Audit and Inspection Report
on the accounts of

Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations and Coordination, Islamabad

For The Financial Year 2015-18

Conducted by:

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DIRECTORATE GENERAL AUDIT (FEDERAL GOVERNMENT) ISLAMABAD

Introduction:

Audit on the accounts of Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations and Coordination, Islamabad for the Financial Year 2015-18 was carried out in November/ December, 2018 by an audit team headed by Mr. Akhtar Majeed, Audit Officer of Directorate General Audit (Federal Government), Islamabad.

Budget and expenditure statement:

The following expenditure was incurred by the management of Drug Regulatory Authority of Pakistan, Islamabad out of Government grant in addition to expenditure incurred from receipt.

(Rs. in Rupees)

Cost Centre	Year	Budget	Expenditure
ID-7153	2015-16	29,248,000	29,247,974
	2016-17	28,313,000	28,311,881
	2017-18	27,460,000	27,459,808

Current Audit Findings

Para-01 Prices of medicines on higher side compared to Bangladesh and India

Section 12 of Drugs Act 1976 states that power to fix maximum prices of drug, etc.- (1) The Federal Government may, by notification in the official Gazette,-

(a) fix the maximum price at which any drug specified in the notification is to be sold; and

(b) specify a certain percentage of the profits of manufacturers of drugs which shall be utilized, in accordance with the rules for purposes of research in drugs.

(2) For the purpose of the exercise of its powers under sub-section (1), the Federal Government may require a manufacturer, stockiest, importer, exporter, retailer or other dealer in drugs to furnish such relevant information as may be necessary.

(3) The Federal Government may, by notification in the official Gazette, delegate any of its powers under this section to any Board or other authority.

Section 7(c)(vii) of Drug Regulatory Authority of Pakistan Act 2012 states that the powers and functions of the Authority shall be to issue guidelines and monitor the enforcement of regulation for pricing and mechanism for fixation of prices of various therapeutic goods under its ambit.

Section 4(1) of Drug Pricing Policy 2018 states that Maximum Retail Price (MRP) fixation of Originator Brand of New Chemical Entities & New Biological Entities in a particular dosage form; strength & delivery system shall be based on average price of the same dosage form and strength of the same brand in India and Bangladesh. If the originator brand is available in only one of these countries, MRP shall be fixed at its par after considering the exchange rate parity.

Section 4 (4) (i) states that MRP of generics shall be fixed at 30% less than the MRP of the Originator Brand.

Scrutiny of following five medicines to check comparability of prices in India and Bangladesh, audit observed that prices of medicines were found to be above. Details are as under:-

S. No.	Name of medicine	Pack Size	Approved MRP in Pakistan (PKR)	Price in Bangladesh (PKR) 1 Takka = 1.59 PKR	Price in India (PKR) 1 INR = 1.83 PKR
1	Sitagliptin 100mg Tablet Generic	10’s	660	477	N/A
2	Entecavir Tablet 0.5 mg	30’s	6,500	4,111	3,112.43
	Entecavir Tablet 1mg	3x10’s	10,800	6,532	5,745.47
3	Risperidone Tablets 1 mg	10’s	120	51	95.20

	Risperidone Tablets 2 mg	10's	195	96	101.46
4	Etanercept Injection 25 mg	1 vial	10,500	N/A	9,333
5	Salmeterol Inhalation	60 meter doses	490	335	N/A

Audit is of the view that price comparison with Bangladesh and India only on new medicines shall not have the desired effect of bringing medicine prices down in Pakistan. It is unfair that old registered medicines continue to be sold for higher prices.

The management did not reply.

Audit recommends that extraordinary prices of medicines may be revised besides fixing of responsibility and investigation for higher prices.

Audit further recommends that prices comparison with Bangladesh and India should be made mandatory for all medicines. In addition, the provision should be retrospectively applied as majority of medicines have already been registered in Pakistan.

Para-02 Late action taken by Registration Board in registration of medicines

Section 7(c)(vii) of Drug Regulatory Authority of Pakistan Act 2012 states that the powers and functions of the Authority shall be to issue guidelines and monitor the enforcement of regulation for pricing and mechanism for fixation of prices of various therapeutic goods under its ambit.

Drug Regulatory Authority of Pakistan, Islamabad was established by the Federal Government on 13.11.2012 and work for registration of medicines also rest with them.

Audit observed that Registration Board of DRAP took an unusually long time to take up cases of registration of medicines. Similarly, a number of applications were received for medicines originating from countries having stringent regulatory authorities. Cases of late registration of medicines in 240th to 250th meetings were noted and placed in Annexure-A. One example case No. 19 of 243rd meeting, even after lapse of three years decision was taken to defer the product for further deliberations. Few examples of late registration of medicines in 240th meeting dated 07.11.2013 are given below:

Name of medicine	**Particulars of Firm application**	**Cases for registration submitted on**	**Cases for registration Decision taken**
Prolia Injection	**GlaxoSmithKline** M/s Amgen Manufacturing Limited, Juncos, Puerto Rico, USA	21.11.2011	07.11.2013

Eprex Injection	**Johnson & Johnson** Manufacturer, Labeling, Packaging and Release Site Originating M/s Cilag AG, Hochstrasse, Schaffhausen, Switzerland	24.08.2011	07.11.2013
Intratect Solution for Infusion	**The Eastern Trade** M/s Biotest Pharma GmbH, Landsteinerstrass, Dreieich, Germany	28.12.2010	07.11.2013
Uman Albumin Solution	**Popular International Ltd** M/s Kedrion S.p.A Loc. Ai Conti, Castelvecchio Pascoli-Barga (LU), Italy	20.08.2011	07.11.2013
Gonal-f Pen Injection	**Merck Specialties Limited** M/s Merch Serono S.P.A VIA Delle Magnolie (LOC Frazionr Zona Industriale), Italy	29.08.2011	07.11.2013
Premarin Cream	**Wyeth Pakistan Limited** M/s Pfizer Canada Inc. Saint-Laurent, Quebec, Canada	30.02.2012	07.11.2013

Audit further observed that management record is silent about what standards have been observed to determine the quality medicines and what methodology has been adopted to take laboratory tests of medicines manufacturing by local and multinational companies.

Audit is of the view that such a long period of waiting for registration decision besides being inhumane hampered the growth of pharma industry in Pakistan.

The management did not reply.

Audit recommends that corrective measures may be taken for timely registration of medicines and fixing of responsibility besides methodology adopted to take laboratory tests may be known to audit.

Para-03 De-Controlled Prices of Medicines

Section 12(1)(a) of Drugs Act 1976 states that power to fix maximum prices of drug, the Federal Government may, by notification in the official Gazette, fix the maximum price at which any drug specified in the notification is to be sold.

Section 7(c)(vii) of Drug Regulatory Authority of Pakistan Act 2012 states that the powers and functions of the Authority shall be to issue guidelines and monitor the enforcement of regulation for pricing and mechanism for fixation of prices of various therapeutic goods under its ambit.

SRO 471(1)/93 dated 6th July 1993 provided a list of 821 medicines and gave blanket approval for rest of medicine prices to be de-controlled.

Audit observed that the majority of medicines in market stand de-controlled as a result of this SRO. Only their price increases are being monitored by DRAP whereas their original high prices stay and DRAP is unable to lower them.

Audit is of the opinion that it is against spirit of Drugs Act 1976 that not all prices of drugs were controlled. SRO prima facie is in violation of Act which calls for price fixation.

The management did not reply.

Audit recommends that responsibility may be fixed as to why measures were not taken to fix the prices of all medicines. Further, every medicine should fall under domain of price control of DRAP.

Para-04 Statement of Qualified opinion by Chartered Accountant on the financial statements of DRAP during the last five years

Rule 3(1) of Drug Regulatory Authority of Pakistan Accounting Procedure and Financial Rules, 2015 states that the accounts of the Authority shall be maintained on double entry system in accordance with the generally accepted accounting principles.

Rule 3(2) of Drug Regulatory Authority of Pakistan Accounting Procedure and Financial Rules, 2015 states that the financial statements of the Authority shall be prepared in accordance with the approved accounting standards as applicable in Pakistan and in the manner as prescribed.

A qualified opinion is a statement issued after an audit is completed by a professional auditor, suggesting that the information provided is limited in scope and/or the company being audited has not maintained its financial statements in accordance with the applicable Financial Reporting Framework. Basically, auditors who deem audits as qualified opinions are advising who so ever is reading the document that the information within the audit is not complete or the accounting methods used by the company do not follow the Generally Accepted Accounting Principles (GAAP) and/or International Financial Reporting Standards (IFRS).

The Securities and Exchange Commission of Pakistan notified International Financial Reporting Standards (IFRS) for preparation of financial statements in Pakistan..

Audit observed that it is the responsibility of DRAP management to prepare its financial statements in accordance with IFRS/ accrual basis but the financial statement of the DRAP Accounts is not being prepared as prescribed. Since establishment of DRAP (13.11.2012) to the financial year 2016-17, Chartered Accountant firms expressed qualified opinions on the financial statements of DRAP as financial statements of the Authority were not prepared in accordance with the approved accounting standards as applicable in Pakistan. Even Audit of Chartered

Accountant for the year 2017-18 has not been arranged in violation of the Act nor Audited Financial Statement for the said year has so far been prepared.

Audit is of the view that despite repeated and repeated qualified opinions on the financial statements, the management of DRAP did not take any action to rectify the situation.

The management did not reply.

Audit recommends that DRAP management should take the necessary actions to prevent the qualification of audit reports besides fixing of responsibility.

Para-05 Non-fixation of prices for Veterinary Biological Vaccines

Section 12(1) of Drugs Act 1976 states that power to fix maximum prices of drug, the Federal Government may, by notification in the official Gazette,-

(a) fix the maximum price at which any drug specified in the notification is to be sold; and

(b) specify a certain percentage of the profits of manufacturers of drugs which shall be utilized, in accordance with the rules for purposes of research in drugs.

Audit observed that prices of 163 Registered Veterinary Biological Vaccines were not fixed by the DRAP as all these vaccines were classified as de-controlled.

Audit is of the view that de-controlled prices of Veterinary Biological Vaccines resulted in high prices.

The management did not reply.

Audit recommends that prices in this area may be regulated so as to bring it into line of DRAP's mandate of ensuring availability of medicines at reasonable prices in the country.

Para-06 Irregular formulation of policy for inspection of manufacturing facilities of manufacturer abroad and conflict of interest by obtaining benefits from the applicants

Para 20(1) of the Drug Regulatory Authority of Pakistan Act, 2012 states that the Authority shall levy and collect such fees, in respect of any of its functions at such rates as may be determined from time to time by the Authority, with the approval of the Policy Board, in accordance with rules.

Para 23 of the Drug Regulatory Authority of Pakistan Act, 2012 states that the Authority may, with the approval of the Federal Government, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

Para 24 of the Drug Regulatory Authority of Pakistan Act, 2012 states that the Authority may, by notification in the official Gazette, with the approval of the Board, make regulations, for its internal working and terms and condition of employees not inconsistent with the provisions of the Act or the rules, for the carrying out of its functions under this Act.

Clause (3)(4)of the SOP for inspection of manufacturer abroad states that after intimation of nominations from Drug Regulatory Authority of Pakistan, applicant shall coordinate the members of the team to arrange visit of manufacturer. Passport, Visa, Boarding/Lodging, Return Air Ticket, Accommodation and all such transport which will be necessary for inspection shall be necessary for inspection shall be the responsibility of the applicant. Moreover daily pocket money US $ 100/- shall be given to the each member of the team prior to proceeding to the inspection through Bank Draft/Demand Draft/Pay order in the name of concerned member of the panel and this draft shall be submitted to DDO (Health) for onward transmission at the rate of two days per inspection. In case of additional time, balance amount shall be submitted by the applicant in the same way on return from the inspection and direct transaction of money shall not be allowed. In case of more than one inspection in different cities of the same country/group, the inter city and intra city transport, daily expenses shall be the responsibility of the manufacturer/applicant. Stay of the team shall be at five star hotel(s); however, if a premise is located in the area where such hotel does not exist, accommodation in the hotel of best rating shall be hired by the applicant.

DRAP authorized 27 participants for inspection of pharmaceutical companies abroad from January 1, 2017 to date and authorize the inspection personnel to avail the benefits mentioned above.

Audit observed that the policy for inspection of manufacturing facilities abroad was neither approved by Policy Board nor Authority. The formulation of policy for inspection of manufacturing facilities of the manufacturer abroad by obtaining benefits from the applicants is resulted in a conflict of interest.

Audit is of the view that the practice of inspection abroad by members on the expenses of the applicants and availing of other benefits may give rise to conflict of interest and this puts to doubt the impartiality and objectivity of the whole exercise.

The management did not reply.

Audit recommends that the Authority shall levy and collect fees from the applicants.

Para-07 Non-utilization of Central Research Fund - Rs. 1,480.849 million

Section 20(2) of Drug Regulatory Authority of Pakistan Act, 2012 states that the Central Research Fund fee shall be deposited in the non-lapsable sub-account of the Authority to be utilized as per existing rules.

Rule 19(14) of Drugs (Licensing, Registering and Advertising) Rules, 1976 states that the Licensee shall, by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978.

Rule 3 of the Drugs (Research) Rules, 1978 states that the Federal Government may utilize the Fund for conducting research, development or evaluation of a drug either itself or through a research institution working under its control or disburse it among investigators or institutions for such purposes subject to such conditions as may be specified and for that matter. It may also utilize the fund to upgrade and establish Drugs Research and testing laboratories and a unit in the Drugs Control Section, Ministry of Health for evaluation and monitoring of the research proposals and projects and management of the fund.

The Drug Regulatory Authority of Pakistan, Islamabad maintained Central Research Fund A/c No. 0010008463700024 in ABL, Civic Centre Melody Branch, Islamabad. An amount of Rs.1,245.293 was invested whereas Rs. 235.556 million is available in the bank account as on 30.06.2018. Audited Financial Statement for the year 2017-18 has not been prepared so far.

Audit observed that the management did not utilize CRF for conducting research, development or evaluation of drugs.

Audit is of the view that non-utilization of CRF for the intended purposes defeated the objective/utility of creation of the Fund.

The management did not reply.

Audit recommends that corrective measures may be adopted to achieve the objectives of establishing the Fund besides provision of justification for non-utilization of CRF.

Para-08 Non-reconciliation and non-transferring of Central Research Fund balance into Authority Account- Rs.974.966 million

Section 20(2) of Drug Regulatory Authority of Pakistan Act, 2012 states that the Central Research Fund fee shall be deposited in the non-lapsable sub-account of the Authority to be utilized as per existing rules.

Section 20(3) of Drug Regulatory Authority of Pakistan Act, 2012 states that the existing Central Research Fund kept with the Federal Government shall be transferred to the Authority immediately after notification of establishment of the Authority.

Rule 19(14) of Drugs (Licensing, Registering and Advertising) Rules, 1976 states that the Licensee shall, by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978.

The management of Drug Regulatory Authority of Pakistan, Islamabad is maintaining the Central Research Fund Account since 13.11.2012 and before its establishment fund was maintained by the Defunct Ministry of Health maintained under Drugs (Licensing, Registering and Advertising) Rules, 1976.

Audit observed that prior to establishment of DRAP, a sum of Rs. 974.966 million up to 30.06.2016 was available in the Central Research Fund Account maintained by AGPR and was required to be transfer in to Authority for conducting research, development or evaluation of drugs but neither fund have been reconciled nor transferred in to authority so far.

Audit is of the view that due to non-transferred of CRF already realized is violation of DRAP,Act 2012.

The management did not reply.

Audit recommends that collective measures may be taken to transfer of CRF in to authority at the earliest so that the objectives of establishing the Fund could be achieved besides reconciliation of the funds maintained by AGPR.

Para-09 Irregular payment of Income Tax on Central Research Fund- Rs. 229.440

Section 49(2) of Income Tax Ordinance, 2001 states that the income of a Provincial Government or a Local Government in Pakistan shall be exempt from tax under this Ordinance, other than income chargeable under the head “Income from Business” derived by a Provincial Government or Local Government from a business carried on outside its jurisdictional area.

Section 49(3) of Income Tax Ordinance, 2001 states that subject to sub-section (2), any payment received by the Federal Government, a Provincial Government or a Local Government shall not be liable to any collection or deduction of advance tax.

Section 49(4) of Income Tax Ordinance, 2001 states that exemption under this section shall not be available in the case of corporation, company, a regulatory authority, a development authority, other body or institution established by or under a Federal Law or a Provincial Law or an existing law or a corporation, company, a regulatory authority, a development authority or other body or institution set up, owned and controlled, either directly or indirectly, by the Federal Government or a Provincial Government, regardless of the ultimate destination of such income as laid down in Article 165A of the Constitution of the Islamic Republic of Pakistan.

The management of Drug Regulatory Authority of Pakistan paid an amount of Rs. 210.121 million for the tax year 2016 and 2017 as tabulated:

Sr. No	**Tax Year**	**Collection**	**Rate of Tax**	**Amount Rs. (million)**
1	2015-16	313,362,202	32%	112.979
2	2016-17	375,682,918	31%	116.461
			Total	229.440

Audit observed that Income Tax was paid on receipts collected relating to Central Research Fund (CRF) which was not taxable under Income Tax Ordinance because it cannot be termed as "Income from Business" as defined in Income Tax Ordinance, 2001.

Audit is of the view that payment of Income Tax on collection of CRF was irregular and unauthorized.

The management did not reply.

Audit recommends that the matter should be taken up with FBR for recovery/refund of Income Tax paid on the balances of CRF.

Para-10 Unauthorized payment of Health Professional Allowance - Rs. 308.591 million

The Federal Government vide Finance Division O.M. No. F.2(13)R-2/2011-777 dated 06.02.2012 granted benefit of one basic pay of running salary as Health Allowance to the "health personnel" in the employment of Federal Government, in BPS scheme, with effect from 01.01.2012.

Para 1 of Finance Division No. F.2(13)R-2/2011-1006 dated 27.10.2014 states that reference to Finance Division's U.O. No. F.2(13)R-2/2012-172 dated 27.03.2012 on the subject and to state that Health Allowance is admissible to the health personnel serving in Federal Government hospitals and clinics.

Finance Division (Regulation Wing) approved the Regulatory officers/officials Pay Scales and Schedule of DRAP Allowances on 17.04.2015 subject to following conditions:

i. The Adhoc Relief Allowances granted in 2010, 2011, 2012, 2013 and 2014 shall not be allowed.

ii. House Rent Allowance, Medical Allowance and Conveyance Allowance may be kept frozen at the proposed level till next revision of DRAP's R.O. Pay Scales.

The management of Drug Regulatory Authority of Pakistan, Islamabad paid Rs. 308.591 million as Health Allowance to its employees during 2015-18. Details are as under:

(Rupees)

S. No.	Year	Amount
1.	2017-18	118,589,043
2.	2016-17	105,683,257
3.	2015-16	84,318,914
	Total	308,591,214

Audit observed that Health Allowance was paid to the employees of DRAP although it was not a Federal Government hospital or clinic as Finance Division clarified that Health Allowance was admissible to the health personnel serving in Federal Government hospitals and clinics only.

Audit further observed that the authorizing of Health Allowance to the Regulatory officers/officials was not approved by the Finance Division (Regulation Wing) in approving the DRAP's R.O. Pay Scales and Schedule of DRAP Allowances.

Audit is of the view that payment of Health Allowance over and above the approval of Finance Division (Regulation Wing) was irregular and unauthorized.

The management did not reply.

Audit recommends that recovery of irregularly paid Health Allowance besides discontinuing the practice forthwith.

Para-11 Irregular revision of DRAP's R.O. Pay Scales 2016 and 2017 and payment of arrears of Pay and Allowances- Rs.68.140 million

Finance Division approved the Regulatory officers/officials Pay Scales and Schedule of DRAP Allowances for R.O Pay Scales of DRAP on 17.04.2015 subject to following conditions:

i. The Adhoc Relief Allowances granted in of 2010, 2011, 2012, 2013 and 2014 shall not be allowed.

ii. House Rent Allowance, Medical Allowance and Conveyance Allowance may be kept frozen at the proposed level till next revision of DRAP's R.O. Pay Scales.

Rule-12(h) of Rules of Business 1973 states that no Division shall, without previous consultation with the Finance Division, authorize the issue of any orders, other than orders in pursuance of any general or special delegation made by the Finance Division, which will affect directly or indirectly the finances of the Federation or which in particular involve a change in the terms and conditions of service of Government servants, on their statutory rights and privileges, which have financial implications.

The management of Drug Regulatory Authority of Pakistan, Islamabad paid Rs. 68.140 million as arrears of Pay and Allowances by granting benefits of Adhoc Relief Allowances of 2010, 2011, 2012, 2013 and 2014 after revision of DRAP's R.O. Pay Scales 2016 and 2017.

Audit observed that an amount of Rs. 68.140 million was paid as arrears of Pay and Allowances to DRAP's employees in contravention to Finance Division directives. DRAP,s R.O. Pay Scales 2016 and 2017 were also revised without obtaining the approval of Finance Division.

Audit is of the view that granting of arrears of Pay and Allowances to DRAP,s employees and revision of DRAP,s R.O. Pay Scales 2016 and 2017 without obtaining the approval of Finance Division was violation of Finance Division instructions.

The management did not reply.

Audit recommends fixing of responsibility for violating of Finance Division instructions besides recovery of the overpaid amounts.

Para-12 Irregular payment of Adhoc Relief Allowances-2016 and 2017 to regulatory scale employees - Rs.27.145 million

Finance Division in its OM No. F.4(3)R-4/2011-Revision dated 04.08.2017 states that grant of Adhoc Relief Allowance 2017 @ 10% of basic pay will be applicable to the employees

of Autonomous/Semi-Autonomous bodies and Corporations, which have adopted the Federal Government's Basic Pay scales Scheme in totality.

Finance Division in its OM No. F.4(3)R-4/2011-Revision dated 28.7.2016 states that that grant of Adhoc Relief Allowance 2016 @ 10% of basic pay will be applicable to the employees of Autonomous/Semi-Autonomous bodies and Corporations, which have adopted the Federal Government's Basic Pay scales Scheme in totality.

Rule-12(h) of Rules of Business 1973 states that no Division shall, without previous consultation with the Finance Division, authorize the issue of any orders, other than orders in pursuance of any general or special delegation made by the Finance Division, which will affect directly or indirectly the finances of the Federation or which in particular involve a change in the terms and conditions of service of Government servants, on their statutory rights and privileges, which have financial implications.

The management of Drug Regulatory Authority of Pakistan, Islamabad paid Rs. 27.145 million as monthly Adhoc Relief Allowances -2016 & 2017 @ 10% each to its Regulatory Officer (RO) scale employees during the year 2016-17 and 2017-18. After the establishment of DRAP, the employees were given the option to join as civil servants in Basic Scale or corporate employees in Regulatory Officer (RO). Approximately half opted to join in RO scales and half in BS scales.

Audit observed that in contravention to Finance Division directives, management paid Adhoc Relief Allowances-2016 and 2017 to DRAP,s R.O. Pay Scales employees. The amount paid is tabulated below:-

Year	**ARA 2016 (10%)**	**ARA 2017 (10%)**
July	0	0
August	1,780,157	2,463,857
September	941,389	1,318,568
October	924,167	1,290,944
November	923,825	1,290,113
December	933,503	1,362,528
January	929,963	1,366,795
February	929,453	1,364,534
March	929,104	1,363,497
April	931,351	1,366,349
May	961,124	1,408,537
June	959,954	1,405,587
Total:-	**11,143,990**	**16,001,309**

Audit is of the opinion that granting of Adhoc Relief Allowance 2016 and Adhoc Relief 2017 to RO scale employees was violation of Finance Division instructions.

The management did not reply.

Audit recommends fixing of responsibility for violating of Finance Division instructions besides recovery of the overpaid amounts.

Para -13 Irregular point to point fixation of the officers/officials who opted for absorption in DRAP

Finance Division (Regulation Wing) approved the Regulatory officers/officials Pay Scales and Schedule of DRAP Allowances for R.O Pay Scales of DRAP on 17.04.2015 subject to following conditions:

i. The Adhoc Relief Allowances granted in 2010, 2011, 2012, 2013 and 2014 shall not be allowed.

ii. House Rent Allowance, Medical Allowance and Conveyance Allowance may be kept frozen at the proposed level till next revision of DRAP's R.O. Pay Scales.

Finance Division vide its O.M. F.3(2)R-4/2015-DRAP dated 24.05.2015 in response to Ministry of National Health Services, Regulations and Coordination U.O.No. F.2-26/2014-Admn.1/DRAP (Vol.V) dated 04.05.2016 in case of point to point fixation of the officers/officials who opted for absorption in DRAP and clarified that point to point fixation of pay of employees, absorbed in DRAP, is administrative matter of DRAP and may be done by DRAP in consultation with its administrative Ministry and Accounts Officer, dealing with its financial transactions.

The management of DRAP vide it's Office Order No. F.2-26/2014-Admn.1(pt) dated 15.06.2016 directed to Director (Budget & Accounts), to fix the pay fixation w.e.f 19.06.2015 on point to point of the officers/officials who opted for absorption in DRAP and instructed that instructions issued by Finance Division(Regulation Wing) vide their letter dated 17.04.2015 may also be followed.

Audit observed that the case of point to point fixation of the officers/officials who opted for absorption in DRAP was neither referred to administrative Ministry and Accounts Officer nor fixation was made in accordance with the instructions issued by Finance Division (Regulation Wing) vide their letter dated 17.04.2015 as the Adhoc Relief Allowances 2010, 2011, 2012, 2013 and 2014 were also paid.

Audit is of the view that extra payment made to the officers/officials who opted for absorption in DRAP in violation of the instructions issued by Finance Division (Regulation Wing) was irregular.

The management did not reply.

Audit recommends that the irregular payment should be recovered and deposited into the government treasury besides discontinuation of the irregularity.

Para-14 Irregular and unauthorized payment of salaries to deputationists

Establishment Division vide O.M. No. 1/13/87-R.l dated 03.12.1990 allows deputation of civil servants to Foreign Service in Pakistan on standard terms and conditions developed in consultation with the Finance Division. Under the terms, officials on deputation are given emoluments in Basic Scales as admissible under the government from time to time and deputation allowance @ 20% (maximum Rs. 12,000).

Rule-12(h) of Rules of Business 1973 states that no Division shall, without previous consultation with the Finance Division, authorize the issue of any orders, other than orders in pursuance of any general or special delegation made by the Finance Division, which will affect directly or indirectly the finances of the Federation or which in particular involve a change in the terms and conditions of service of Government servants, on their statutory rights and privileges, which have financial implications.

The management of DRAP allowed the 18 deputationists to readjust their pay and allowances in accordance with R.O. Pay Scale.

Audit observed that although the deputationists in DRAP were posted on standard terms and conditions but they were all paid under the R.O. Pay Scale without any justification.

Audit is of the view that extra payment made to deputationists was in violation of the standard terms and conditions for the deputationists.

The management did not reply.

Audit recommends that the irregular payment should be recovered and deposited into the government treasury besides discontinuation of the irregularity.

Para-15 Unauthorized opening of bank accounts and retention - Rs. 336.799 million

Clause 6(1) of the Drug Regulatory Authority of Pakistan Accounting Procedures and Financial Rules, 2015 states that the bank accounts of the Authority shall be opened with any

scheduled bank or financial institution with the concurrence of Ministry of Finance.

The management of DRAP opened five commercial bank accounts with different banks and retention of Rs. 336.799 million at the end of June, 2018.

Audit observed that the bank accounts were opened without the concurrence of the Finance Division. The balances in these bank accounts at the end of June were as follows:-

S. No	Bank Name	Detail of Account	Balance as on June-18	Balance as on June -17	Balance as on June-16
1	ABL	CRF (A/c No. 0010008463700024. Civic Center Melody	235,556,185	744,149,951	91,266,681
2	ABL	DRAP (A/c No. 0010008463700047) Civic Center (Melody)	71,628,391	808,959,967	119,192,740
3	ABL	DRAP (A/c No. 0010008463700018) Civic Center (Melody)	22,818,234	28,636,371	6,461,220
4	NBP	CRF A/c No. 16681-8 9 (G-9 Markaz)	2,533,843	2,533,843	2,466,227
5	NBP	DRAP A/c No. 11212-6 (G9 Markaz)	4,262,766	9,935,928	11,745,947
Total Balances			336,799,419	1,594,216,060	231,132,815

Audit is of the view that opening of commercial bank accounts in violation of instructions of the Finance Division was unauthorized.

The management did not reply.

Audit recommends that either these bank accounts should be closed or the accounting procedure of the DRAP may be amended besides fixing of responsibility for the unauthorized opening of bank accounts.

Para-16 Irregular expenditure on hiring of office accommodation and renovation work- Rs.298.658 million

According to Finance Division O.M. No. F.8(69)R.14/83/2001-452 dated 18.10.2001 hiring of private properties for office accommodation by the Federal Government must be supported by the following documents:

1. Statement of space entitlement along with details of sanctioned strength of officers/officials duly approved by Works Division as per their letter No. 10(11)/71-WIII dated 17.08.1971.
2. Assessment Certificate issued by Pak PWD in accordance with specifications of the premises.

Ministry of Housing and Works vide O.M. No. F.2(1)2000-Policy dated 14.04.2008 fixed the rent @ Rs. 30 per square ft. for "Other Areas" of Islamabad and allowed 25% extra rent for high rise and centrally air conditioned buildings at all cities.

The management of Drug Regulatory Authority of Pakistan, Islamabad made advertisement newspapers for hiring the building for office accommodation. Two bidders qualified technically whose financial bids were opened and M/s Telecom Foundation was selected for hiring of their building. An agreement for hiring of 30,021 square ft. office accommodation @ Rs. 155 per square ft. in TF Complex, Mauve Area, G-9/4, Islamabad @ Rs. 4,653,255 p.m. was made on 25.07.2014 for three year commence w.e.f. 20.08.2014. As per agreement on expiry of one year, the rent fixed shall be increased by 10% annually from the commencement of the 2nd year and onward. After the expiry of three year period, another agreement was made on 29.11.2017 w.e.f. 20.08.2017 for one year period @ Rs. 187.55 per square ft. An amount of Rs. 252.393 million was paid as rent during 2014-18. An amount of Rs. 43.555 million was paid to-date to contractor M/s Rehman Construction on the renovation works/additional works and a claim of contractor of Rs. 2.710 is still payable which shows that work is still in progress. An amount of Rs.10.627 million was also incurred for purchase of furniture items in addition to renovation work.

Audit observed as under:

1. The building was hired without observing the scales of office accommodation fixed by Ministry of Housing and Works.
2. Rent and Area Assessment Certificate was not obtained from Pak PWD for hiring of office accommodation.
3. Office accommodation was hired @ Rs. 155 per square ft. in violation of Housing and Works Division O.M. No. F.2(1)2000-Policy dated 14.04.2008.
4. Heavy amounts were incurred on renovation and procurement of furniture without any justification as sufficient dead stock items of defunct ministry of Health was transferred to DRAP.
5. A contract agreement for renovation work of the building was made on 09.06.2015 after about one year of hiring of office accommodation and work was continuing for more than two years. The payment of hiring of office accommodation of both periods was doubtful.

Audit is of the view that hiring of office accommodation on higher rates without obtaining rent and area assessment certificate from Pak PWD and incurred of heavy expenditure on renovation was irregular and unauthorized.

The management did not reply.

Audit recommends that responsibility should be fixed for the irregularities besides expenditure be got regularize by obtaining post facto approval of Finance Division.

Para-17 Improper functioning of DRAP due to non-appointment of regular CEO and Directors

In terms of Section 4(1) of the DRAP Act, 2012 the Authority shall consist of a full time Chief Executive Officer (CEO) and thirteen Directors who shall be appointed by the Federal Government on the recommendation of Board, whose qualifications, terms and conditions shall be such as may be prescribed. The Directors shall be designated as,—

a) Director Pharmaceutical Evaluations and Registration
b) Director Drug Licensing
c) Director Quality Assurance and Laboratory testing
d) Director Medical Devices and Medicated Cosmetics
e) Director Biological Drugs
f) Director Controlled Drugs
g) Director Pharmacy Services
h) Director Health and OTC Products (non-drugs)
i) Director Costing and Pricing
j) Director Budget and Accounts
k) Director Administration, Human Resources and Logistics
l) Director Legal Affairs
m) Director Management Information Services

Section 23 of DRAP Act, 2012 states that the Authority may with the approval of the Federal Government, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

Ministry of National Health Services, Regulations and Coordination vide letter No. F.3-6/2012(G&R) (pt-III) dated 02.02.2018 assigned the charge of the post of CEO, DRAP on look after basis to Dr. Sheikh Akhtar Hussain, Additional Director (RO-14) w.e.f 02.02.2018 till the appointment of regular incumbent of the post. After the expiry of the three month, same charge was again made to the officer w.e.f. 06.05.2018. The Drug Regulatory Authority of Pakistan in its 1st Policy Board meeting held on 21.01.2013 approved to designate the senior most officers (equivalent to B-19) as Directors in their own pay scale till the appointment of regular officers.

Audit observed as under:

1. Qualifications, terms and conditions for the appointment of CEO and Directors shall be such as may be prescribed means rules prescribed under the Act but neither rules required under Section 23 were framed with the approval of Federal Government nor qualifications, terms and conditions were prescribed.
2. The DRAP Policy Board did not furnish recommendations for appointment of regular Directors to be appointed by the Federal Government as the Policy Board failed to make regulations for the act of its sub-committees. Due to which 10 out of 13 Directors of the authority were appointed as Directors in their own pay scale on look after charge since establishment of DRAP and this exercise is remained in practice after a lapse of six years. There is no provision in DRAP Act, 2012 to designate senior officers as Directors without approval of the Federal Government which is violation of the Act. At present following officers are working against posts of Director in excess of three months period.

Name of Officer	**Original Grade & Post**	**Current Position**
Mr. Obaidullah	R.O-14, Addl Director	Director PE & Registration
Mr Ghulam Rasool Dutani	BS-19, Addl Director	Director Licensing
Dr. Abdur Rashid	BS-19,Addl Director	Director Health & OTC
Mr. Faqeer Muhammad Sheikh	R.O-14, DDG	Director Controlled Drugs

3. Presently, CEO of the authority is also working on look after charge basis since Feb, 2018 and after the expiry of the three month, same charge was again made to the officer w.e.f. 06.05.2018. After the expiry of the three month, management failed to provide any documently evidence for its new position whereas Establishment Division has clearly instructed that charge of a post can only be made after approval of the competent authority to the senior most officer available in the organization and present at place where the vacancy may have occurred if he is otherwise fit and eligible for promotion should be considered. The officer working as CEO is Additional Director (R.O-14) whereas three Directors (R.O-15/BS-20) are working and CEO was not selected from them. This is violation of the Act and Establishment Division instructions.
4. Degrees verification of DRAP employees were not carried out. Even after receipt of a complaint against the DDG (Dr. Sheikh Akhtar Hussain), Ex-CEO directed to verify his degrees which have not been made so far.

Audit is of the view that non-appointment of regular CEO/Directors of the Authority and designating the senior officer since long is violation of DRAP Act, 2012. Thus DRAP Authority is functioning improperly.

The management did not reply.

Audit recommends that regular CEO/Directors of the Authority may be appointed forthwith and fixing of responsibility for non-observance of instructions issued by Establishment Division besides taking corrective measures to non-recurrence of irregularities in future.

Para-18 Non-obtaining written statement from DRAP employees and Board Members regarding non-existence of Conflict of Interest

Section 18 of DRAP Act 2012 states that no person shall be appointed as CEO, Director, consultant, advisor, officer or employee of the Authority if he or she has any financial or professional conflict of interest. No person shall be member of the Board or Director if he has immediate family members (parent, child, sibling or spouse) as senior officials or owners of concerns dealing in therapeutic goods.

Audit observed that no certificates from DRAP employees and Board Members regarding non-existence of Conflict of Interest were obtained under the DRAP Act to ascertain that they had no conflict of interest. Similar certificate from current CEO has not been obtained whereas same certification from ex-CEO was obtained.

Audit is of the view that in absence of certificate presence of conflict of interest could not be verified.

The management did not reply.

Audit recommends that corrective measures may be taken and Section-18 of the Act be followed in letter and spirit.

Para-19 Non-recovery of CRF receipts

Para 8 of GFR Volume-I states that subject to such general or specific instructions as may be issued by Government in this behalf, it is the duty of the Revenue or Administrative Department concerned to see that the dues of Government are correctly and promptly assessed collected and paid into the treasury.

Rule 19(14) of Drugs (Licensing, Registering and Advertising) Rules, 1976 states that the Licensee shall, by the 30th June and the 31st December each year, whichever is immediately after

the annual financial closing of the company contribute one percent of the gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978.

The management of Drug Regulatory Authority of Pakistan, Islamabad collected receipts on account of Central Research Fund amounting to Rs. 942.583 million for the years 2015-16, 2016-17 and 2017-18 from 514, 564 and 503 companies respectively.

Audit observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18.The management did not reflect these recoverable receipts as Receivables in the balance sheet of the fund.

Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts.

Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts.

The management did not reply.

Audit recommends recovery of due receipts of CRF and financial statements of DRAP should be corrected.

Para-20 Appointment of auditors without approval of the Auditor General of Pakistan and payment-Rs. 0.725 million

Finance Division O.M. No. F. 3(1)-Inv III/80-406 dated 25.03.1981 states that in the case of autonomous bodies/corporations, where under the statutory provisions appointments are to be made by the Federal Government it has been decided:

(a) Before, submitting the name of the auditor(s) for approval to the Board of Directors, the Institution should get the approval of the Auditor General of Pakistan.

(b) The request for approval to the Auditor General of Pakistan should be routed through the Institution's administrative Ministry/Division.

(c) Auditor General of Pakistan may ensure that all auditors are changed after five years.

(d) Finance Division may be approached for relaxation of these orders only in cases of extreme nature.

The management of Drug Regulatory Authority of Pakistan, Islamabad appointed following three, Chartered Accountants as auditors of the DRAP.

S/No	Name	Year	Amount of fee
1	Deloitte Yousuf Adil	2016-17	275,000
2	KPMG Taseer Hadi	2015-16	250,000
3	Ernst & Young Ford Rhodes Sidat Hyder	2014-15	200,000
		Total	725,000

Audit observed that the auditors were appointed without approval of the Auditor General Pakistan.

Audit is of the view that the appointment of auditors without approval of the Auditor General Pakistan was irregular and unauthorized.

The management did not reply.

Audit recommends appointment of auditors with the approval of the Auditor General Pakistan and fixing of responsibility for the irregularity.

(FEDERAL GOVERNMENT)
Benevolent Fund Building, Zero Point
ISLAMABAD

No. Audit-I/DGAFG/AIR/DRAP/Mo.NHSR&C/2017-18/ Dated: -01-2019

(Akhtar Majeed)
Audit Officer

Copy forwarded to:-

The Secretary, Ministry of National Health Services, Regulations and Coordination, G-5, Islamabad

Chief Executive Officer, Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations and Coordination, TF Complex, Mauve Area, G-9/4, Islamabad with the request to furnish detailed replies in annotated form within seven days after receipt of Audit and Inspection Report.

(Akhtar Majeed)
Audit Officer

Minutes of 241st Meeting of Registration Board

Name of Medicine	Name of Manufacturer	Date of Application	Date of Decision taken by Registration Board
Urobar Tablets	M/s Barrett Hodgson Pakistan (Pvt) Karachi.	26-07-2010	23-12-2013
Mobikare plus Tablets	-do-	15-07-2010	23-12-2013
Diaset plus Tablets	-do-	26-07-2010	23-12-2013
Pioglit Tablets (30mg/4mg)	M/s Pakistan Pharmaceutical Products (Pvt) Ltd. Karachi.	23-07-2010	23-12-2013
Piojet Tablets 45 mg	-do-	21-07-2010	23-12-2013
O-Zole Capsule	-do-	21-07-2010	23-12-2013
Piomet Tablets (15mg/850mg)	-do-	23-07-2010	23-12-2013
Estrol Tablets 2.5 mg	M/s Genix Pharma Private Limted.44,45-B, Korangi Creek Road, Karachi	14-09-2010	23-12-2013
RBC Oral Drops 50 mg	-do-	14-09-2010	23-12-2013
Mazole Tablets 20 mg	M/s Macter International (Pvt.) Ltd, Karachi -75700	22-07-2010	23-12-2013
Dipip Dry Suspension 15mg	M/s Hilton Pharma (Pvt). Ltd. Karachi.	16-09-2010	23-12-2013

Minutes of 245th Meeting of Registration Board

Name of Medicine	Name of Manufacturer	Date of Application	Date of Decision taken by Registration Board
Megafol 2.5 mg	Pharmatec Pakistan (Pvt) Ltd Karachi	11-05-2010	29-09-2014

Secool Ophthalmic Solution	Remington Pharma, Lahore	09/09/2010	29-09-2014
Plycin Cream	Standard Drug Company, Hyderabad	27-04-2010	29-09-2014
Fero-F Tablet	-do-	27-04-2010	29-09-2014

Minutes of 246th Meeting of Registration Board

Name of Medicine	**Name of Manufacturer**	**Date of Application**	**Date of Decision taken by Registration Board**
Pameron Injection	M/s. Nawan Laboratories (Pvt) Ltd., Karachi.	24-12-2010	11-12-2014
Shina Gold Drench	M/s. Mallard Pharmaceutic als (Pvt) Ltd., Multan.	15-12-2010	11-12-2014
Shinazan Plus Drench	-do-	15-12-2010	11-12-2014
Sanoxicam Injection	M/s. Sanna Laboratories, Faisalabad.	30-12-2010	11-12-2014
SCS-Forte Injection	-do-	30-12-2010	11-12-2014
Sanacol-50 Water Soluble Powder	-do-	30-12-2010	11-12-2014
Strefen Lozenge Flurbiprofen BP 8.75mg	M/s. Reckitt Benckiser Healthcare International, Karachi. M/s. Notting Site, Nottinghamshire, United Kingdom.	04-06-2012	11-12-2014
Azarga Eye Drop Suspension 5ml	Applicant: M/s. Ali Gohar & Co. (Pvt) Ltd., Karachi. / Manufacturer: M/s. S.A. Alcon-Couvreur N.V. Rijksweg 14, 2870 Puurs, Belgium	02-03-2010	11-12-2014
Klenar Sachet 15000 mg	M/s PharmaEvo, Karachi	02-11-2009	11-12-2014

Minutes of 248th Meeting of Registration Board

Name of Medicine	**Name of Manufacturer**	**Date of Application**	**Date of Decision taken by Registration Board**
Mesiline 400mg Tablet	Noa Hemis Pharmaceutical, Karachi	30-7-2010	19-03-2015

Etecav 0.5 mg Tablet	-do-	30-7-2010	19-03-2015
Roxicam Tablet 10mg	Semos Pharmaceutical, Karachi.	02-03-2010	19-03-2015

Minutes of 249th Meeting of Registration Board

Name of Medicine	**Name of Manufacturer**	**Date of Application**	**Date of Decision taken by Registration Board**
Benlysta Belimumab 120mg	GlaxoSmithKline, Karachi Marketing Authorization holder: Glaxo group Ltd,UK. Manufacturer site M/s Hospira Inc, Kansas, USA; Secondary Packaging & Release Site GlaxoSmithKline Manufacturing S.p.a., Pharma, Italy.	07-06-2012	19-05-2015
ITA New (ND)	Vet line International Lahore	24-06-2010	19-05-2015
Avi Ibd Plus	-do-	29-06-2010	19-05-2015

O/N

1. Audit on the accounts of Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations and Coordination, Islamabad for the year 2015-18 was carried out by an audit team headed by the undersigned.
2. Para-1 to 17 are recommended as PDP,s
3. As directed by the Director General to issue the Audit and Inspection Report immediately. AIR has been prepared and placed for approval please.

Akhtar Majeed
Audit Officer

Director (A-I)