

No.F.13-5/2024-DDLT Government of Pakistan

Drug Regulatory Authority of Pakistan

Quality Assurance and Laboratory Testing Division Prime Minister's National Health Complex, Chak Shahzad Islamabad

Islamabad, the 25th March, 2025

The Additional Director, Drug Regulatory Authority of Pakistan,

Lahore.

The Additional Director,

Drug Regulatory Authority of Pakistan, Karachi.

The Officer Incharge,

Drug Regulatory Authority of Pakistan, Quetta.

The Additional Director,

Drug Regulatory Authority of Pakistan, Islamabad.

The Additional Director,

Drug Regulatory Authority of Pakistan, Peshawar.

Subject: DISPOSAL OF THE CASES OF SHORT SHELF LIFE

I am directed to refer to the subject cited above and to state that the Chief Executive Officer (CEO), Drug Regulatory Authority of Pakistan (DRAP) being "Licensing Authority" under Chapters 2 and 3 of the Drugs (Import and Export) Rules 1976, had constituted a committee to dispose of the cases of short shelf life vide letter No. F.3-3/2014-pt(I&E) dated 26-02-2014 and the terms and reference of the committee were amended vide letter No. F.3-3/2014-pt(I&E) dated 26-09-2024.

2. The CEO, DRAP being "Licensing Authority" is pleased to devolve the "Committee to Dispose of the Cases of Short Shelf Life" and delegate his powers under Chapters 2 and 3 of the aforesaid rules read with Section 5(3)(d) of DRAP Act 2012 to the following officers, in the manner specified below:

Sr. No.	Remaining shelf life	Authorized Officer
1	Pharmaceutical Raw Material (including API and Excipient) and Finished drug products having remaining shelf life of 75% and more than 75% calculated from the date of IGM.	Assistant Director /
2	Pharmaceutical Raw Material (including API and Excipient) and finished drug products having remaining shelf life from 50% to less than 75% calculated from the date of IGM.	Officer Incharge of
3	Pharmaceutical Raw Material (including API and Excipient) and finished drug products having remaining shelf life less than 50% calculated from the date of IGM.	DR AP Islamahad

4	Vaccines, sera, blood products and other thermolabile drugs having total shelf life of two (02) years or less but having a remaining shelf life from 50% or more than 50% calculated from the date of IGM.	
5	Vaccines, sera, blood products and other thermolabile drugs having total shelf life of two (02) years or less but having a remaining shelf life from 40% to less than 50% calculated from the date of IGM.	Officer Incharge of
6	Vaccines, sera, blood products and other thermolabile drugs having total shelf life of two (02) years or less but having a remaining shelf life less than 40% calculated from the date of IGM.	
7	Vaccine, sera, blood products and other thermolabile drugs having total shelf life of more than 02 years having a remaining shelf life of 60% or more than 60% calculated from date of IGM.	
8	Vaccine, sera, blood products and other thermolabile drugs having total shelf life of more than 02 years having a remaining shelf life from 50% to less than 60% calculated from date of IGM.	Officer Incharge of
9	Vaccine, sera, blood products and other thermolabile drugs having total shelf life of more than 02 years but having a remaining shelf life less than 50% calculated from date of IGM.	Director QA<,

- 3. If Additional Director / Officer Incharge is not available or posted, the case shall be referred to Director (QA<) for decision. Moreover, DRAP's field offices shall maintain record of such granted approvals and mention in monthly activity report.
- 4. This issues with the approval of the CEO, DRAP.

Deputy Director (QA<-VII)

Copy to:

Director (QA<), DRAP Islamabad

• Director (MIS), DRAP Islamabad with request to upload the letter on the website.

Chairman, PPMA

- Executive Director, Pharma Bureau
- Chairman, PCDA
- P.S. CEO-DRAP