June 23, 2026

CDSCO

Draft sets shorter timelines for device manufacturing licences

Draft G.S.R. 515(E) would amend rules 20, 21, 23 and 25 of the Medical Devices Rules, 2017, shortening scrutiny, audit, inspection and licence grant periods.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) has published draft rules, G.S.R. 515(E) dated June 23, 2026, to further amend the Medical Devices Rules, 2017. The draft appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 464 of June 24, 2026. It is proposed under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940, and is published after consultation with the Drugs Technical Advisory Board. The rules would be called the Medical Devices (...Amendment) Rules, 2026, with the number left blank. Unless specified otherwise, they would come into force on the date of their final publication in the Official Gazette.

KEY FACTS

AUTHORITY

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Ministry of Health and Family Welfare (Department of Health and Family Welfare)

DOCUMENT

Draft rules, G.S.R. 515(E)



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Rule 20 deals with State Licensing Authority licences and loan licences to manufacture Class A (other than non-sterile and non-measuring) and Class B devices. The draft substitutes sub-rule (5): "The State Licensing Authority shall complete the scrutiny of the application in respect of Class B device and to be assigned to notified bodies within a period of thirty days from the date of online submission of application." If rectifiable deficiencies are pointed out in that time, the period runs from their removal. A new sub-rule (5A) carries over the present sub-rule (5), a notified body audit of Quality Management System conformance before grant of licence, without its words "in respect of Class B device".

For Class B, the draft also replaces clauses (i) and (ii) of rule 20(6) and adds a clause (i)(a). The State Licensing Authority would ensure the registered notified body audits the site within thirty days of the application being assigned to it. If the audit finds non-conformance with Quality Management System requirements, compliance would be verified within twenty days of the manufacturer's compliance report. The notified body's final report, with recommendations, would be due within fifteen days of the completion of the audit. The rules now set ninety days from the application for the audit and thirty days for the report; no amendment since October 14, 2022 has changed rule 20. Clause (iii), the twenty days to decide after the audit report, stays as it is.

For Class C and Class D devices, licensed by the Central Licensing Authority, the draft shortens three periods. Scrutiny of the application under rule 21(4) would go from "forty five" to "thirty" days from online submission. Inspection of the manufacturing site before grant under rule 23(1) would go from "sixty" to "fifty five" days from the date of application. The decision on a licence in Form MD-9 or a loan licence in Form MD-10 under rule 25(1) would go from "forty-five" to "twenty" days from receipt of the inspection report. A new rule 23(3) would require compliance verification within fifteen days of the manufacturer's compliance report where the inspection finds non-conformance with Quality Management System requirements.

Objections and suggestions may be addressed, within thirty days from the date copies of the Gazette are made available to the public, to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, C Wing, First Floor, Kartavya Bhavan 1, New Delhi - 110001,

or emailed to drugsdiv-mohfw@gov.in. The draft gives no closing date and proposes nothing on import licences. It is signed by Harsh Mangla, Joint Secretary, under F. No. X.11035/112/2024-DRS-Part(1). Final amendments to the rules followed on August 14, 2026, in G.S.R. 743(E) and G.S.R. 744(E), on other subjects; neither changes rules 20, 21, 23 or 25. CDSCO's list of Gazette notifications showed no final rules from this draft on October 28, 2026.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Draft rules, G.S.R. 515(E)
Dated	June 23, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 464, June 24, 2026
Proposes to amend	Medical Devices Rules, 2017: rules 20, 21, 23 and 25
Applies to	Applicants for a licence or loan licence to manufacture Class B devices (State Licensing Authority) or Class C and D devices (Central Licensing Authority)
Class B scrutiny	Thirty days from online submission (new rule 20(5))
Class B audit	Within thirty days from assignment to the notified body; compliance verification within twenty days of the compliance report; final report within fifteen days of the completion of the audit (rule 20(6))
Class C and D scrutiny and inspection	Scrutiny from forty five to thirty days (rule 21(4)); inspection from sixty to fifty five days (rule 23(1)); compliance verification within fifteen days of the compliance report (new rule 23(3))
Class C and D decision	Forty-five to twenty days from receipt of the inspection report (rule 25(1))
Comment period	Thirty days from the date copies of the Gazette are made available to the public
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, C Wing, First Floor, Kartavya Bhavan 1, New Delhi - 110001, or drugsdiv-mohfw@gov.in
Takes effect	On the date of final publication in the Official Gazette, unless specified otherwise
Status	No final rules on CDSCO's list of Gazette notifications on October 28, 2026

Related	G.S.R. 743(E) and G.S.R. 744(E), August 14, 2026: final amendments to the Medical Devices Rules, 2017 on other subjects
File number	F. No. X.11035/112/2024-DRS-Part(1)
Signed by	Harsh Mangla, Jt. Secy.

Licensing time limits in the draft

Rule	Covers	In the rules now	Proposed
20(5)	Class B: State Licensing Authority's scrutiny and assignment to notified bodies	None set for scrutiny (the present sub-rule (5) is the audit requirement)	30 days from online submission
20(6)(i)	Class B: notified body audit of the site	90 days from the date of application	30 days from assignment to the notified body
20(6)(i)(a), new	Class B: compliance verification after non-conformance in the audit	None set	20 days from the manufacturer's compliance report
20(6)(ii)	Class B: notified body's report to the State Licensing Authority	30 days from completion of audit	15 days from completion of audit (final report with recommendations)
21(4)	Class C and D: Central Licensing Authority's scrutiny	45 days from online submission	30 days
23(1)	Class C and D: inspection of the site before grant	60 days from the date of application	55 days
23(3), new	Class C and D: compliance verification after non-conformance in the inspection	None set	15 days from the manufacturer's compliance report
25(1)	Class C and D: grant or rejection of licence (Form MD-9) or loan licence (Form MD-10)	45 days from receipt of the inspection report	20 days

The draft notification (PDF, 698 KB)

Source: Gazette of India, CG-DL-E-27062026-273896.

Checked against the official copy on October 28, 2026.

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Read online: indusdesk.com/cdsco/insights/draft-sets-shorter-timelines-for-device-manufacturing-licences/