Chapter-II

Performance Audit

HEALTH AND FAMILY WELFARE DEPARTMENT

2.1 Information Technology Audit of e-Aushadhi

With a view to strengthening and streamlining the supply chain management system for storage and distribution of drugs and consumables in the State of Punjab and to eliminate the prevailing manual system of processes followed in the hospitals where the chances of human errors are significant, a customized Drugs and Vaccine Distribution Management System (DVDMS) named 'e-Aushadhi' was implemented (August 2014) in Health and Family Welfare Department (Department). An information technology audit of the 'e-Aushadhi' brought out shortcomings/deficiencies in its implementation that undermined the achievement of its objectives in the State. Some of the significant audit findings are summarised below:

Highlights

- **The Department had not prepared any time-bound roll-out plan for implementation of e-Aushadhi system for 360 health institutions still to be covered.**

  (Paragraph 2.1.6.1)

- **In the absence of a barcode system, users were not entering the data on real time basis resulting in critical data input errors.**

  (Paragraph 2.1.7.2 (ii & iii))

- **As many as 4,405 delivery challans were freezed after a delay of up to 531 days. In 1,424 instances, the drugs/consumables were accepted with shorter shelf-life by three Drug Warehouses. The users while verifying the supplies of drugs/consumables ignored the system alert with regard to shorter shelf-life in these cases.**

  (Paragraph 2.1.7.3 (i)(a) & (ii))

- **1,324 samples of drugs/consumables were sent for quality check to Central Quality Control Cell (CQCC) after a delay of up to 412 days.**

  (Paragraph 2.1.7.4 (iii))

- **Test reports of samples of drugs/consumables were received after a delay of up to 315 days (387 batches) from Government laboratory and up to 51 days (686 batches) from empanelled laboratories. Activation of drugs not of standard quality (NOSQ) and their distribution showed that the system was not robust and lack of internal control diluted the quality assurance for testing of drugs/consumables.**

  (Paragraph 2.1.7.5 (ii & iv to vii))

- **Inadequate logical access controls, application standards, audit trails and non-conducting of internal audit showed weak information system security of e-Aushadhi.**

(Paragraph 2.1.8)

2.1.1 Introduction

The Department of Health and Family Welfare, Punjab is providing preventive, promotive and curative healthcare through a network of various District Hospitals (DH), Sub Division Hospitals (SDH), Community Health Centres (CHC), Primary Health Centres (PHC) and Sub-Centres (SC). The State Government provides free generic medicines to all health institutions. In order to strengthen and streamline the supply chain management system for storage and distribution of drugs and consumables in the State of Punjab, a Memorandum of Understanding (MoU) was signed (July 2013) between the Punjab Health Systems Corporation[1] (PHSC) and Centre for Development of Advanced Computing (CDAC)[2], Noida for implementation of a customized Drugs and Vaccine Distribution Management System[3] (DVDMS) named 'e-Aushadhi'. The system was rolled out in August 2014.

e-Aushadhi is a web based Supply Chain Management system which deals with purchase, inventory management and distribution of various drugs and consumables to the health institutions of the State. Initially, the application (DVDMS) was in Oracle, but later on, it was converted to PostGRES (Open Source). The application was developed using programming language Java, with front-end as Red Hat JBoss 6.1 and Database in PostGRES 9.1 (EDB). It was hosted at CDAC, Noida and had five modules *viz.*-

- **Inventory Management**: It is the entry point for all the modules operated by Drug Warehouse (DWH) and all the health institutions. It includes sub-modules for raising demands, issuing stock, receiving stock, acknowledging of stock, issue to patient, challan process, receiving from third party and acknowledgement of stock transferred;

- **Order Management**: It is used for generation of Purchase order, replacement order and condemnation register and is operated by PHSC;

- **Supplier Interface Desk**: The suppliers enter the details of the stock dispatched;

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1 The Punjab Health Systems Corporation was enacted through a special Act of Legislation to provide for the constitution of a Corporation for establishing, expanding, improving and administering medical care in the State of Punjab.

2 CDAC is the premier Research and Development (R&D) organization of the Ministry of Electronics & Information Technology (MeitY), Government of India for carrying out R&D in IT, Electronics and associated areas.

3 Already implemented in States of Rajasthan and Maharashtra.

- **Quality Control Desk**: The module is used for sending samples of drugs/consumables from DWHs to Central Quality Control Cell (CQCC) by DWH, allotting samples to Government/empanelled laboratories and entering laboratory results by CQCC; and

- **Financial Management**: All details related to payment such as material receipt report validation, passing of supplier bills, etc. are done in this module by PHSC.

The objectives of the e-Aushadhi application were to:

- streamline the purchase, supply and distribution of the drugs in the State in optimized and efficient manner;

- enhance the usage of technology as a cost-effective solution to support the Drug Warehouse administration;

- support the operational and strategic information needs of the drug stores; and

- provide an infrastructure for sharing of information throughout the State.

Chart 2.1: Work flow diagram of e-Aushadhi system

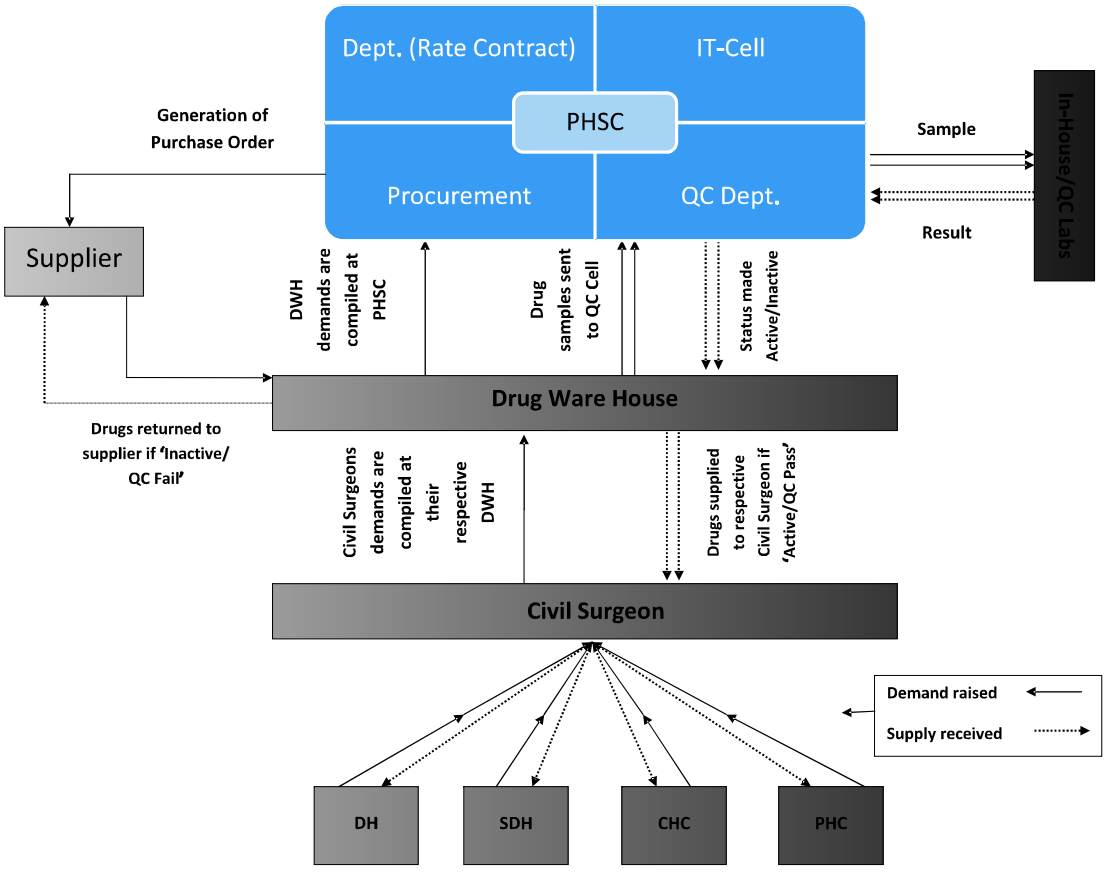
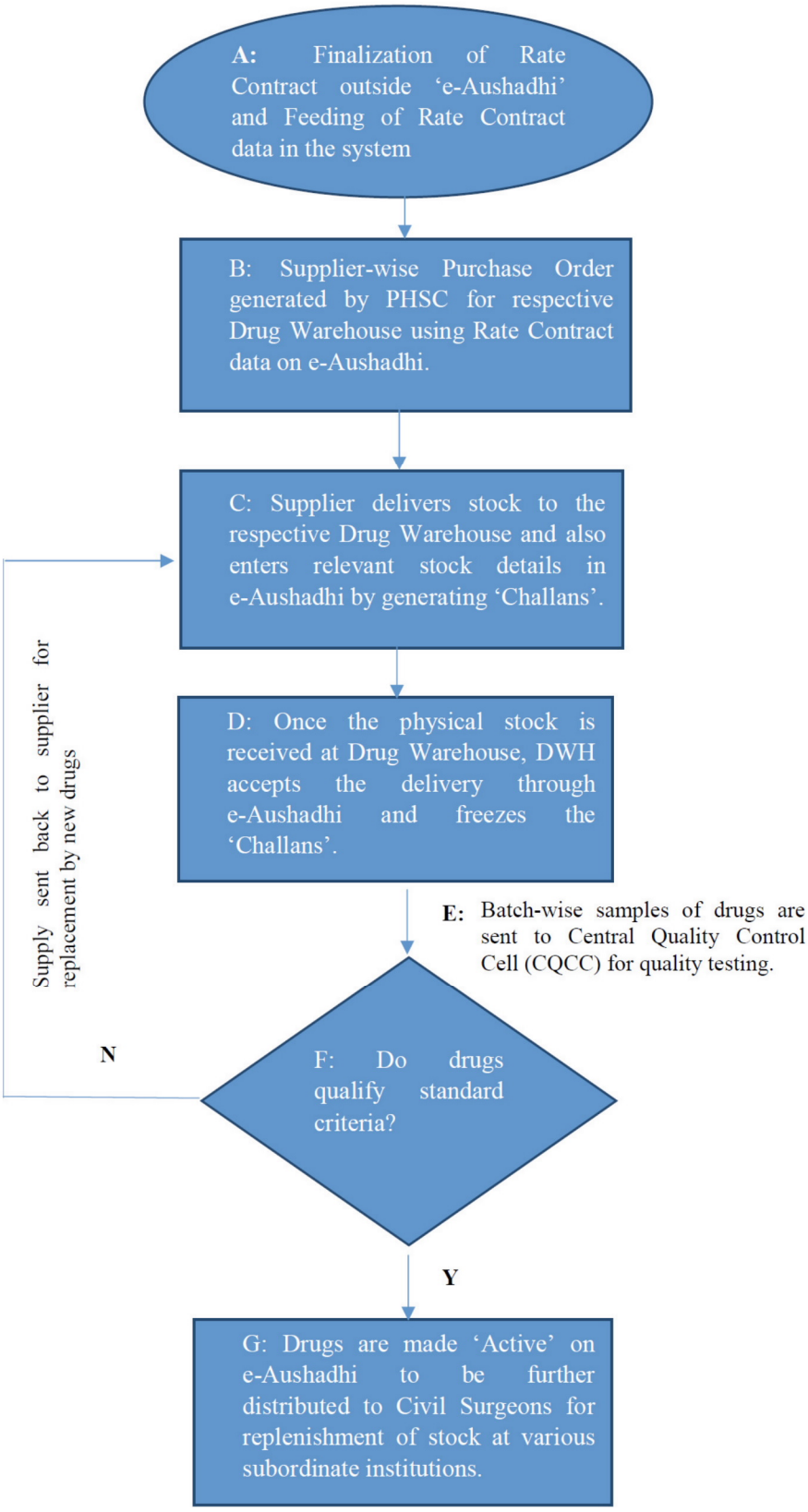


Chart 2.2: Process flow diagram of e-Aushadhi system



2.1.2 Organisational set-up

The Additional Chief Secretary, Department of Health and Family Welfare (DH&FW) is the administrative head and the Director, Health and Family Welfare is the departmental head for providing quality health services to public. The PHSC was declared (September 2013) a nodal agency (Implementing Agency) to do all kinds of procurement activities including rate contract of drugs/consumables, other purchases, etc., placement of purchase orders, receipt of supplies, testing of drugs, online management of inventory through IT based Drug Inventory Management System (e-Aushadhi).

2.1.3 Audit objectives

The audit objectives were to ascertain whether:

- planning and implementation of e-Aushadhi system was effective;
- input, processing and output controls were adequate to ensure integrity of the system and it complied with the rules and procedures; and
- reliable controls were in place to ensure security of information system.

2.1.4 Audit scope and methodology

The e-Aushadhi application was implemented in 103 institutions[4] in first phase. Though the application was rolled out in August 2014, it came into operation in March 2015. The Information Technology (IT) Audit covered the period 2015-18 and was conducted between January and August 2018 by test-check of records of PHSC, seven[5] out of 22 District Hospitals (DH), three[6] Regional Drug Warehouses (DWH) and Central Quality Control Cell (CQCC) at Kharar. The data analysis was done with the help of an analytical tool 'Interactive Data Extraction and Analysis' (IDEA).

An entry conference was held with the Principal Secretary, Health and Family Welfare Department in February 2018 wherein the audit objectives, scope & methodology and audit criteria were discussed. The findings of the information technology audit were discussed with the Additional Chief Secretary (ACS), Department of Health and Family Welfare in the exit conference held in January 2019. The replies furnished by the Government/Department in the exit conference and subsequently received in February 2019 have been suitably incorporated in the report.

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[4] Drug Warehouse (3); District Hospitals (22); Sub Divisional Hospitals (41); Community Health Centres (36); and Primary Health Centres (1).

[5] (i) Amritsar; (ii) Gurdaspur; (iii) Hoshiarpur; (iv) Jalandhar; (v) Patiala; (vi) Sangrur; and (vii) Sri Muktsar Sahib, by adopting Probability Proportional to Size Without Replacement (PPSWOR) method, taking expenditure incurred on procurement of drugs and consumables as the size measure.

[6] (i) Bathinda; (ii) Kharar; and (iii) Verka.

2.1.5 Audit criteria

The audit criteria were derived from the following sources:

- Memorandum of Understanding between PHSC and CDAC;
- e-Aushadhi User Manual;
- e-SAFE guidelines issued by Department of IT, GoI and generally accepted good IT practices; and
- Drugs & Cosmetics Act, 1940, Drug Policy of the State Government (2012-13), Rate Contracts, other instructions issued by Department of Health and Family Welfare, Punjab.

Audit findings

2.1.6 Planning and management

2.1.6.1 No milestones set for roll out

There are 485[7] health institutions in the State. In the first phase, the implementing agency (IA) decided (October 2014) to implement e-Aushadhi in 100 (out of 485) institutions and three[8] Regional Drug Warehouses[9] (DWH). The application was implemented in these institutions up to March 2015 but no timelines were fixed for rolling out the system in the remaining health institutions.

Out of 100 health institutions, 80 were using the system, one[10] was not generating indents through the system and 19 were generating indents through the system but were not issuing the items in stock to different hospital wards through the system. Further, out of five modules of e-Aushadhi, one sub-module 'Issue to patient'[11] (end user) under the main module 'Inventory Management' was not functional in any of the health institutions as of March 2018.

In August 2017, it was decided that supply of medicines and consumables to DHs, SDHs, CHCs and PHCs of a district would be routed through the Civil Surgeon. Hence, it was crucial to ensure adequate storage capacity of stores operated by Civil Surgeons. However, this was not done as a result of which orders were revised (October 2017) allowing Senior Medical Officers of DHs, Ludhiana and four out of the sampled district hospitals (Amritsar, Hoshiarpur, Jalandhar and Mata Kaushalya Hospital, Patiala) to draw their medicines directly from respective DWHs. Due to this, 273 out of 3,501 stock items were issued manually to these DHs by the respective Civil Surgeons of four test-checked districts during the period from September 2017 to February 2018.

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7 District Hospitals (22); Sub Divisional Hospitals (42); Community Health Centres (157); Primary Health Centres (239), Civil Surgeons (22) and Medical Colleges (03).

8 (i) Bathinda (covering eight districts); (ii) Kharar (covering six districts); (iii) Verka (covering eight districts).

9 A centralized store for receipt, storage and distribution of drugs/consumables to various health institutions.

10 CHC Khemkaran.

11 Drugs prescribed by the doctor of the institute are issued to the patient through this sub-module.

The Department stated (July 2019) that 22 Civil Surgeons and three medical colleges had been covered under e-Aushadhi system and attributed the reasons for not rolling out the system in the remaining (360) health institutions throughout the State to shortage of manpower.

2.1.6.2 Project cost

The work of implementation of e-Aushadhi was assigned (July 2013) to CDAC at a cost of ` 3.29 crore[12] to be completed in four stages within one and half years from the date of signing of MoU (15 July 2013) though it was valid up to July 2015.

It was observed that all stages of the project were completed by April 2016 although the MoU had expired in July 2015. However, CDAC continued to handle the project as of March 2018, on the basis of extensions given by IA for executing various activities, thereby enhancing the project cost to ` 5.04 crore (excluding taxes), of which an amount of ` 3.99 crore had been paid to CDAC as of March 2018. Further, out of the enhanced project cost of ` 1.75 crore (` 5.04 crore *less* ` 3.29 crore), an amount of ` 1.13 crore could have been avoided as detailed below:

(i) As per MoU, the data hosting charges and software support charges for e-Aushadhi application were fixed at ` 0.15 crore (excluding taxes) for a period of 18 months and 12 months respectively from the date of signing off User Acceptance Testing (UAT). In case of hosting beyond the said period, the cost of hosting and software support was to be charged with 15 *per cent* increase on yearly basis.

UAT of e-Aushadhi system was signed off on 24 July 2014 and the application was made functional on 1 August 2014. However, extensions were given to CDAC for data hosting and software support till March 2018 for which additional expenditure amounting to ` 0.79 crore[13] was incurred. IA did not take cognizance of taking over these activities, as no action was taken even after State Data Center (SDC)[14] being managed by the Department of Governance Reforms, Punjab was made operational with effect from October 2017. SDC was hosting several IT applications implemented in the State, free of cost. **The total avoidable expenditure on account of data hosting charges (` 0.07 crore) and software support charges (` 0.11 crore) worked out to ` 0.18 crore for the period from October 2017 to March 2018.**

(ii) IT Cell is responsible for assisting in data entry tasks related to generation of MIS reports and purchase orders, monitoring information flow in the system right from generation of indents to supply of drugs and consumables to the various health institutions. As per MoU, the IT Cell would be managed by CDAC for 17 months from the date of initiation of service i.e.

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[12] Includes charges of ` 0.88 crore for Open Source Conversion of the application as per addendum to MoU (March 2014); project management cost of ` 0.13 crore; and cost of ` 0.17 crore in respect of third party softwares for the purpose.

[13] ` 0.27 crore for Data hosting and ` 0.52 crore for software support.

[14] The main purpose of SDC is to provide a physical facility for hosting various State level e-Government applications.

from 18.02.2014 to 15.07.2015 at a fixed cost of ` 0.43 crore. Thereafter, extension was given for 12 months from 17.07.2015 at a cost of ` 0.35 crore[15] per annum. As per MoU, requisite trainings were imparted to staff for the e-Aushadhi system at a cost of ` 0.15 crore[16]. However, the Department failed to develop in-house expertise for operating the IT Cell and IA kept giving (August 2017) extensions to IT Cell service till July 2018. **Thus, the total cost of project on account of IT Cell service worked out to ` 0.95 crore[17] for the period from 17.07.2015 to 31.03.2018.**

The Department attributed (February 2019) the reasons for providing extensions to above elements of the project to the system being in implementation stage and stated that customizations were being made in the application as per the requirements of IA and field staff. The reply of the Department was not in line with the project plan and deliverables of MoU.

2.1.7 Audit findings according to Process Flow covering application controls

2.1.7.1 Next step (B) is supplier-wise generation of Purchase Order by PHSC for concerned Drug Warehouse using Rate Contract data. Findings related to this are discussed below:

Drugs were not classified as Fast, Medium and Slow moving in the database in order to have better monitoring of consumption pattern of drugs/consumables. Besides, re-order levels in respect of quantity of drugs/consumables had not been defined in the system for generating alerts for issuing of purchase orders for stock replenishment. The IA stated (February 2019) that the MIS report was available in the dashboard.

The relevant provisions should have been mapped in the database for ensuring automatic triggers and minimizing human intervention.

2.1.7.2 Next step (C) is that supplier enters relevant stock details in the system using Supplier Interface Desk module against the Purchase Order by generating challans and delivers stock to the respective Drug Warehouse accordingly. Findings related to this are discussed below:

(i) In 3,358 out of 6,158 records, delivery challan date was greater than the delivery date. But the system did not restrict this discrepancy.

(ii) There were 952 out of 13,322 records in the system with same batch numbers but different expiry/manufacturing dates. Batch numbers in 68[18] cases were modified even after verification and freezing of delivery challans. This discrepancy could lead to depiction of expired drugs/consumables in the system, as discussed in paragraph 2.1.7.6 (vii). The Department stated (February 2019) that batch numbers were modified due to errors committed by the suppliers while entering the stock details in the system. **Thus, in-built validation checks were not available in the system which resulted in data**

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15 Calculated on pro-rata basis.
16 As of January 2017, payment of ` 0.02 crore had been made.
17 ` 35.16 lakh per annum x 32 months and 15 days.
18 DWHs, Bathinda (26); Kharar (12) and Verka (30).

input errors. No unique identifier has been allotted to the batch of drugs for traceability of modified records. It was further noticed that IA had decided (April 2016) to introduce barcode[19] system in order to verify/capture details of supply on receipt from suppliers in the system for which nine bar code readers were also purchased. **Despite data input errors, the barcode system was not implemented as of March 2018.**

(iii) **System was allowing null entries for some crucial fields like manufacturing date, expiry date, quantity of samples issued to CQCC.** As many as 935 records were entered in the system with null manufacturing date. Further, in 969 records, null entries or dummy expiry date (01/01/2000) were found in the transaction tables used for issuing the stock items. The Department stated (February 2019) that the system did not allow null entries and identified records were entered for training purpose. The reply was not acceptable as all these identified cases were flagged as valid records in the system.

(iv) Units for quoting the rates are not uniform as in some cases it is quoted as 10 for tablets/capsules, in other case it is quoted as 10x10 for tablets/capsules and for an injection it is quoted as an ampoule. Therefore, in the system, a unique ID has been assigned for each unit. However, in five test-checked cases, these IDs were mapped improperly, as 'No.' unit instead of '10x10 tablet/capsule strip' were assigned to the i tems. **Thus, incorrect rates were mapped in the system as a result of which wrong valuation of drugs/consumables was being reflected in the output results.** The Department stated (February 2019) to have rectified the discrepancy after being pointed out (July 2018) by Audit.

2.1.7.3 Next step (D) is that Drug Warehouse accepts the delivery through the system and freezes the challans. Findings related to this are discussed below:

(i) Freezing of stock

The drugs and consumables procured centrally by PHSC are received directly in respective DWHs. As per Drug Policy (2012-13) and e-Aushadhi User Manual, the respective DWHs are required to acknowledge and freeze supply challans after verification of NABL[20] reports which are uploaded in the system by the respective suppliers in respect of each batch of drugs. Freezing is the process for validating and adding the stock in the inventory of the receiving store prior to quality check. The DWH after freezing the fresh stock of items provides the details to Central Quality Control Cell (CQCC), which after analyzing the details, collects drug samples through Drug Inspectors for onward transfer to Government/empanelled laboratories for testing. The testing laboratories are to provide sample reports within 10 or 21 days[21] depending upon the testing period of sample prescribed for various categories of drugs and consumables. The test reports are received in CQCC for further

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19 A barcode is a visual, machine-readable representation of data; the data describes something about the object that carries the barcode

20 National Accreditation Board for Testing and Calibration Laboratories.

21 Time limit of reporting in respect of Government laboratories was not available.

process. The supplies are deemed to be completed only after receipt of quality certificates from the laboratories and till then the drugs are kept in "Quarantine" status (Not to be issued).

Freezing is the first stage of supply chain and any delay in freezing the stock will have a spill over effect on other stages of supply chain management. To ensure no delay in freezing, there should be a window in which DWH is required to complete the process within a reasonable timeframe. This will also ensure that the items supplied without necessary attachments like NABL report, invoice etc. are returned to the suppliers. Similarly, there should also be a window to complete the process of sending samples to CQCC for quality check within a reasonable timeframe. **The Department did not define any timelines for streamlining these processes.**

Analysis of e-Aushadhi database revealed that:

(a) In 4,405[22] out of 6,914 instances, for the period from April 2015 to March 2018, delivery challans were freezed after delays ranging from 3 to 531 days. Of these, in 4,139 cases (94 *per cent* of total cases of delay), the delay was in the range of 3 to 50 days. **Delay in freezing of challans results in reducing the shelf-life of drugs besides increasing the warehousing costs.** The delay in freezing of challans during 2015-16 and 2016-17 was mainly attributed to non-receipt of NABL reports. The Department stated (February 2019) that instructions had been given to all the suppliers to upload NABL reports at the time of entering the bills in the system. However, **the system has no provision to restrict acceptance of stock without NABL report.**

(b) NABL reports in 174 cases (DWHs, Bathinda: 54; Kharar: 67; and Verka: 53) were not uploaded by the suppliers in the system during August 2016[23]-March 2018 though the challans were acknowledged. Of these, 84 challans were freezed. **The system did not restrict freezing of challans in cases where NABL reports were not uploaded.** The Department stated (February 2019) that requisite instructions in this regard had been issued to the suppliers and DWHs.

The system should not allow suppliers to submit stock details without uploading NABL reports. However, under exigent circumstances, the supplier may be allowed to submit the stock details without NABL reports, samples of which in turn could be sent to CQCC for quality testing. But, there should be a provision in the system for raising red flags to the concerned head of organisation for all such cases.

(ii) Shelf-life of drugs

As per drug policy (2012-13) of the State Government and terms and conditions of rate contracts, the material supplied should have five-sixth ($5/6^{th}$) shelf-life remaining at the time of delivery. Analysis of data, however, revealed that in 1,424 out of 13,322 instances, the drugs/consumables were accepted with shorter shelf-life by DWHs Bathinda (461) ranging between

[22] DWHs Bathinda: 1,343 (3 to 304 days); Kharar: 1,625 (3 to 531 days); and Verka: 1,437 (3 to 430 days).

[23] Supplier interface was introduced in August 2016.

37 to 83 *per cent*, Kharar (406) ranging between 18 to 83 *per cent* and Verka (557) ranging between 20 to 83 *per cent* at the time of delivery during 2015-18. Out of these, six[24] drugs got expired at three DWHs. **Though the system had the in-built feature for giving alerts regarding shorter shelf-life of drugs/consumables, it provided users the option to accept drugs with lesser shelf-life. This was an undue advantage to suppliers as they could supply drugs with lesser shelf-life by contravening terms and conditions of the rate contracts.**

2.1.7.4 Next step (E) is that batch-wise samples of drugs are sent to Central Quality Control Cell (CQCC) for quality testing. Findings related to this are discussed below:

Drawal of samples from DWHs for quality check

Prior to August 2017, samples from common batches of drugs received at the DWHs were being drawn for quality check randomly from only one DWH. Protocol for testing of medicines and consumables was changed in August 2017 which prescribed that samples from all batches would need to be drawn from all DWHs by the district level committee headed by the Deputy Medical Commissioner and sent to CQCC. It was further emphasized that the selection of empanelled laboratory should be done on random basis.

(i) **In 463[25] out of 6,049 cases, samples were issued by three DWHs in advance i.e. prior to freezing of challans, but there was no validation check in the system to restrict this.** In absence of this check, there is a possibility that a particular stock item for which the above sample was issued in advance could be rejected/returned on the basis of any shortcoming like non-availability of NABL report, shortfall in quantity received, and so on.

(ii) It was noticed that Form 17 (an intimation to a person from whom sample is taken), which is required to be used by Drug Regulatory Authorities while drawing samples as mandated under Section 23 of Drugs & Cosmetics Act, was not being generated through the system in respect of Government laboratories and intimation regarding sample collection in respect of empanelled laboratories was being sent by the DWHs to CQCC through e-mail.

(iii) As many as 1,324 out of 6,049 samples of drugs were sent to CQCC by three DWHs[26], during the period from April 2015 to March 2018 after a delay of up to 412 days. Of these, in 1,220 cases (92 *per cent* of total cases of delay), the delay was in the range of 4 to 50 days.

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[24] DWHs (i) Bathinda: Two (Clotrimazole Vaginal Pessaries 100 mg with Applicator (Batch No.VZ-254), Diclofenac Sodium Tab 50 mg (Batch No.DRP-801)); (ii) Kharar: Three (Pentazocine Lactate Injection 30mg/ml (Batch No.PZ1522), Anti D-Immunoglobulin Inj 300 mg (Batch No.A10016001), Gentamycin Inj. 80 mg (Batch No.I-3917)); and (iii) Verka: One (PVC Ryles tube silicon sterilized disposable X-ray opaque line FG 14 (Batch No.DRT005)).

[25] DWHs Bathinda: 117; Kharar: 231; and Verka: 115.

[26] DWHs Bathinda: 419 (4 to 322 days); Kharar: 248 (4 to 158 days), Verka: 657 (4 to 412 days). Samples in respect of common batches were being collected from one DWH and testing of some of the items *viz.* chlorine pallets, disposal chest electrodes, urine container, etc. was not required.

The Department attributed (February 2019) the delay in sample collection to shortage of staff and assured that such delays would be curtailed during the course of time.

(iv) Analysis of data in respect of three DWHs revealed that samples of 539[27] out of 1,848[28] batches of items i.e. drugs/consumables were not drawn from the respective DWHs for quality check during the period from August 2017 to March 2018.

The CQCC stated (May 2018) that there was no MIS report available in the system to identify batches of items pending for testing from respective DWHs.

2.1.7.5 Next step (F) is that CQCC sends samples to the empanelled/Government laboratories for testing and enters the result of laboratory report in system. Standard quality drugs are made 'Active' for distribution and drugs those are not of standard quality (NOSQ) are made 'Inactive' and the respecti ve stock of those drugs is returned to supplier by the respective Drug Warehouse for replacement. Findings related to this are discussed below:

Delay in quality check of drug samples and issue of sub-standard drugs

The supplies of drugs/consumables are deemed to be completed only after receipt of quality certificates from the laboratories and till then the drugs/consumables are kept in "Quarantine" status (Not to be issued). The quality certificates/reports are to be uploaded by the laboratories in the system. If the drugs/consumables pass the laboratory test, the CQCC updates the status thereof in the system as "Active". Where the drugs /consumables fail the laboratory test, the status is updated as "Rejected". Active status drugs/consumables are ready for issue while rejected drugs/consumables are returned to the suppliers. **There was no provision in the system for uploading the reports. The test reports were being sent to CQCC through e-mails and the relevant entries were captured manually in the system on their receipt.**

(i) **No provision was made in the system for random selection of empanelled laboratory and it was being done manually by CQCC.** Besides, list of empanelled laboratories was not updated as it was displaying names of those laboratories which were no longer empanelled.

(ii) During 2015-18, out of 5,894 batches of drugs/consumables, test reports of 387 samples were received with delay of up to 315 days[29] from Government laboratory[30]. Of these, in 85 *per cent* of cases, the reports were received with delays of up to 50 days and in 10 *per cent* cases, the reports were received with delay ranging from 51 to 101 days. Test reports for

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27 DWHs Bathinda (167); Kharar (193); and Verka (179).

28 DWHs Bathinda (543); Kharar (646); and Verka (659).

29 Delay has been calculated taking a benchmark of 30 days for reporting by Government laboratories, as per the guidelines issued by Ministry of Health and Family Welfare, GoI.

30 There is only one Drug Testing Government laboratory situated at Kharar in the State.

686 batches (out of total 691 cases of delay) of drugs/consumables were received with a delay of up to 51 days from empanelled laboratories[31].

(iii) Penalty is leviable on the empanelled laboratories by PHSC at prescribed rates for different periods of delay. Master data related to testing fee for different drugs was not available in the system, in the absence of which penalty charges on account of delay in submission of reports were not being computed by the system. CQCC was computing the period of delay manually.

Thus, delay in streamlining the process for supply of drugs diluted the objective of distribution of the drugs in the State in optimized and efficient manner.

Analysis of database and test-check of manual records such as drug sample test reports, drug sample collection records in CQCC and three DWHs at Bathinda, Kharar and Verka revealed the following:

(iv) In six[32] cases checked randomly, **drugs declared as 'Not of Standard Quality' (NOSQ) as per the laboratory report were found activated in the system and these drugs were also issued (February 2015-March 2018) to the health institutions**.

The sample of Cetrizine Syrup IP (Batch No. 06036-BPB5) taken (April 2016) from DWH, Kharar was declared (May 2016) of standard quality by an empanelled laboratory. Subsequently, on repeat-testing the same batch of medicine after taking sample from DWH, Kharar, the Government laboratory declared (27 December 2016) the medicine as NOSQ. Similarly, sample of Lactulose 3.335 gm/5ml syrup (Batch No. STL-16468) drawn (April 2017) by Drug Inspector, Central Drugs Standard Control Organization, GoI under the provisions of Drugs and Cosmetics Act, 1940, was declared as NOSQ on 18 July 2017. However, DWH Kharar continued to issue these medicines even after they were declared as NOSQ, as no action had been taken by CQCC to change the status to 'inactive" in e-Aushadhi sy stem. Resultantly, 7,400 units of Cetrizine Syrup IP (Batch No. 06036-BPB5) and 1,200 units of Lactulose 3.335 gm/5ml syrup (Batch No. STL-16468) had been issued by DWH, Kharar to various Government hospitals during May 2017 and August-November 2017 respectively. It was further noticed that the data related to re-testing of batches of items had not been entered in the system. **Thus, non-availability of drug sample test reports in the system resulted in activation of NOSQ declared drugs.**

The ACS while assuring to look into the matter stated (January 2019) that responsibility in this case would be fixed.

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[31] There were five testing laboratories as of March 2018 namely (i) Devansh Testing & Research Laboratory; (ii) Ozone Pharmaceuticals Ltd.; (iii) Standard Analytical Lab; (iv) Delhi Test House; and (v) Sophisticated Industrial Materials Analytic Labs Pvt. Ltd.

[32] (i) Isoxsuprine HCL Injection (Batch No.1412017); (ii) Phenytoin Sodium Injection (Batch No.BIO16702); (iii) Calcium (Vitamin D-3) 250 IU tablets (Batch No.OC-623); (iv) Cetrizine Syrup IP (Batch No. 06036-BPB5); (v) Lactulose 3.335 gm/5ml syrup (Batch No. STL-16468); and (vi) Amoxicillin and Potassium Clavulanate tablet (Batch No. YAP52135).

(v) As many as 2,02,454 number of tablets/injections of six[33] test-checked drugs were issued to various health institutions prior to receipt of quality test reports from respective laboratories, of which thre [34] drugs were declared as NOSQ. **The system should debar issuance of drugs without uploading of quality test reports.**

Audit noticed in the test-checked districts that out of 1,80,689 Oxytocin injections issued to various health centres before receipt of its quality test report (NOSQ) from laboratory, 60,197 injections had been consumed.

The Department stated (January 2019) that due to urgent requirement, medicines were issued on the basis of test report submitted by the manufacturer. However, on receipt of test report from the laboratory declaring the medicines as sub-standard, the distribution of medicines was stopped.

Since, the system design should have restricted the issue of drugs which were marked as 'Quarantine" or 'Inactive", drugs is sued prior to receipt of reports indicate failure of validation checks in the system.

(vi) In seven[35] test-checked cases, no record related to quality tests were available with the CQCC though these drugs were found activated in the system.

The CQCC stated (May 2018) that neither the samples of some of the drugs were received nor were activated by them, and a few were activated inadvertently and the IT Cell had been requested to deactivate the same. The reply of CQCC should be seen in the light of the fact that as per protocol, the status of drugs could be defined by CQCC only. This showed that **the system lacked robust checks for limiting privileges of actions to authorized users. Besides, the System was not capturing unique IP address for an individual user system in the user logs for traceability**, as discussed in paragraph 2.1.8.5. Database and application logs were not provided to Audit for further analysis.

For ensuring lack of bias in testing drugs and consumables, it is recommended that confidentiality be maintained regarding details of empanelled laboratories to which samples are sent for quality check. Similarly, details of suppliers should not be disclosed to the laboratories while sending samples. Further, it may be a good practice to have reports of empanelled laboratories cross validated by other accredited laboratories occasionally for having higher degree of quality assurance.

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[33] (i) Ceftriaxone & Sulbactum Injection 5gm (Batch No. 315-45) quantity: 2,400; (ii) Phenytoin Sodium Injection (Batch No. BIO16702) quantity: 1,050; (iii) Calcium (Vitamin D-3) 250 IU tablets (Batch No. OC-623) quantity: 11,250; (iv) Ringer Lactate injection (Batch No. P16F096) quantity: 5,065; (v) Amlodipine tablet (Batch No. STN-170405) quantity: 2,000; and (vi) Oxytocin injection (Batch No. P6A058) quantity: 1,80,689.

[34] (i) Oxytocin injection (Batch No. P6A058); (ii) Phenytoin Sodium Injection (Batch No. BIO16702); and (iii) Calcium (Vitamin D-3) 250 IU tablets (Batch No. OC-623).

[35] (i) Trifluperazine 5 mg tablet (Batch No. HT150221); POP Bandage-4 Batch Nos. (ii) 7091; (iii) 7649; (iv) 7650; (v) 7651; (vi) Paracetamol injection 150 mg/ml (Batch No. PLI2510); and (vii) Amlodipine tablet 5 mg (Batch No. MNT-152913).

(vii) The DWH, Bathinda had received 1.97 lakh Calcium+ Vitamin D3 tablets (Batch No. OC-619) on 20 January 2017. However, test report of the sample received (16 May 2017) from Government laboratory declared this medicine 'not of standard quality' (NOSQ), as the c ontents of Vitamin D3 was found to be Zero I.U/UC [36] against the labelled claim of 250 I.U/UC. Subsequently, on repeat-testing of the sample of same batch taken (October 2017) from the same DWH, the medicine (Calcium+ Vitamin D3) was declared (8 December 2017) of standard quality by Government laboratory, without considering/analysing the contents of Vitamin D3. Audit noticed that the whole quantity (1.97 lakh tablets) had been issued (22 February-5 March 2018) to CSs of four [37] districts for onward supply to hospitals under their jurisdiction.

The DWH, Bathinda stated (August 2018) that the medicine was issued only after the same was made active by CQCC in e-Aushadhi system for issue to Government hospitals. On being enquired from CQCC, it was stated (August 2018) that they had not received any adverse test report of the medicine, instead a report issued by Government Analyst declaring the medicine of standard quality was received in CQCC and accordingly the medicine was made active in the system. The Director, Food and Drug Laboratory [38], Punjab stated (October 2018) that the concerned parameter (Vitamin D3) was not considered in the report (8 December 2017) due to technical error and software problem arising at that time. There was no provision in the Drugs and Cosmetics Act, 1940 for retesting the same sample of medicine once declared NOSQ by the same laboratory. However, reasons/ circumstances under which the same batch of medicine from same place was got re-tested were not provided to Audit. The ACS while assuring to look into the matter stated (January 2019) that responsibility in this case would be fixed.

The system should not allow re-testing of a drug declared as NOSQ. This showed that the system was not robust and lack of internal control diluted the quality assurance for testing of drugs/consumables.

2.1.7.6 Next step (G) is that Drugs made 'Active' a re distributed to Civil Surgeons for replenishment of stock at various institutions. Findings related to this are discussed below:

Inadequacies in transactions relating to issue of drugs

As per instructions issued by IA from time to time (October 2014-October 2017), all 100 health institutions and three DWHs were to use online system for receipt and issue of drugs/consumables to the end user.

Analysis of data and test-check of manual records revealed that the system was not used by DH, Gurdaspur for a period of eight [39] months,

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[36] International Unit/Unit conversion.

[37] (i) Barnala (16,640); (ii) Bathinda (90,000); (iii) Faridkot (40,000); and (iv) Moga (50,000).

[38] Government Laboratory.

[39] July 2017 to February 2018.

DH Hoshiarpur for six[40] months and DH Sangrur for more than one and a half years[41]. It was further noticed that:

(i) Medicines can be issued from one health institution to another by generating a drug transfer order on the system. If any item is in short supply in any health institution, then a drug transfer order can be created for the hospital store having excess quantity of the item. It was, however, noticed that this process was obviated and 170 items of drugs/consumables were received manually by the selected DHs[42] from CHCs/PHCs and were not recorded in the system afterwards. Further, 239 items of drugs/consumables were received by the selected DHs[43] from respective DWHs without raising any demand. Thus, detail of indenters and consumption of these drugs could not be traced through the system.

(ii) Stock details of 375 Hepatitis-C drugs received by the selected DHs were not entered in the system since procurement (May 2016) and these drugs were distributed manually by the respective DWHs and the Civil Surgeons during the period from June 2016 to February 2018. Test check of records at DH, Jalandhar revealed that two[44] of these drugs had expired. The online system for receipt and distribution of Hepatitis-C drugs was adopted from March 2018 onwards.

(iii) As many as 53 drugs/consumables with quantity ranging from 100 to 84,000 valuing ` 11.09 lakh though shown as issued on 31 August 2017 in the system were not found recorded as receipts in the stock register maintained in the OPD ward of the District hospital, Hoshiarpur. DH, Hoshiarpur did not give any reply.

(iv) The receiving store has to acknowledge receipt of items through 'Acknowledge' desk. After acknowledgement, the items are added in the receiving store and the same is deducted from the issuing store. However, in 129 out of 987 instances, return indents[45] were not acknowledged by DWHs, Bathinda (79), Kharar (34) and Verka (16) due to which veracity on the transfer of stock could not be ascertained.

(v) User creates an indent for receiving items from the issuing store i.e. DWH/Civil Surgeon/Sub-store. An indent can be for single drug/consumable or it can be a composite indent comprising more than one drug. In case of a composite indent, once the indent is generated, system clears the indent even if a single item is issued against the demand for multiple items. Thus, the

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40 February 2017 to May 2017 and September 2017 to October 2017.

41 April 2015, June 2015, January 2016, June 2016 to September 2016, November 2016 to April 2017, July 2017, August 2017 and October 2017 to January 2018.

42 DHs (i) Amritsar (0); (ii) Gurdaspur (7); (iii) Hoshiarpur (6); (iv) Jalandhar (18); (v) Patiala (14); (vi) Sri Muktsar Sahib (7); and (vii) Sangrur (118).

43 DHs (i) Amritsar (13); (ii) Gurdaspur (14); (iii) Hoshiarpur (53); (iv) Jalandhar (56); (v) Patiala (65); (vi) Sri Muktsar Sahib (21); and (vii) Sangrur (17).

44 Capsule Ribavirin-20 (Batch No.2HR4364 & 2HR4365); Tablet Ledipasvir 90 mg and Sofosbuvir 400 mg (Batch No.8052538).

45 Return request is initiated in case of excess stock or when issued stock is to be returned to DWH.

system does not give the correct status of pending indents. However, in case none of the item is issued, the indent remains as pending in the system.

Audit noticed that the system allowed generation of new indents for similar items for which earlier indents were pending. There was no provision in the system to clear the pending indents before generating new indents for similar items. Analysis of database and test-check of MIS reports revealed that as of March 2018, 183 indents [46] for 1,637 drugs, included repeat order for 385 drugs, in respect of seven test-checked DHs pertaining to the period April 2015 to February 2018 were pending for issue in the system. **System should not allow creation of repeat orders for those drugs where previous orders for the similar drugs were pending.**

Analysis of data and e-Aushadhi application for the period 2015-18 revealed the following:

(vi) The system did not have the provision for issuing drugs on the basis of 'First Expiry First Out' (FEFO). In 24,164 out of 6,74,253 instances, FEFO method was not followed while issuing the drugs/consumables. Users who issue the stock were able to select any batch irrespective of the expiry date. **The system was neither enforcing issue of drugs in seriatim of expiry dates nor it was generating any alert to select drug nearing expiry.** The user had to verify the same from MIS report. The Department stated (February 2019) that when drugs were issued to sub-stores, FEFO pattern was followed. It was added that the requisite system alerts for identification of drugs nearing expiry would be incorporated in the system. The reply of the Department was not convincing, as in 6,060 out of 24,164 instances, the drugs were issued to sub-stores by DWHs where FEFO was not applied.

(vii) During analysis of database and MIS reports in respect of seven test-checked DHs and three DWHs, 1,006 [47] drugs/consumables were found expired during 2015-18. It was noticed that data related to 6,120 indents issued off-line (not in real time) were entered in the system after a delay of up to 947 days by using issue to sub-store off-line screen. In this delayed process, the system did not allow to enter those indents of drugs/consumables issued off-line which had already expired at the time of data entry at later stage.

The IA and DH, Amritsar stated (March and May 2018) that the institutes were not working online at that time and therefore the drugs were reflecting in their stock balances. All the drugs were consumed before expiry and system was showing them as expired because online posting of some transactions could not be completed. The fact, however, remains that **the system was not showing correct position of expired drugs thereby impairing effective inventory management through e-Aushadhi.**

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[46] (i) Amritsar (80); (ii) Gurdaspur (12); (iii) Hoshiarpur (18); (iv) Jalandhar (46); (v) Patiala (19); (vi) Sangrur (1); and (vii) Sri Muktsar Sahib (7).

[47] DHs (i) Amritsar (11); (ii) Gurdaspur (409); (iii) Hoshiarpur (139); (iv) Jalandhar (5); (v) Patiala (10); (vi) Sri Muktsar Sahib (45); (vii) Sangrur (296); DWHs (viii) Bathinda (70); (ix) Kharar (10); and (x) Verka (11).

The above inadequacies indicated that the procedure for recording of inter-unit transfers was not properly followed and there was no effective control over inventory management.

2.1.7.7 Other system discrepancies

(i) No dashboard reflecting daily activities was accessible to users at DWHs and DHs though the same was available with IA. The Department stated (February 2019) that MIS reports were available. In case any requirement related to dashboard occurred, it would then be provided to the users. The reply of the Department was not acceptable as it was the responsibility of IA to determine the requirements for making an interactive system.

(ii) Drug Brand Master table defines a unique ID for all the stock items i.e. drugs, consumables or sutures. However, it was found that multiple IDs were allotted to the same items[48].

(iii) 'Third party issue' module is used to issue items to institutions such as Zila Parishads, Jails etc. who have been assigned a unique ID for identification in the system. Analysis of data in respect of three DWHs revealed that multiple master record entries were made for the same institutions whereas in some of the records name of the institution was left blank. Test-check of MIS report with the master table records revealed 20 such records. Stock items valuing ` 86.90 crore[49] were issued using 'third party issue' module (offl ine) during 2015-18. Due to the above discrepancy, MIS report was not reflecting correct status of stock issued to the respective institutes.

(iv) **System should not allow 'Zero' quantity for sample while issuing the stock items to CQCC for quality testing.** Whereas, 'Zero' sample quantity was accepted by the system in six cases.

2.1.8 Information system security

2.1.8.1 Logical access controls

In any computerized system, data access is required to be restricted to authorized users only. Audit observed that the logical access controls available in the application were inadequate due to the following reasons:

 Single user ID allotted was shared by multiple users in three DWHs. In three test-checked DHs viz. Amritsar, Jalandhar and Patiala, the user ID of Senior Medical Officer was shared with Pharmacists for performing the functions of approval of transactions related to demand/issue of drugs/consumables. In the absence of individual user IDs, the transactions made in the system could not be traced to an individual.

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[48] (a) 'Dextrose 25%' and 'Dextrose I.V 25%'; (b) 'Dis posable syringe 10ml' and 'Syringe 10cc'; (c) 'IFA (Large)' and 'Iron and Folic Acid (Large)'; and (d) 'Povidone Oint 5%' and 'Povidine Ointment 5%'.

[49] DWHs, Bathinda (` 23.72 crore); Kharar (` 34.03 crore); and Verka (` 29.15 crore).

 Login access to first time users of a system is allowed using default passwords created by the system administrator. After this, as a best practice[50], the system should prompt the users to create new passwords. Further, users should not be allowed to reuse previously changed passwords. Analysis of data revealed that the passwords were not changed since allotment in respect of 47 users and 73 users reused previously used passwords. Further, 1,957 users were allotted common default passwords by the administrator. The Department stated (February 2019) that in spite of providing instructions, majority of the users were using default password.

Thus, in the absence of segregation of duties and weak access controls, the system was vulnerable to errors or manipulation.

2.1.8.2 Application standards

As a best practice, the e-SAFE GD210 guidelines[51] issued by Department of IT, GoI, refers that the application should display an approved system use notification message before granting access, informing the potential users. The system use notification message provides appropriate privacy and security notices and remains on the screen until the user logs on to the information system. The application notifies the user, upon successful login, of the date and time of the last login, and the number of unsuccessful login attempts since the last successful login. Interface of the web application, however, revealed that none of the provisions except for details of last login were incorporated.

2.1.8.3 IT Security Policy, Business Continuity Plan and Disaster Recovery Plan

IT Security policies, procedures, and their enforcement enables an organisation to protect its IT infrastructure from unauthorised users. IT security policy for an organisation lays out the requirements for the organisation and its employees to be followed in order to safeguard its critical assets. Further, the objective of having a Business Continuity and Disaster Recovery Plan and associated controls is to ensure that the organization can still accomplish its mission and it would not lose the capability to process, retrieve and protect information maintained in the event of an interruption or disaster leading to temporary or permanent loss of computer facilities. However, no such policy documents were provided by IA, stating (July 2018) that these were available with CDAC.

Further, as a best practice[52], the third party security audit of the system was required to be conducted from cert-in empanelled agencies prior to hosting of the system. However, the same was got conducted in July 2017 by CDAC after more than three years of implementation of the system (August 2014). **Though as per the certification, the application was OWASP[53] compliant but third party security audit was not conducted for the application.**

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50 As per password policy of National Informatics Centre.

51 Important aspects covering system/user authentication were seen.

52 As per guidelines for Indian Government Websites issued by Department of Information Technology, Ministry of Communication and Information Technology, GoI (Paragraph 7.7.1).

53 Open Web Application Security Project (OWASP) is a charitable organization focused on improving the security of software.

2.1.8.4 Internal audit

Effective internal audit satisfactorily reviews the computer systems and ensures that the controls are in place. Audit observed that:

- **There was no audit module in the e-Aushadhi system to generate customized reports for facilitating conduct of internal audit.** The Department stated (February 2019) that the staff of CDAC (IT Cell) operating from PHSC had conducted internal audit and verified the physical stock of all the three DWHs. The reply was not convincing as the internal audit was conducted once in March 2018 after being pointed out by Audit.

- The Food and Drugs Administration (FDA), DH&FW, Punjab directed (June 2016) the Zonal Licensing Authorities (ZLAs) from Sangrur, Amritsar and SAS Nagar to conduct monthly stock verification of drugs and consumables at three DWHs Bathinda, Amritsar (Verka) and Kharar respectively. Audit, however, noticed shortfalls ranging between 38 and 90 *per cent* in carrying out the monthly stock verification at DWHs between June 2016 and March 2018, even when discrepancies related to the quantity of stock and its distribution were being pointed out in the stock verification reports by ZLAs. The reasons for shortfall were attributed to multifarious duties assigned to ZLAs. The Department assured (January 2019) to conduct the stock verification of medicines and consumables in a time bound manner in future.

It was also noticed that the entries related to the physical stock verification were not captured in the system.

2.1.8.5 Audit trail

Audit trail depicts the flow of transactions necessary in a system in order to track the history of transactions, changes/modifications in data, system failures, erroneous transactions, etc. Analysis of the database revealed that:

- **User systems were not assigned unique IP address to keep track of unauthorized use of system**, as in some cases, the users denied to have created records, as discussed in paragraph 2.1.7.5(vi). It was observed that a common IP address was assigned to multiple user systems.

- Login IDs were not captured in 844 out of 13,459 records in case of unsuccessful login attempts.

- In five[54] tables, date/time stamp was not functional thereby creating doubt on the credibility of data.

The discrepancies mentioned above indicate inadequate audit trails in the system.

[54] (i) gblt_user_mst; (ii) hstt_return_req_dtl; (iii) hstt_issue_dtl; (iv) qc_issue_rec_dtl; and (v) qc_dtl.

2.1.9 Conclusion

The e-Aushadhi system had many gaps, due to which the objectives of its implementation in the State could not be achieved in full measure. The Department had not prepared any roll-out plan for implementation of the e-Aushadhi system in remaining health institutions of the State. Non-functioning of bar code system resulted in various inadequacies relating to issue of drugs and system discrepancies which impaired the quality assurance system and effective inventory management through e-Aushadhi. Instances of delay in freezing of stock of drugs/consumables and sending samples to CQCC, late receipt of quality test reports from empanelled/Government laboratories, issue of sub-standard drugs, acceptance of drugs/consumables with shorter shelf-life and availability of substantial number of expired drugs/consumables in the system were noticed. Besides, inadequate logical access controls, application standards, weak validation controls, inadequate audit trails and non-conducting of internal audit showed weak information system security.

2.1.10 Recommendations

In the light of audit findings, the State Government may consider:

(i) shifting of servers to State Data Centre for providing better network connectivity to the respective users;

(ii) developing in-house expertise to take over the activities performed by IT Cell (CDAC);

(iii) self generation of purchase orders by the system in case re-order level of a drug is reached. To allow human judgement, editable forms can be generated and sent to the approving authority which may edit or otherwise directly approve;

(iv) implementing bar coding system which is already present in e-Aushadhi system to avoid human errors and to enable real time data processing;

(v) framing timelines and its adherence to every functional stage in the system;

(vi) red flag alert generation for critical deadlines or incidents which should be made available to relevant supervisory level;

(vii) framing departmental policies on Business Continuity Process/Disaster Recovery, Information Technology Security, Human Resource and Segregation of duties;

(viii) reconciliation of physical stock annually *vis-a-vis* the system; and

(ix) reviewing user logs to rule out any security incident.