कर्मचारी राज्य बीमा निगम
(श्रम एवं रोज़गार मंत्रालय,भारत सरकार)
EMPLOYEES' STATE INSURANCE CORPORATION
(Ministry of Labour & Employment, Govt. of India)

मुख्यालय/HEADQUARTERS'
पंचदीप भवन, सी.आई.जी मार्ग, नई दिल्ली -110 002
Panchdeep Bhawan,C.I.G. Marg,New Delhi-110002
www.esic.gov.in, ☎011-23604773, dmc-rc@esic.nic.in

E-Office No. 278/ U-25/12/Drug Policy/ 2014-Med V/Pt-1 /605 Dated:17.01.2024

To,

Director (Medical) Delhi/Director (Medical) Noida
Deans & Medical Superintendents -All ESIC Hospitals
Regional Directors-All States
SMO's- All States
Director ESIS Hospitals -All States

Sub: Testing of quality of drugs approved in valid DGESIC Rate Contract/s - reg.

Sir/Madam,

Reference captioned subject, it is informed that maintenance of Quality plays a very important role in drugs issued to ESIC beneficiaries, the lack of procedure of which, has been a key observation in the recent Audit conducted by the CAG for several States.

In this context, kind attention is drawn towards the terms & conditions of DGESIC Rate Contract (Drugs & Dressings) w.r.t clause for 'Testing of Drugs' duly reproduced as below:

"Regular and random testing of drugs will be under taken by ESI from Govt./Govt. approved laboratories at the time of supply and at any time during the shelf life or whenever any defect is noticed.

The Director General, ESI Corporation shall be at liberty to undertake regular and random testing of the drugs supplied by the pharmaceutical firm/ bidder at regular interval to maintain and ensure the quality of drugs."

In reference to above, it is observed that ESI Institutions are not sending samples for testing regularly &/or submitting information of samples sent for testing to ESIC Hqrs office for which instructions were already issued vide letter no. U-25/12/Drug Policy/ 2014-Med V/Pt-1 /04 dated 21/01/2015.

It is again reiterated that:

1. Acceptance of supply of all drugs (Indian/Imported) procured through valid DG ESIC Rate Contracts should mandatorily be accompanied with In-House testing report and the same should be checked at Inspection by the nominated Inspecting officers.
2. All ESI Institutions should mandatorily send batches of drugs as samples for testing regularly to Govt./Govt. approved Laboratories, in adherence to terms & conditions of respective valid DG ESIC Rate Contract/s.
3. The quantity of batch/sample sent for testing and the receipt thereof, should be as per terms and conditions governing the local contracts for Testing, of respective Institution.

1/3.

4. The stock of respective drugs for which batches/samples have been sent for Quality testing, should be released for consumption after the receipt of Quality report.
5. The selection of samples sent for testing should be done prudently by the Medical Store keeping in context the Inventory Stock position, supply orders in pipeline, buffer stock, online information on ESIC website etc such that under no circumstances the withholding of the respective Batch sent for Testing till the receipt of report should result in 'Stock out' of the respective drug/s or result in frivolous Local Purchase.
6. It is mandatory to maintain records for both the samples sent for Testing by the Institution as well as that collected by the State Drug Inspector (as the case maybe).
7. Simultaneously, the information of the drugs sent for Testing and samples collected by the State Drug Inspector (as the case maybe) should be forwarded to the office of the Medical Commissioner of respective Zone and Med V Rate Contract Division, ESIC Hqrs office in the format below, by 5th of each coming month in soft copy (Excel Format only) to dmc-rc@esic.nic.in from the official ID of the Head of the Institution :

Name of ESI Institution: _____

S. No.	RC No.	Name of Pharmaceutical Firm	Name of Item	Item No. & Page No. as per RC	Drug License Number and place of production	Batch No	D.O Mfg & D.O Expiry	Date of sampling

8. ESI Institutions should mandatorily check ESIC website for the uploads regarding samples sent for testing. If authentic information regarding submission of specific batch of sample sent for testing is available with user unit, the same batch may not be sent for testing again.
9. For all samples declared **"Not of Standard Quality"**, information along with self-attested copy of the Test Report duly countersigned by Dy. Medical Superintendent/Medical Officer Incharge of Store should be sent to ESIC Hqrs office in the format given below with in a period of seven days form the date of receipt of report:

Name of ESI Institution: _____

S. No.	RC No.	Name of Pharmaceutical Firm	Name of Item	Item No. & Page No. As per RC	Drug License Number and place of production	Batch No	D.O Mfg & D.O Expiry	Date of sampling	Name of Laboratory/ Govt. agency reporting the NSQ	Report No.	Date of report

10. The data for samples sent for Testing from all ESI Hospitals within the respective State and any NSQ reported thereof should be mandatorily also sent to the office of the Medical Commissioner of the respective zone.
11. All ESI Institutions should initiate penal action (replacement of batch of drug with a different batch/ recovery, deduction of testing charges etc) as per terms and conditions of the DG ESIC Rate Contract.
12. **Quality assurance of drugs is not only an essential clause in the terms & conditions of the Rate Contracts but also plays a vital role in maintaining distribution of life saving drugs to patients.**

The above instructions are for mandatory adherence by all Heads of Institutions. Any legal repercussion arising in respect to non-adherence of Quality shall lie solely with the Heads of Institution.

This issues with the approval of Medical Commissioner.

Warm regards,

17.01.2024.

(Dr. Sangeeta Mathur)

Dy. Medical Commissioner (RC)

उप चिकित्सा आयुक्त (आर. सी.)/Dy. Medical Commissioner (RC)
क.रा.बी.नि. (मु.)/E.S.I. Corporation (H.Q.)
श्रम एवं रोजगार मंत्रालय, भारत सरकार
Ministry of Labour & Employment, Govt. of India
पंचदीप भवन, सी. आई. जी. मार्ग., नई दिल्ली–2
Panchdeep Bhawan, CIG Marg, New Delhi-2

Copy for information to:

1. PPS to DG,FC,CVO
2. PS to Medical Commissioner (Procurement & SST)
3. PS to Medical Commissioner (Medical Services & Medical Education)
4. Medical Commissioner of respective Zones.
5. DMC (MS) <u>with request for addition of number of samples sent for testing and any NSQ reported in the monthly DO letter sought from ESI Institutions.</u>
6. <u>All DG ESIC RC approved Pharmaceutical firms for compliance to supplying the respective item under the Drug License Number and plant as quoted in the Tender.</u>

17.01.2024.

Dy. Medical Commissioner (RC)

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E-Office No. 278/ U-25/12/Drug Policy/2014-Med V/Pt-I/686 Dated:-13.02.2024

To,

Director (Medical) Delhi/ Director (Medical) Noida
Deans & Medical Superintendents -All ESIC Hospitals
Regional Directors – All States
SMO's- All States
Director ESIS Hospitals -All States

CORRIGENDUM

Sub: Testing of quality of drugs approved in valid DGESIC Rate Contract/s reg.

Ref: Web Upload issued vide Console No. 15630 dated 17.01.24

Sir/ Madam,

Pursuant to the web upload issued from ESIC Hqrs Office vide Console No.15630 dated 17.01.24 pls find below a Corrigendum w.r.t. Point No. 1 of the said web upload, detailed as below:

Point -1	Corrigendum- Point to be read as
"Acceptance of supply of all drugs (Indian/Imported) procured through valid DG ESIC Rate Contracts should mandatorily be accompanied with **In-House testing report** and the same should be checked at Inspection by the nominated Inspecting officers"	Acceptance of supply of all drugs (Indian/Imported) procured through valid DG ESIC Rate Contracts should mandatorily be accompanied with : • Test Report for the particular batch of medicines tested by the Government/ Government approved Laboratories along with each supply by the approved Rate Contract Holder and the same should be checked at Inspection by the nominated Inspecting officers. • For Imported items:- In-house test report of Principal manufacturer with each batch of supply by the approved Pharmaceutical firm and the same should be checked at Inspection by the nominated Inspecting officer.

This issues with the approval of Medical Commissioner.

With regards,

13.2.24

डॉ. Dy. Medical Commissioner (RC)
उप चिकित्सा आयुक्त (क्षेत्र ... (RC)
क.रा.बी.नि. (मु.) ... (H.Q.)
श्रम एवं रोजगार मंत्रालय, भारत सरकार
Ministry of Labour & Employment, Govt. of India
पंचदीप भवन, सी. आई. जी. मार्ग, नई दिल्ली–2
Panchdeep Bhawan, C.I.G. Marg, New Delhi-2
Dy. Medical Commissioner (RC)

Copy for information to:

1. Website Content Manager with request for uploading on ESIC website.
2. Guard file

कर्मचारी राज्य बीमा निगम
(श्रम एवं रोज़गार मंत्रालय,भारत सरकार)
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E-Office No. 278/ U-25/12/Drug Policy/2014-Med V/Pt-I/ 708 Dated:-26.02.2024

To,

Director (Medical) Delhi/ Director (Medical) Noida
Deans & Medical Superintendents -All ESIC Hospitals
Regional Directors – All States
SMO's- All States
Director ESIS Hospitals -All States

Sub: Testing of quality of drugs approved in valid DGESIC Rate Contract/s reg.

Ref: ESIC Hqrs Web-upload dated 17.01.2024 followed by corrigendum dated 13.02.2024 (copies enclosed).

Sir/ Madam,

Reference captioned subject, kind attention is hereby drawn towards the web-upload Console Sl. No. 15630/2024 dated 17.01.2024 and corrigendum dated 13.02.2024.

In this context, it is informed that no information w.r.t. testing of quality of drugs has been received from any ESI Institutions for the month of January'2024 in the required format except the following:

1. ESIC Hospital Adityapur
2. CMS, ESI Scheme Ahmedabad.

Hence, it is again reiterated that in order to monitor the quality of drugs, ESI institutions are once again instructed by the Medical Commissioner (Procurement) to submit the required information w.r.t the drugs sent for testing/ samples collected by the State Drug Inspector (as the case maybe) to the office of the Medical Commissioner of respective Zone and Rate Contract Cell (Med-V), ESIC Hqrs Office strictly in the format given below by 5th of each month in soft copy (Excel Format only) to dmc-rc@esic.nic.in:

S. No.	RC No.	Name of Pharmaceutical Firm	Name of Item	Item No. & Page No. as per RC	Batch No	D.O Mfg. & D.O Expiry	Date of Sampling

This issues with the approval of Medical Commissioner (Procurement).

With regards,

26.2.24.

Dy. Medical Commissioner (RC)

Copy for information to:

1. Zonal Medical Commissioner for information.
2. ICT Division with a request to create a separate section on ESIC website for circulars/information of drugs sent for testing and testing report thereof.
3. Website Content Manager with request for uploading on ESIC website.
4. Guard file

26.2.24

Dy. Medical Commissioner (RC)