162.50	2750	22992
010860	AH(RR)	1000	4/09	361		101000
	CH(SC)	260	10/09	373.36	260	29474
	CHAF	160	6/09 to 11/09	330 – 617.76	260	34221
260015	AFMSD Mumbai	30496	9/08 to 11/09	30.32 - 33.74	29.36	233916
	CHAF	5800	7/09 to 11/09	31.7 - 35.66		24346
270711	CH(SC)	6500	9/08	14.95	6.88	52455
				Total extra expen	diture ₹	4440913

Source: Data compiled from supply order details furnished by DDOs

Apart from the fact that the DDOs procured drugs at widely varying rates, the rates were also much higher than the RC rate eventually obtained by DGAFMS. The extra expenditure in local procurement of nine drugs in the intervening period amounted to ₹ 44.41 lakh.

#### Requirement for RCs not projected accurately

A test check of local purchases of 11 PVMS items by three Depots during 2008-09 and 2009-10 revealed that even though the turnover of each of the 11 PVMS items

exceeded ₹ 20 lakh annually as shown below they were not considered for concluding RC:

**Table- 46: Details of items not covered under rate contract (₹ in lakh)** 

PVMS	Nomenclature	Procu	red by AF	MSD	2009-10	Procui	red by AF	FMSD	2010-11
No.		Delhi	M'bai	Lknw	Total	Delhi	M'bai	Lknw	Total
010123	Lignocaine HCL 2% Solution with	19.80	08.24	-	28.04	18.99	9.56		28.55
	Adrenaline 2 ml Inj								
010253	Aspirin (Soluble) 350 mg Tab	19.65	-	08.23	27.88	19.65	4.49	7.54	31.68
010562	Interferon Beta 1 a prefilled Syringe	09.62	03.08	09.96	22.66	38.85	18.4	9.93	67.18
	contains 30 to 60 mcg								
010565	Sumatriptan 50mg Tab	10.00	18.36	09.92	38.28	38.84	9.24	9.94	58.02
012491	Cough Sedative Syrup each 5 ml contain	28.98	09.57	11.60	50.15	9.67	9.07	2.97	21.71
	chlorpheniramine maleate (1 ltr)								
012708	Calcium Carbonate 500 mg Tab	16.52	02.63	02.81	21.96	8.65	4.53	5.27	18.45
013223	Azithromycin dihydrate 250 mg Tab/Cap	26.02	19.00	09.35	54.37	18.54	9.50	9.99	38.03
013245	Erythromycin Ethyl Succinate for oral susp	19.98	09.52	17.71	47.21	9.99	17.38	2.40	29.77
	containing Erythromycin base 100 mg								
010636	Rifampicin 450 mg + Isonex 300 mg	19.23		09.84	29.07	9.90	8.44	13.72	32.06
	combination								
010721	Methyl Prednisolone Sodium Succinate	09.98	01.39	09.98	21.35	10.97			10.97
	1000 mg Inj								
011009	Erythropoeitin Human Recombinant 2000	09.98	09.24	05.25	24.47	7.31		6.35	13.66
	IU								

Source: Data compiled from supply order details furnished by DDOs

RCs in respect of the above items had not been concluded till March 2011. Consequently local procurements were made by the three AFMSDs at widely varying rates. It could be seen that although these items qualified for coverage under RC in 2009-10 and 2010-11, with reference to their annual consumption in 2008-09, yet these were not considered by DGAFMS for conclusion of RCs on the premise that they did not meet the threshold consumption limit of ₹ 20 lakh. This had resulted in extra expenditure of ₹ 34.94 lakh in their local procurement by the three AFMSDs.

#### Local purchase of medicines covered under Rate Contracts

We noticed that hospitals frequently resorted to local purchase of items at rates higher than those approved in the RC. It would be seen from the table below that six hospitals procured drugs included under RC from other firms at rates higher than the applicable RC rate resulting in an extra expenditure of ₹73.22 lakh:

Table- 47: Extra expenditure on LP of items covered under DGAFMS RC

Hospital	Extra expenditure (₹ in lakh)	Details of Medicines covered under RC procured locally
CH SC Pune	13.41	Inj Midazolam 5 mg, Tab
MH Ambala	5.11	Mycophenolate, Inj Bleomycin, Inj
INHS Ashwini	26.30	Irinotecan, Inj Erythropoietin, Tab
MH Kirkee	10.24	Tranexamic Acid, Tab Diltiazem, Tab
MH Agra	14.53	Ramipril, Tab Perindopril,
CH WC Chandimandir	3.63	Clindamycin Tube.
Total	73.22	

No action was taken to recover the extra amount on account of higher price paid from the RC firm in terms of the contract provisions.

CH SC Pune stated that LP of items covered under RC were made to tide over possible non-availability of drugs as RC supply orders take time to materialise and the DDOs did not have authority to place orders on the RC holding firms.

The contention is invalidated by the fact that the local purchases were made in anticipation of delay, without actually placing the orders on the RC firms in the first instance. Further, the contention that DDOs do not have authority to place orders on RC holding firms is also incorrect as DDOs are delegated powers to place orders on RC holding firms as per Note 8(b) to Schedule XII of delegation of financial powers.

#### LP of RC items available under DGS&D RC

As per DPM 2009, goods for which DGS&D has Rate Contracts can be procured directly from the suppliers.

We noticed that CH (SC) Pune, AFMSDs Delhi, Mumbai and Lucknow in violation of the instructions resorted to procurement of items locally at rates higher than the rate contracts. Thus, non observance of instructions to procure drugs through RC resulted in extra expenditure of ₹35.28 lakh on local procurement by four DDOs as shown in Table below:

Table-48: Extra expenditure on LP of items available under DGS&D RC

Item	DDO	Qty of LP	Period	Range of LP rate(₹)	RC rate	Extra expdr
					(₹)	(₹)
X ray	AFMSD Delhi	154000	8/10 to 1/11	45.24		889774
film	AFMSD Mbai	18950	8/10	45.24	39.46	109488
17x14	CH SC	10050	1/10 to 3/11	0 to 3/11 47.98 to 56		122172
X ray	AFMSD Delhi	160000	8/10 to 1/11	22.81	19.90	466000
Film	AFMSD Mbai	12000	8/10	22.81		34950
12x10	CH SC	16400	1/10 to 3/11	41.52 to 22.52		163606
X Ray Film	AFMSD Delhi	65000	8/10 to 1/11	15.21	13.27	126133
10x8	AFMSD Mbai	17450	8/10	15.21		33862
	CH(SC)	11100	1/10 to 3/11	16.40 to 18		71369
X Ray Film 15x12	CH(SC)	13250	1/10 to 3/11	33.78 to 40.50	31.36	73174
Hand	AFMSD Delhi	588278	10/10 to 3/11	7.22 to 8.38	6.55	674224
gloves	AFMSD Lknw	249000	2/11	7.95		347504
	CH SC	160000	1/10 to 3/11	7.25 to 11.23		415480
		Total extra ex	penditure ₹			3527736

Source: Data compiled from supply order details furnished by DDOs

In reply to the query regarding procurement at higher rates CH SC Pune stated that keeping in view the past experience of delay in receipt from CPSE and RC Holding firms, items were procured locally from registered vendors for smooth functioning of hospitals. While it is accepted that supply of medical stores can brook no delay, CHSC could not produce any records regarding attempts made to source the items from the RC firms.

#### **Fall Clause in Rate contracts**

The rate contracts concluded by the DGAFMS contain a 'Fall Clause' to protect the interests of the buyer. The clause stipulates that in the event of a fall in rate during the currency of the RC the benefit shall be passed on to the buyer and for this purpose an undertaking is obtained from the vendor. It also devolves on the DGAFMS to carry out market survey to give effect to the Fall Clause.

We observed that during 2009-10 CH (SC) and CH (WC) locally procured 10 items during the currency of their RC, at rates lower than the rate in the RC concluded by the DGAFMS. Nevertheless the DGAFMS continued procurement through RCs at higher rates resulting in an extra expenditure of ₹ 3.71 crore, as shown below:

Table- 49: Extra expenditure due to non application of fall clause

PVMS No.	Nomenclature	LP Rate (₹)	RC Rate(₹)	Diff. (₹)	Quantity procured through RC	Extra expendi ture (₹)
011613	Somatostatin Inj 3 mg	642	878.8	236.8	5315	1258592
012846	Monteleukast 5 mg Tab	38.48	56.16	17.68	163100	2883608
012487	Bromhexine syrup 5 ml containing 4 mg of bromhexine HCL bottle of 100-150 ml	9.55	11.44	1.89	400640	757210
013203	Amoxycillin 875 mg + Clavulanic acid 125 mg Tab	11.34	12.83	1.49	255154	380179
013263	Teicoplanin 400 mg Inj	559	707.20	148.20	10464	1550765
		426.40	707.20	280.80	27066	7600133
010129	Lignocaine HCL Jelly 2% Tube of 30 mg with plastic nozzle	13.34	27.69	14.35	91174	1308347
011472	Hydrogen Peroxide Solution	24	59.80	35.80	228275	8172245
011184	Indonomido SP 1.5 mg Toh	1.66	5.16	3.5	581100	2033850
011104	Indapamide SR 1.5 mg Tab	2.49	5.16	2.67	2835000	7569450
010886	Zoledronic Acid 5 mg Inj	280	395.20	115.20	952	109670
012946	Leflunomide 10 mg Tab	4.39	36.1	31.70	110640	3507288
			To	otal extra	expenditure ₹	37131337

Source: Data compiled from supply order details furnished by DDOs

The above cases illustrate that implementation of the Fall Clause in the Rate Contracts needs to be monitored by the DGAFMS by undertaking appropriate market survey. The above cases also call for action vis-a-vis the suppliers for adjustment of the excess rates paid, after proper enquiry.

#### **Recommendation No 8**

DGAFMS may revamp the system of operation of RCs to make it more efficient and suited to the needs of consignees. Backlogs in concluding RCs may be removed. Effective steps may be taken to ensure that DDOs do not resort to local procurement without placing orders on RC holders in the first instance.

The Ministry in their response stated that the advantages of RC were well appreciated. The requirement of RCs with reputed brands was also agreed to and that the process of concluding more RCs was being resorted to and it had picked up pace.

# 5.6 Low compliance by AFMSDs in supply

AFMSDs at Delhi, Mumbai and Lucknow are the provisioning and stocking echelons responsible for servicing the requirements of hospitals by ensuring supplies through RCs and Central procurements. Indenting Procedure requires indents to be complied with as quickly as possible and reduce the non availability to the minimum by issuing suitable substitutes wherever possible.

The compliance rate of supply at three AFMSDs was extremely unsatisfactory as indicated below:

Depot	Period	No of items demanded	No of items issued	Compliance rate (percentage)
AFMSD Lucknow	2006-07 to 2010-11	680750	272446	40
AFMSD Delhi Cantt	2006-07 to 2010-11	679584	330568	49
AFMSD Mumbai	2006-07 to 2010-11	713578	305743	43

**Table- 50: Compliance rate at AFMSDs** 

The low compliance was attributed by the depot to manpower deficiency, large inventory making it impossible to procure all items, varying MMFs and restricted financial powers. This perforce results in increased allotment to hospitals under local purchase by the DGAFMS as brought out in Chapter II of this report and increased local purchase.

#### **Delay in compliance**

The maximum time laid down in Indenting Procedure of December 2005 for compliance of indents by AFMSDs is eight weeks up to the stage of despatch (viz. 56 days). We examined cases of March 2009, March 2010 and March 2011 in respect of AFMSD Lucknow covering Eastern Command and Central Command, which revealed that compliance within time was only 5 *per cent*, 6 *per cent* and 29 *per cent* during March 2009, 2010 and 2011, respectively, as detailed below:

Table- 51: Delay in issue of stores

Month	Total	No. of cases	No. of cases	Percentage of	f compliance	
	cases	processed in	delayed beyond	Within time	Beyond time	
		time	56 days	frame	frame	
March 2009	92	05	87	05	95	
March 2010	268	17	251	06	94	
March 2011	104	30	74	29	71	

While compliance by AFMSDs during 2006-07 to 2010-11 fell short of the requirement there were also delays in issue even where stores were available for issue against indents. This necessitated local purchases by the dependent hospitals to meet their requirements, which were not subject to quality inspection.

#### Local procurement of drugs declared Not Available (NA)

The indenting procedure laid down by the DGAFMS in December 2005, stipulates that expendable items demanded will be issued to the extent of availability in stock in AFMSDs and items not available will be marked as 'NA' and intimated to the indenting unit within eight weeks. The indenting units are empowered to make LP of such items to meet the urgent requirement not exceeding two months.

We collected information from 10 hospitals for December 2008, 8 for December 2009 and 5 for December 2010 in order to assess the impact of NA certificates on local procurement. Supply orders against the NACs received were analysed after allowing 7 days for processing the case and 14 days for inviting quotation. In other words, delay in LP was counted beyond 21 days from the receipt of the NACs. The following picture emerged:

Table- 52: Delay in issue of NA and LP order

Month	No. of	No. of	NA received	NA delayed		NA delayed LP made		LP delayed	
	Hospitals	cases	within time	beyond 56 days		beyond 56 days within time		beyond 21 days	
			No.	No.	Range	No.	No.	Range	
December 2008	10	125	51	74	19-206 days	8	117	4-245 days	
December 2009	8	91	56	35	5-171 days	9	82	4-124 days	
December 2010	5	75	0	75	36-141 days	23	52	5-178 days	

It can be seen from the above that not only were the NA certificates received late but also the hospitals took an unduly long time to locally procure a large number of items, raising doubts about the urgency of the requirement. Such medicines could have been procured under existing RCs at lower rates.

#### Recommendation No 9

The AFMSDs may ensure supplies to dependent hospitals, so that local procurement by such hospitals is minimised.

The Ministry agreed with the recommendation.

# 5.7 Local procurement of drugs

The DPM 2005 permits local procurement for meeting requirements of only ad hoc and urgent nature. The local procurement of medical drugs/stores is governed by the system of open/ limited tendering as per the delegation of financial powers made to hospitals.

As explained in the Chapter on Financial Management, the share of LP in total procurements has shot up by 135 *per cent* during the period between 2006-07 and 2010-11. Consequently, LP increased to cover more than half the procurements made in AFMS instead of for emergent requirements. The main causes for this are the drastic fall in number of RCs and failure of AFMSDs to service the requirements of hospitals.

## Local procurement of drugs at widely different rates

A test check of local procurements of 15 PVMS drugs by hospitals covered under the Performance Audit revealed wide variation in the rates of procurement during 2006-07 to 2009-10 as indicated below:

Table- 53: Variation in rate of PVMS drugs across hospitals

Sl. No.	<b>Description of Item</b>	PVMS No.		Variation in	n rate (in ₹) e variation)	
			2006-07	2007-08	2008-09	2009-10
1.	Diclofenac (Voveran) Gel	012920	6.98 to 59.17	5.93 to 43	7.5 to 45	7.24 to 48
	1% Tube of 30 gm		(748)	(625)	(500)	(563)
2.	Fluconazole 150 mg	010660	3.6 to 3.81	1.5 to 28	0.33 to 31.5	1.3 to 28.90
	Cap/Tab		(6)	(1767)	(9446)	(2123)
3.	Inj Mannitol 20% bottle	011513	55.86 to 198	34.71 to 110	20 to 109	19.4 to 99.84
	of 350 ml		(254)	(217)	(445)	(415)
4.	Inj Calcium Gluconate	012712	0.34 to 23	1.88 to 28.50	2.1 to 23.99	2.45 to 24.11
	10% 10 ml		(6665)	(1416)	(1042)	(884)
5.	Diclofenac Sodium Tab	010257		0.09 to 1.46	0.18 to 1.19	0.17 to 18
	50 mg			(1522)	(561)	(10488)
6.	Tramodol HCL 50 mg/ml	010294	3.96 to 20.6	3 to 23	2.86 to 25.90	2.04 to 25
	Inj		(420)	(667)	(806)	(1126)
7.	Inj Multivitamin	012718	5.68 to 12.3	4.18 to 15	1 to 13	2.69 to 14.9
		'	(117)	(259)	(1200)	(454)
8.	Thiopentone Inj of 0.5 mg	010111	21.67 to 32.50	19 to 56.85	21.84 to 50	23 to 45.75
	w/o water for Inj		(50)	(199)	(129)	(99)
9.	Bupivacaine HCL 5	010115	15.13 to 47.90	15.13 to 49	14.85 to 55.50	16.13 to 32.5
	mg/ml 20 ml Inj		(217)	(224)	(274)	(102)
10.	Bupivacaine HCL 5	010116	9.75 to 16.90	1.76 to 90	7.45 to 47.86	8.75 to 35.89
	mg/ml heavy 4ml Inj		(73)	(5014)	(542)	(310)
11.	Paracetamol 325 mg and	010278	0.50 to 3.95	0.43 to 6.20	0.47 to 4.80	0.40 to 8.50
	Ibuprofen 400 mg Tab		(690)	(1342)	(921)	(2025)
12.	Pantoprazole 40 mg Tab	011637	0.84 to 8.59	0.61 to 8.59	0.62 to 5.6	0.55 to 6.24
			(923)	(1308)	(803)	(1035)
13.	Omeprazole 20 mg Cap	011636	0.60 to 4.59	0.29 to 4.59	0.29 to 4	0.30 to 19.9
			(665)	(1483)	(1279)	(6533)
14.	Oral Rehydration powder	011688	1.58 to 11.4	1.58 to 12.93	2.97 to 12.5	2.35 to 12.5
	sachet of 20.5 mg		(622)	(718)	(321)	(432)
15.	Inj Pentazocin 30 mg amp	010288	3.05 to 5.1	2.98 to 5	2.65 to 4.5	2.9 to 4.09
	of 1 ml		(67)	(68)	(70)	(41)

(The range in rates indicated under a column is between various hospitals)

Source of data: Data compiled from information furnished by hospitals indicating procurement rate of above items.

It can be seen that even in respect of common drugs in use by all hospitals there was wide variation in the procurement rates. For example for Oral Rehydration powder, (PVMS-011688) the rate varied from ₹1.58 {CH (AF) Bengaluru} to ₹12.93 (INHS Ashwini) and for Voveran Gel (PVMS-012920) from ₹6.98 (MH Ambala) to ₹ 59.17 (INHS Jeevanthi).

Similarly, the variation in local procurement rates in respect of NIV items is shown under:

Table- 54: Variation in rate of a few NIV items across hospitals

SL. No.	Items	Variation in rate ₹ (percentage variation)				
		2007-2008	2008-2009	2009-2010		
1	Inj Insulin Glargine 300 IU 3	451.00 to 2282.92 (406)	453 to 2194.40 (384)	297.97 to 2230.00 <b>(649)</b>		
2	Inj Insulin Glargine 300 IU 10	Nil	1839 to 2131 <b>(16)</b>	417.89 to 2330.00 (458)		
3	Suspension digene 170 ml	Nil	12 to 46.50 <b>(288)</b>	9.5 to 41.50 (337)		
4	Inj Dextrose 10%	11.50 to 30.00 <b>(161)</b>	10.34 to 30.40 <b>(194)</b>	12.8 to 150.00 <b>(1072)</b>		
5	Tab Voveran SR 150mg	0.5 to 2.5 <b>(400)</b>	0.49 to 3.8 <b>(676)</b>	0.73 to 3.30 (352)		
6	Inj Sodium Hyaluronate 1%	49.90 to 1513 <b>(2932)</b>	368.90 to 688 ( <b>87</b> )	459.00 to 1800 <b>(292)</b>		
7	Inj Diltiazem	20.1 to 23.00 <b>(14)</b>	18.55 to 24 ( <b>29</b> )	18.19 to 23 <b>(26)</b>		
8	Inj Adrenaline	1.75 to 5.7 <b>(226)</b>	1.27 to 17.60 <b>(1286)</b>	1.41 to 45.50 <b>(3127)</b>		
9	Inj Fentanyl	12.90 to 35 <b>(171)</b>	12.90 to 129.20 (902)	12.9 to 126 (877)		
10	Inj Lognocaine 4% Topical	17.00 to 245.00 <b>(1341)</b>	21.99 to 24.30 <b>(11)</b>	19.80 to 23.60 <b>(19)</b>		
11	Inj Lignocaine with Adrenalin	15.06 to 26.00 <b>(73)</b>	8 to 27.90 <b>(249)</b>	6.25 to 24.00 <b>(284)</b>		
12	Inj Magnesium Sulphate	1.2 to 7.52 <b>(527)</b>	0.69 to 21.00 ( <b>2944</b> )	0.84 to 6.80 <b>(710)</b>		

(The range in rates indicated under a column is between various hospitals) Source of data: Data compiled from information furnished by hospitals.

The variation in rates of items commonly used such as Digene and Inj Dextrose was inexplicably wide. In respect of Digene (170 ml bottle) hospitals had procured it at rates ranging from ₹ 9.50 per bottle (AH R&R) to as high as ₹ 41.50 (178 MH). Similarly the procurement rate of Inj Dextrose varied from ₹ 12.8 (CH WC) to as high as ₹ 150 (MH Kirkee).

The fact that there are huge price variations in local procurements of drugs across various hospitals ranging upto even 100 times, implies one of the following two possibilities:

- Drugs in many cases are being procured locally at exorbitant prices.
- Drugs in many cases are being supplied at abnormally low prices which raise serious questions about their quality given the fact that supplies in local

procurement are accepted in hospitals based on only visual inspection by a Board of officers.

The Ministry stated that the rates of drugs vary depending on brands and quantity procured. It added that the process for concluding more RCs was on and it had picked up pace.

#### Recommendation No 10

In view of the wide variation in rates and brands of PVMS/NIV drugs/consumables, locally procured across hospitals, DGAFMS may take effective steps to regulate their procurement by suitable standardisation of specifications and increasing their coverage through RCs and central purchase by AFMSDs.

# Local purchase of PPP items from other than Pharma Central Public Sector Enterprises (CPSE)

In August 2006, the Ministry of Chemicals and Fertilisers required all purchasing departments of Government of India to place orders on Pharma 'Central Public Sector Enterprises' (CPSE) and their subsidiaries for pharmaceutical products. It also stipulated that drugs would be supplied at the rates fixed by the National Pharmaceutical Pricing Authority (NPPA) less discount of 35 *per cent*. In all, 102 items were covered under this Purchase Preference Policy (PPP).

However, it was observed that depots/hospitals resorted to local purchases from suppliers other than CPSEs as shown in the Table 55.

Depots/Hospital Period Value (₹ in lakh) AFMSD Lucknow 2008-09 to 2010-11 55.73 2007-08 to 2010-11 AFMSD Mumbai 176.00 2007-08 to 2010-11 AFMSD Delhi Cantt 56.23 CH NC 2007-08 to 2010-11 27.19 166 MH 2007-08 to 2010-11 41.27 92 BH 2007-08 to 2010-11 31.24 2007-08 to 2010-11 MH Jodhpur 28.61 AH RR 2009-10 to 2010-11 10.42 CH WC 2009-10 to 2010-11 3.95 MH Ambala 2009-10 to 2010-11 9.13 MH Deolali 2007-08 to 2009-10 9.56 MH CTC Pune 2007-08 to 2010-11 14.21 **Total** 463.54

Table- 55: Details of local purchases from other than CPSEs

The hospitals contended that CPSE firms did not supply medicines in time, no response was received from them and no authorized dealers were available in the

region. They also asserted that the CPSE rates in some cases were higher than LP rates.

DGAFMS, through the Ministry of Defence, should have approached the Ministry of Chemicals & Fertilizers to address their concerns with regard to the PPP policy.

# 5.8 Individual cases of irregularity in procurement

#### Case 1: Irregular tender enquiry by INHS Jeevanthi

INHS Jeevanthi followed the system of issuing Tender Enquiry (TE), calling for discounts to be offered on the MRP without indicating the item/quantity required. The vendor offering maximum discount was accepted, on whom all the orders were placed during the year.

The system of procurement adopted by INHS Jeevanthi is unprecedented and is not supported by provisions in any manual, code, rules or regulations.

# Case 2: Procurement of PVMS items as NIV items by MH Deolali and at MH CTC

As per delegated powers local purchase of PVMS items can be made after obtaining 'NAC' from AFMSD. For local purchase of 'NIV' items, no NAC is required. We noticed instances where hospitals resorted to local purchase of PVMS items by indicating them as NIV items. The cases are discussed below:

MH Deolali is dependent on AFMSD Mumbai for supply of items under PVMS list. However, to avoid obtaining NAC from AFMSD, MH Deolali procured 20 PVMS items valuing ₹ 3.36 lakh indicating them as 'NIV' items. MH Deolali stated in reply that it was not in the list of DDO. In fact, as MH Deolali is not a DDO and is dependent on AFMSD Mumbai, it has to obtain a NAC from the Depot for procurement of PVMS items as per the delegated powers. Such procurements illustrate misuse of delegated powers.

At MH CTC we noticed that 113 PVMS items valuing ₹ 63.77 lakh were procured as 'NIV' items. In reply MH CTC stated that the procurements were made under emergency as the drugs were life saving medicines and any delay in their administration would have proved fatal. MH CTC, however, did not clarify as to why these medicines were indicated as 'NIV' items.

# 5.9 Overstocking of drugs

As per the prescribed stocking policy, quantities of reserve holding and working stocks are calculated based on monthly maintenance figure (MMF) which is the

average of preceding ten months consumption. For short life items the stocking is permitted for six months (including reserve of three months) and for long life items for nine months (including reserve of three months) based on the MMF.

The position at two AFMSDs, one Base Hospital, three Military Hospitals, one Field Hospital and one Sectional Hospital is discussed below:

#### (i) AFMSD Delhi

At AFMSD Delhi we noticed that as on 31 March 2011, the Depot held 210 drugs, valuing ₹ 3.80 crore in excess of the requirement based on the average MMF. Of the 210 drugs the quantity held in respect of 96 drugs, constituting 46 *per cent*, would be sufficient for more than two years, by which time their shelf life would have expired as shown below:

Table- 56: Stratification of surplus stock at AFMSD Delhi

Drugs	held	Quantity sufficient for						
surplus		Up to 2 years 2-5 years More than 5 years						
210		114	55	41				

In fact in case of some of the medicines, overstocking was so huge that it covered the requirement of 6 to 109 years based on average MMF, as shown in the table below:

Table- 57: Stock held at AFMSD Delhi

	AFMSD Delhi								
PVMS No.	Nomenclature	Cat. of Item	Average MMF	Stock held*	Over stocking {Stock held - (Avg MMF x 6 for SL and 9 for LL)}	Cost of over stock in ₹	Period required for consumption in year		
050288	Stop cock 3 way	LL#	59.29	24587	24053.39	187616	35		
050317	Tubing drain	LL	23.67	31299	31085.97	194288	109		
100781	Wire Liga	LL	18.07	1934	1771.37	663201	9		
130196	Polybutylate	LL	15.75	3276	3134.25	719028	17		
011972	Nourish Renal 100 gm	SL^	910.75	70474	65009.5	2358544	6		
221601	AV Fistula	LL	102.88	12957	12031.08	12031	10		
012840	INH+PAS GRANULES	SL	170	30354	29334	625108	15		
170124	Fibrinogen	LL	3.94	390	354.54	856271	8		
011112	Inj Nicorandil 48 mg Amp	LL	15.38	5563	5424.58	603648	30		

#LL = Long life, ^ SL = Short life \*As on 31.3.2012

We observed that over-provisioning of medical stores by the DGAFMS and the Commandant, AFMSD, Delhi had resulted in expiry of shelf life of the stores in storage leading to heavy loss.

Our analysis of procurements of two drugs, involving loss of ₹ 88.25 lakh, revealed the following:

#### Case 1:

The MMF of the item PVMS No. 011972 Nourish Renal was indicated as 118 packets (sachets) in the account card. In November 2006, the AFMSD placed an order on M/s Plus Mark Pharma for supply of 10,000 packets of the said medicine @ ₹ 55.40 per packet which was received by the depot in March 2007 with expiry date of January 2009. In addition to this the DGAFMS also issued a supply order, on 2 December 2006, on M/s Vital Neutraceuticals Pvt Ltd. Ambarnath against RC, concluded with the firm on the same day, for procurement of 1,58,004 sachets of the medicine @ ₹33.78 per sachet. Against this the depot received 60,000 sachets in January 2007 with expiry date of December 2008.

Out of 70,000 sachets available with the depot, only 6,646 sachets were issued during January 2007 to September 2008 and life of remaining 63,354 sachets expired in December 2008 and January 2009. Thus over-provisioning of stores resulted in loss of ₹ 23.56 lakh.

#### Case 2:

The MMF of PVMS No. 012840 INH+ PAS Granules is 170 based on the average consumption between January 2006 and October 2006. Against supply order issued by the DGAFMS on 14 December 2006 the depot received 25200 Nos in February 2007 with date of expiry as December 2009.

As of February 2007, the depot held 25,265 Nos of the item (65 previous balance + 25200) of which 18,388 had crossed the stipulated life in December 2009 without any issue beyond June 2009. The value of this stock was ₹ 39.18 lakh.

Although the Depot indicated MMF as 757 this was not borne out by the consumption pattern during the period January 2006 to October 2006.

In addition to the above, 12,000 Nos of the same item, for issue to ECHS, were also received by the depot in May 2007, with date of expiry as March 2010 under procurement order issued by the DGAFMS in March 2007. Out of this 11,966 Nos attained their stipulated shelf life and were lying in stock as of May 2011 resulting in loss of ₹ 25.50 lakh.

Thus in the above two cases alone, medical stores aggregating ₹ 88.25 lakh had crossed the shelf life in storage due to procurement far exceeding the requirement, resulting in avoidable loss to the exchequer.

#### (ii) AFMSD Mumbai

At AFMSD Mumbai we noticed that as on 31 March 2011, the depot was holding 460 drugs in excess of authorisation. Analysis of the sufficiency of the quantity held revealed the following.

Table-58: Stratification of surplus stock at AFMSD Mumbai

Drugs held	Quantity sufficient for					
surplus	Up to 2 years	2-5 years	More than 5 years			
460	263	136	61			

As can be seen from the table, of the 460 drugs, 197 drugs (constituting 43 *per cent*) had stocks sufficient for a period of more than two years, by which time the life would expire.

Similarly, at AFMSD Mumbai, there were several cases of overstocking, of which one medicine had been stocked to last for 346 years, as indicated in the following table:

Table-59: Stock held at AFMSD Mumbai

	AFMSD Mumbai							
PVMS No.	Nomenclature	Cat. of Item	Average MMF	Stock held	Over stocking {Stock held - (Avg MMF x 6 for SL and 9 for LL)}	Period required for consumption in Year		
010706	Cyclosporin A micro emulsion Cap 100 mg	SL^	231.67	46732	45342	17		
011108	Tab Isosorbide dinitrate 10 mg	SL	37765	6634850	6408260	15		
011179	Tab Captoprill 25 mg	SL	390	211800	209460	45		
011376	Trioxsalen Tab 25 mg	LL#	1286.67	491910	480330	32		
011657	Tab 3-Aminno Salicylic acid 400 mg	LL	1058.75	158710	149181	12		
011765 N	Voglibose 0.2 mg Tab	SL	570.58	2365662	2362239	346		
012489 B	Cough expectorant syrup	SL	3940.29	7308276	7284634	155		
012690	Drotavenine HCL 1% Inj 20 mg/ml	SL	105.46	41846	41213	33		

**#LL = Long life, ^ SL = Short life** 

#### (iii) Other hospitals

We noticed that at one Base Hospital, Military Hospitals Allahabad, Jabalpur, Gaya, one Field Hospital and Sectional Hospital Talbehat, the laid down procedure for calculation of MMF was not adhered to. A test check of the calculation of MMF for 132 medicines during 2010-11 at these hospitals revealed that the MMF worked out was either in excess or less than the average consumption in the preceding 10 months.

Thus procurement procedures were not followed scrupulously by the indenting/procuring authorities resulting in loss to the tune of ₹ 88.25 lakh at AFMSD Delhi alone.

# 5.10 Procurement of drugs with less than prescribed shelf life

The stocking policy laid down by DGAFMS requires that the AFMSDs do not accept expendable stores having less than five-sixth of their residual life.

Test check for the month of December in 2008, 2009 and 2010 at AFMSD Lucknow revealed that 22 items valuing ₹46.64 lakh with shelf-life less than the five-sixth prescribed were accepted.

Test check for the month of January in 2008, 2009 and 2010 at AFMSD Delhi revealed that 52 items valuing ₹2 crore with shelf-life less than the five-sixth prescribed were accepted.

Test check for the month of January 2008 at AFMSD Mumbai revealed that 20 items valuing ₹23.07 lakh were accepted in January 2008 with less than the prescribed residual shelf life.

# 5.11 Procurement of deleted drugs

A 'Drug Review Committee' (DRC) at DGAFMS undertakes review of drugs in PVMS list and declares them as obsolete or obsolescent or as suitable for deletion. Such declaration is made under an "Amendment List" (AL) which is then issued to the AFMSDs and DGMS's of Army, Navy & Air Force to ensure implementation by the hospitals under their respective jurisdiction. Following parameters govern the deletion of a drug from the PVMS list:-

- Drug not in vogue;
- Drug not in very high demand;
- Drugs which have become obsolete due to life threatening side effects; and
- Introduction of a new drug.

Based on the DRC meeting in September 2008, the DGAFMS issued the AL to the DGMS's in June 2009 for implementation.

We noticed that even as late as in March 2011, the hospitals had continued to procure the drugs that were deleted as shown in the table below:

**Table-60: Details of procurement of deleted drugs** 

Hospital	Value (₹ in lakh)	Illustrative list of deleted medicines procured			
Command Hospital WC	18.66	Erythroprotein, Norfloxacine Eye drop, Amikacin Sulphate, Salbutamol.			
Army Hospital RR	9.20	Secnidozole, Thalidomide 100 mg, Glutamide 250 mg, Lignocaine			

Hospital	Value	Illustrative list of deleted medicines procured			
	(₹ in lakh)				
Base Hospital Delhi Cantt	2.56	Tab Doxazocin, Thalidomide 100 mg, Tab Ketoanlogue Tab Betalistidine			
MH Gaya	1.17	Piroxicarm 40 mg, Cetrizine 100 mg, Levo Salbutomal, Sulphacetamide			
Base Hospital Barrackpore	2.59	Tab Penicillamine 250 mg, Tab Leflunamide, Tab Cetrizine, Lignocaine			
CHAF Bangalore	4.83	Erythyroprotein, Norfloxacine, Tab Salbutamol 4 mg, Inj Methyl Prednislone			
INHS Ashwini	14.06	Erythyroprotein, Norfloxacin Eye Drops Betahestine 16 mg, Paradichlorobenzene			
INHS Jeevanthi	0.71	Gabapentin, Keototifn 1mg Tab, Tab Salbutamol 4 mg, Tab Decnidazole			
MH CTC Pune	4.36	Allendronate sodium 35 mg, Norfloxacine eye drops, Salbutamol 4 mg, Isoprenaline HCI			
CH SC Pune	21.52	Inj Granulocyte, Inj Lignocaine, Tab Doxazosin, Inj Amikacin Sulphate			
MH Alwar	Not available	Gabapentin 400 mg, Salbutamol4 mg, Nifedifin 10 mg, Erythyroprotein			
Total	79.66				

CH WC stated that though an item may have been deleted from PVMS list it was not banned. AH (R&R) and BH Delhi Cantt replied that procurement was made as these were demanded by the Wards. MH Gaya, MH Alwar and BH Barrackpore stated that AL had not been received by them. CH (AF) Bengaluru and INHS Ashwini contended that use of medicines would be gradually stopped in a phased manner. INHS Jeevanthi stated that AL had not been received by the hospital and the medicines procured were issued to avoid loss.

MH CTC stated that these drugs were obsolete only in PVMS and were not banned by the Drug Controller of India and hence procured as per requirement. CH (SC) stated that procurement of deleted drugs was made as these were not banned in India though deleted from PVMS list.

It can thus be seen that the system evolved by the DGAFMS to delete procurement of drugs either on grounds of a drug not being in vogue or high demand or having threatening side effects or new substitute drug having been introduced, was not being implemented strictly at the hospital level.

Such deviations in procurement of deleted drugs vitiate the established system designed to achieve better patient care. The continued procurements even after issue of the Amendment List also show that the DGAFMS was not monitoring its own instructions in this regard.

## 5.12 Reserves for disaster relief management and war maintenance

#### **Bricks for Disaster Relief Management**

To ensure quick response for management of disaster/emergency and preparedness for International Missions, the DGAFMS, in August 2006, decided to stockpile certain medical and surgical items. This system of stockpiling has been termed as 'Brick'. The examination of the holdings under Brick, earmarked to AFMSD Lucknow and Mumbai, revealed shortfalls, as shown below:

Table-61: Details of authorisation and holding of Brick

Type of Brick	No. of items required	No. of items held for bricks		No. of items with Nil stock at		Percentage of short fall	
		Lucknow Mumbai		Lucknow	Mumbai	Lucknow	Mumbai
		No.	No.	No.	No.		
International	94	54	25	40	69	43	73
<b>Basic Medical</b>	119	53	69	66	50	55	42
Surgical	219	78	180	141	39	64	18

Data compiled from details furnished by AFMSDs about stock held for bricks

Thus it would appear that the disaster management plan was yet to be fully complied with even after lapse of three years of its sanction. This may hinder quick response to emergencies.

#### War maintenance reserve

In supersession of all instructions issued earlier, the DGAFMS formulated a revised instruction in January 2004, re-iterated in March 2011, governing 'War maintenance reserve'. The reserve was to be maintained by AFMSDs/AMSDs/FMSDs on behalf of the Commands as per the scale per set of 'Expendable' and 'Non Expendable' items indicated therein for issue on short notice. The depots are required to maintain the required number of sets on behalf of the Commands identified therein with the provision of periodical turn over of the stocks of items to avoid loss due to expiry of life of drugs.

Our examination revealed that as of April 2011 there was deficiency of 46 *per cent* of expendable and 100 *per cent* of non expendable items stocked against war maintenance reserve at AFMSD Lucknow.

#### Recommendation No 11

Effective steps may be taken to replenish items listed out in Brick and war maintenance reserve so that these can be issued at short notice.

The Ministry stated that a system was already in place and was also followed.

Based on the instances of deficiencies in stockpiling of items as brought out in the paragraphs above, it is obvious that the system was not being complied with and needed redressal.

# 5.13 Other aspects of contract management

#### Delay in materialisation of supply orders under RC/LP

We carried out test check of materialisation of supply orders placed by CH SC, CH (AF) and INHS Ashwini between October 2010 and December 2010 under RC/LP. The details of supply orders placed by the three hospitals are given in the table below.

Table-62: Delays in supply under LP and RC orders

	CH SC		CH(	AF)	INHS Ashwini	
	LP	RC	LP	RC	LP	RC
No. of supply orders	315	Nil	786	35	2276	23
placed						
Supplied within PDC	162	Nil	634	12	214	Nil
Supplied after PDC	153	Nil	152	23	2062	23
Delay	49%	Nil	19%	66%	91%	100%

Data compiled from information furnished by hospitals

It can be seen from the above table that at INHS Ashwini 91 *per cent* of LP orders were supplied after the scheduled delivery date. At CH SC and CH (AF) the delay in LP orders was 49 *per cent* and 19 *per cent*, respectively. Similarly, there were large delays in the materialisation of orders placed under RC. At INHS Ashwini, none of the orders placed under RC materialised within the specified delivery schedule. At CH (AF) there was delay in delivery in 66 *per cent* of orders under RC.

#### Risk and expense purchase

DPM-2005 enables a purchaser to effect risk and expense purchase in the event of a supplier failing to honour the contracted obligations.

We saw in AFMSD Lucknow that despite incorporation of risk expense clause in the supply orders, the same was not invoked in 31 test checked cases out of 1303 cases cancelled by the Depot during the period 2005-06 to 2010-11, resulting in excess purchase cost of ₹ 35.16 lakh remaining unrecovered.

#### Non replacement of medicines nearing expiry

As per the instruction issued by DGAFMS in October 2006 supply orders placed by DDOs should contain a clause for free replacement of medicines lying unconsumed three months before date of expiry by the vendors. In case the vendors do not replace the stock, the DDOs are empowered to make recovery of the cost of medicines to be replaced from pending bills.

In the following cases, we noticed that no action was initiated by the DDOs to ask the vendors to replace the unconsumed stock. In cases where the vendors were intimated about the replacement, no recovery could be made by the DDOs due to non-compliance by the vendors.

Table- 63: Action not taken by the DDOs

Hospital/Depot	Value of stores held
AFMSD Delhi	₹ 5.01 crore
AFMSD Lucknow	₹ 4.34 crore

Table-64: Action initiated but recovery not made

Hospital/Depot	Value of stores held
AFMSD Mumbai	₹ 4.70 crore
CH WC Chandimandir	₹ 0.17 crore (LP)
	₹ 0.51 crore (RC)

Thus, despite measures put in place for effecting economy in purchase and safeguarding Government interest by way of replacement of unconsumed stock, the post contract management of procurement revealed loose implementation of prescribed procedures which resulted in avoidable holding of drugs without replacement.

# 5.14 Quality inspection

DGQA is mandated to carry out sample inspection of all supplies against RC either through its own test facilities or at NABL accredited laboratories. It also carries out inspection of local purchase of all drugs exceeding ₹ 1.5 lakh and in all cases where a complaint has been reported by hospitals. In addition, post lab test of drugs held in stock is required to be undertaken by DGQA based on samples forwarded by the hospitals. Controllerate of Quality Assurance (Materials) Kanpur [CQA (M)] is the Authority Holding Sealed Particulars (AHSP) of drugs and CQA (General Stores) Kanpur is the AHSP for surgical items.

We noticed deficiency in holding of specifications and technical staff, inadequate test equipment/facilities, poor coverage of AMC of the test equipment and non-adherence to test procedure as explained in the succeeding paragraphs.

#### **Deficiency of authorised specifications**

CQA (M) held the approved specifications for only 592 drug items out of 985 maintained in PVMS Section '01'. Similarly CQA (GS) held the specifications of only 178 surgical items out of 408 mentioned in PVMS Section '05'. Thus there was deficiency of 40 per cent and 56 per cent in the specifications held by CQA (M) and

CQA (GS), respectively. This meant that the AHSP would not be able to undertake proper inspection of drugs and surgical items.

### **Deficiency of technical staff**

The deficiency in the cadre of technical staff at SQAE (GS) Delhi increased from 35 per cent in 2008-09 to 38 per cent in 2010-11 against the authorization. In case of CQA (M), deficiency ranged from 32 per cent in 2005-06 to 42 per cent in 2010-11 and in case of CQA (GS) it ranged from 32 per cent to 40 per cent during the same period. The deficiency in technical staff places constraints on the effectiveness and quality of testing.

#### Non availability of test facilities

Test facilities are required for evaluating physical parameters and chemical composition. In the absence of such test facilities at SQAE (GS) New Delhi, CQA (GS) Kanpur and CQA (M) Kanpur, the drugs were cleared with partial testing as discussed below.

#### SQAE (GS) Delhi

SQAE (GS) Delhi is authorised 15 types of test equipment. As of March 2011, five items of equipment were not held by it. Of the remaining ten equipment held, two equipment viz. Ultra Violet Spectrophotometer and High Performance Liquid Chromatograph (HPLC) procured in January 1997 and August 1999 were reported to be obsolete and suffering from frequent breakdowns.

#### CQA (M) Kanpur

CQA (M) held 52 test equipment. However, two equipment viz. UV spectrometer and Constant Temperature Bath were under repair.

#### CQA (GS) Kanpur

CQA (GS) Kanpur did not hold 3 of the 25 test equipment required.

#### **Post Lab Test**

In October 2006, the DGQA formulated the guidelines for selection of samples for testing of locally procured drugs to be undertaken as Post Lab Test (PLT) of tablets, capsules, injectables (liquid), powder injectable, ointments/creams (less than 100 gms), sutures, syringes (dry), syrups (liquid) and eye drops. The guidelines indicated the types of tests for the above categories and the quantity to be expended in the test. In November 2006, DGAFMS envisaged repeat test under certain circumstances. The DGAFMS instructed AFMSD/AMSDs and Transfusion Centres to adhere to these instructions.

In February 2008, the DGAFMS reiterated the instructions as the DGQA had intimated that sufficient quantity of local purchase samples were not being forwarded to SQAE/CQA (M) Kanpur for testing. The DGMS (Army/ Navy/Air force) were also required to instruct the hospitals/Units under their command to comply with the DGQA's instructions.

#### Compliance by hospitals

We examined the compliance by AFMSDs, DDOs and other hospitals to the requirements of Post Lab Test in respect of local procurement made by them.

Non compliance to PLT was noticed at all major hospitals viz. CH (SC), AH (R&R), INHS Ashwini, Base Hospital Delhi Cantt, MH Amritsar, MH Kirkee and MH Akhnoor.

The compliance by CH (AF) Bengaluru was meagre as it had sent samples of only three drugs in 2009-10 and five drugs in 2010-11. Although CH (WC) claimed that samples of drugs were sent to CQA on regular basis, the records produced for audit actually pertained to vigilance check on supply of spurious drugs as directed by HQ WC and not of PLT. The compliance by AFMSD Mumbai could not be ascertained as it had maintained no record of samples sent for PLT until February 2010. Subsequently the depot sent 78 samples from March 2010 to May 2011. MH Ambala intimated that it had sent samples of 28 drugs during March 2008-11.

The non-compliance by hospitals was attributed to meagre quantities involved in local procurements. A Board of Officers was being detailed every month to see the quality of medicines with reference to their expenses after physical verification of the medicines and samples being sent to CQA only in case of complaints by Wards against a particular batch of medicine.

#### Post Lab Test at CQA (M)

Volume of testing done by CQA (M) in respect of LP samples received from Medical Units was as under.

Year	No. of Samples Received	No. of Samples Rejected	Samples Rejection (in percentage)
2006-07	210	31	15
2007-08	166	37	22
2008-09	165	33	20
2009-10	172	35	20
2010-11	125	39	31
Total	838	175	

Table-65: Samples inspected and sentenced

It could be seen from the above that rate of rejection had increased from 15 *per cent* to 31 *per cent* during 2006-07 to 2010-11. The average rejection during the three year period of 2008-09 to 2010-11 was 24 *per cent* approximately.

#### Inspection

All purchases exceeding ₹ 1.50 lakh as well as procurements under the rate contract are to be inspected by the DGQA or by the NABL duly supported by their Inspection Note. We noticed that drugs were accepted by the hospitals even without the Inspection Note as discussed below.

- (i) In 53 orders, each valuing above ₹ 1.50 lakh, the medicines were accepted by CH WC without Inspection Note during October 2009 to March 2010.
- (ii) At AH (R&R), we test checked sample orders of cases where the local purchase had exceeded the limit of ₹ 1.5 lakh. It was seen that in four cases of purchase of medicines valuing ₹ 24.10 lakh the Commandant was indicated as the inspection authority. The stores supplied were inspected by the Board of Officers of the hospital and accepted though the supplies had not been accompanied by Inspection Note of DGQA/NABL report, thus contravening the said instructions.
- (iii) Similar test check of six orders valuing ₹ 30 lakh at CH SC revealed that the inspection agency was indicated as Commandant of the hospital. The supplies were inspected and accepted by the Board of Officers even though it was not accompanied by inspection note of DGQA/NABL.
- (iv) Test check of seven orders valuing ₹ 27.61 lakh, each valuing above ₹ 1.50 lakh, placed by AFMSD Mumbai indicated inspection of the stores by the depot. The supplies were inspected and accepted by the board indicating submission of NABL report by the supplier. The test report was, however, not verifiable from the documents accompanying the payment of the bills.
- (v) Similarly, AFMSD Delhi accepted stores against four orders valuing ₹ 37.79 lakh, based on test reports from laboratories which are not accredited by NABL. Although the orders specifically provided report to be supplied by NABL accredited laboratory, it was noticed that the test report did not bear NABL logo.

Thus the requirement of inspection by appropriate agency was not adhered to by the DDOs. Such acceptance of drugs without Inspection Note carried the risk of acceptance of substandard drugs by the hospitals.

This comment is also supported by the results of a survey conducted by the College of Defence Management wherein it was found that the clientele perceived the quality of medicines supplied in service hospitals to be poorer than those available in the market.

#### **Incomplete Inspection**

As per Defence Quality Assurance Organisation [Standing Orders (Technical)] of November 2001, whenever any sample or store is delivered to the Quality Assurance Officer for inspection/ test, Quality Assurance Agency should give clear cut verdict on the store. At SQAE (GS) Delhi we test checked 159 cases, received between July 2010 and July 2011, and noticed that in 46 cases reports were issued though the testing facility was not available, 14 cases were closed even without testing the samples and in 13 cases reports were finalised while the required test equipment was out of order.

During 2009-10 and 2010-11, CQA (M) Kanpur cleared 88 samples despite non-existence of test facilities and 38 samples were cleared without complete test for want of required certified Reference Standard and Working Standard from the supplier/manufacturer of the drugs.

CQA (M) stated that LP contracts were placed by user units in which DGQA was not the quality assurance agency, therefore, the firm could not be forced by the DGQA to extend firm's own test facilities or that of NABL accredited laboratories for tests left out. It agreed, however, that the tests could be enforced by the authority placing the orders. It further said that only the report on test parameters for which facilities were available at CQA (M) or were voluntarily extended by the firms was sent to the user units for appropriate action.

Given the serious deficiencies in inspection of stores against LP contracts as discussed above the inspection system prescribed for drugs was not effective in providing quality assurance for drugs supplied to the hospitals. This is an issue of significant concern since the bulk of procurement by the hospitals was being made within the limit of ₹ 1.5 lakh which was outside the ambit of quality checks by DGQA/NABL accredited laboratories. It is to be noted that acceptance of drugs in absence of test facilities carried the risk of substandard stores being made available to patients with little chance of replacement in case of poor quality detected later.

#### Delay in receipt of test reports

Prompt receipt of test report from CQA (M) is essential for the hospitals to ensure that unfit drugs are weeded out from the stock. Delay in this regard carries the risk of unfit drugs being administered to the patients.

We noticed that there were considerable delays in intimating the test results to the hospitals as discussed below.

(i) During 2006 to 2010, AFMSD Lucknow forwarded 893 samples for testing. Of these, 77 samples were found unfit for issue, 64 samples could not be tested for want of testing facility and in 19 cases the document was silent about the conduct of

test and the results thereof. Further scrutiny revealed that the time taken for communicating the results of 77 samples which were not fit for consumption, ranged from 49 to 456 days. Meanwhile, the depot issued the drugs to the dependent hospitals. Even in respect of 64 cases closed for want of testing facility, the time taken for communicating the closure ranged from 35 to 435 days.

- (ii) Of the 453 samples sent by AFMSD Delhi for testing during the above said period, 328 medicines were found fit for consumption. Of the balance 125 samples, test reports for 91 cases were not received as of March 2011, which included 14 samples sent as early as in 2006-07. In 34 cases, the inspecting authority had declared the drugs unfit for consumption after a lapse of 3 to 14 months from the date of sending the samples. Out of the 34 medicines declared unfit, the entire stock of 17 medicines was issued to the indentors by the time test reports were received. Even after the receipt of test report declaring the medicines unfit, eight medicines were issued to the indentors.
- (iii) AFMSD Mumbai had maintained no record of samples sent for post lab test until 07 March 2010. Subsequent to this date the depot sent 78 samples up to 25 May 2011. Out of these, 14 test reports declaring the items fit for consumption were received after a delay of one to three months from the date of sending of the samples. In respect of 64 samples, test reports were awaited as of August 2011.

The high rate of rejection (as high as 31 *per cent*) combined with widespread absence of post lab tests and inadequacy of facilities in DGQA's organisation indicated that the quality risks of locally procured medicines might be much higher. Under the prevailing arrangements, bulk of the procurements made by the hospitals is only visually inspected by the Board and as such there is no assurance to their quality.

#### **Recommendation No 12**

Immediate and effective steps are required to make the quality assurance system in AFMS more robust both for pre despatch inspection and post lab tests of drugs and consumables.