CME INDIA | PRACTICE UPDATE

Once-Weekly Insulin Icodec (Awiqli®): Getting the Missed-Dose Rule Right

A critical appraisal of the circulating missed-dose algorithms — and what actually applies in India

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Bottom line first

- **There is no real contradiction between the two circulating posts.** The first post ("0–3 days to the next dose → change the day; 4–6 days → keep the day") is the EMA type 2 rule, simply restated from the other end of the week. Days remaining = 7 − days elapsed. Both statements are the same rule.
- **The genuine EMA–FDA differences lie elsewhere** and were not correctly identified: the EU label never tells a patient to skip a dose, while the US label does; and the EU label keeps the original injection day in the early window, while the US label always resets it.
- **For Indian practice, the EU-type algorithm is the operative one.** Awiqli was launched in India for adults with type 1 and type 2 diabetes — an EU-type indication. The US label covers type 2 diabetes only and its "skip the dose" instruction should not be imported into Indian counselling.
- **The first post omits type 1 diabetes entirely.** In T1D there is no "keep the day" branch — the injection day always moves to the day the missed dose was taken.
- **One principle unifies both labels: never give two icodec injections less than 4 days apart.**

1. The India-relevant (EU-type) algorithm

Awiqli is authorised in the EU for **treatment of diabetes mellitus in adults** — both type 1 and type 2. The Indian launch indication mirrors this. The SmPC gives two separate missed-dose rules.

Type 2 diabetes

Time elapsed since the missed dose	What to do	Effect on the schedule
≤ 3 days	Inject as soon as remembered.	KEEP the original weekly day. The next dose falls 4–6 days later — a genuinely shortened interval. Monitor fasting glucose through that week.
> 3 days	Inject as soon as remembered.	CHANGE the weekly day to the day the missed dose was given. Continue once weekly from there.

Type 1 diabetes

- Inject as soon as remembered — there is no 3-day branch and no option to preserve the original day.
- The weekly injection day becomes the day the missed dose was administered.
- Perform frequent fasting plasma glucose monitoring. In ONWARDS 6, severe or clinically significant hypoglycaemia occurred in 85% of icodec-treated T1D patients versus 76% on degludec (19.93 vs 10.37 episodes per patient-year). The SmPC restricts icodec in T1D to patients in whom a clear benefit from weekly dosing is expected.

Returning to a preferred injection day

Both EU rules permit a return to the original day — not by shortening the interval, but by **successively extending the gap between subsequent doses** until the desired day is reached. This useful option was absent from the circulating text and is worth teaching: patients who inject on a fixed household or clinic day (Sunday, market day, dialysis day) can be brought back gradually and safely.

2. The US label — and why it is not interchangeable

Awiqli received initial US approval in 2026 for **adults with type 2 diabetes only**. There is therefore no US missed-dose rule for type 1 diabetes at all.

Time elapsed since the missed dose	What to do	Effect on the schedule
≤ 4 days	Inject as soon as possible.	Resume weekly dosing one week from the day the make-up dose was given — i.e. the day ALWAYS resets.
> 4 days	**SKIP the missed dose.**	Take the next dose on the regularly scheduled day. Increase glucose monitoring.

The US label separately states that a planned change of injection day is acceptable provided at least 4 days have elapsed since the last dose — the same 4-day floor that the EU rule produces arithmetically.

Where the two labels genuinely diverge

1. Window length: 3 days (EU) versus 4 days (US).
2. Early window: the EU label preserves the original injection day; the US label always resets it. The EU approach therefore accepts an inter-dose interval as short as 4 days; the US approach never does.
3. Late presentation: the EU label always gives the dose; the US label omits it altogether. The EU rule trades a little stacking risk for continuity of basal cover; the US rule trades several days of hyperglycaemia for absolute avoidance of overlap.
4. Indication: type 1 + type 2 (EU, and India) versus type 2 only (US).

3. Point-by-point appraisal of the circulating text

Statement as circulated	Verdict	Correct position
"0–3 days to the next dose → change the day; 4–6 days → keep the day"	**Correct**	This is the EU type 2 rule expressed as days remaining rather than days elapsed. The two framings are arithmetically identical (remaining = 7 − elapsed).
"EMA and FDA use different algorithms — the two posts conflict"	**Partly wrong**	The premise is right (the labels do differ) but the two posts do not conflict with each other. The real differences are the 3- vs 4-day window, day-reset behaviour, and the US "skip" instruction.
Rule presented without distinguishing diabetes type	**Incomplete**	Critical omission for India, where Awiqli is approved for T1D as well. In T1D the day always shifts; there is no "keep the day" branch.
"FDA: within 4 days of the missed dose, take it and continue weekly"	**Misleading**	"Continue weekly" understates the instruction. The US label resets the weekly day to one week from the make-up dose, and beyond 4 days directs the patient to omit the dose entirely.
"Half-life approximately 196 hours, about 8 days"	**Needs care**	Both approved labels state a subcutaneous half-life of approximately one week, independent of dose. The ~196 h (~8 day) figure comes from clinical pharmacology reporting and is widely quoted in launch coverage. Either may be cited, but the missed-dose algorithm is label-defined and modelled — it is not derived from half-life arithmetic, and should not be taught as though it were.
"Never double the dose to compensate"	**Correct**	Retain and emphasise. Dose-doubling and erroneous repetition of the one-time 50% loading dose are the two

Statement as circulated	Verdict	Correct position
		commonest overdose mechanisms with this molecule.
Omission: gradual return to the original day	Missing	The EU label explicitly allows the original day to be regained by successively lengthening subsequent intervals.

4. Worked examples for Indian practice (EU-type label)

Type 2 diabetes — scheduled every Monday

- **Remembers on Wednesday (2 days late).** Inject Wednesday. Keep Monday as the injection day — next dose in 5 days. Advise fasting glucose checks over the coming week, particularly days 2–4 after the make-up dose, when hypoglycaemia clustered in the ONWARDS trials.
- **Remembers on Thursday (3 days late).** Inject Thursday. Monday is retained — an interval of exactly 4 days, the shortest the label permits. This is the branch that most warrants monitoring, and the one to avoid in the frail elderly, in advanced CKD, and in anyone still on a sulfonylurea.
- **Remembers on Friday (4 days late).** Inject Friday. Friday now becomes the weekly day. Under the US label this same patient would still take the dose and reset to Friday; only beyond 4 days do the labels part company.
- **Remembers the following Saturday (5 days late).** EU/India: inject Saturday; Saturday becomes the new weekly day. US: the dose would be skipped. Follow the Indian package insert — do not omit the dose on the strength of the US algorithm.

Type 1 diabetes — scheduled every Sunday

- **Remembers on Tuesday (2 days late).** Inject Tuesday. Tuesday becomes the new weekly day — the T2D "keep the day" branch does not apply. Intensify fasting glucose monitoring, ensure bolus insulin is uninterrupted, and check ketones if glucose is high. If Sunday is preferred for practical reasons, restore it gradually by lengthening subsequent intervals, never by shortening one.

5. Counselling points to standardise

- Never double a dose, and never add the one-time 50% initiation dose to any injection after the first.
- Never allow fewer than 4 days between two icodec injections — the single rule that holds across both labels.
- Do not adjust the weekly dose for acute illness or short-term changes in diet or activity; the long half-life makes such adjustment unreliable. Modify carbohydrate intake or other glucose-lowering agents instead, and use rapid-acting insulin for significant hyperglycaemia.
- Awiqli is U-700. Dialling is in 10-unit steps and the counter reads units directly — no conversion. Warn against dose-selection habits carried over from weekly GLP-1 pens; this is a labelled medication-error risk.
- Reduce or stop sulfonylureas and glinides when initiating, and reinforce this at every missed-dose event.
- Recovery from hypoglycaemia may be delayed. Re-check glucose repeatedly after treating an episode rather than assuming resolution.
- Record the injection day in writing — on the pen carton or a family calendar. Most missed-dose confusion in practice is a diary problem, not a pharmacology problem.

6. Indian availability

Awiqli was launched in India in July 2026 for adults with type 1 and type 2 diabetes, making India the seventh country of launch. A 70-unit weekly dose was priced at approximately ₹261, with a 1 mL (700-unit) pen at ₹2,611 and a 3 mL (2,100-unit) pen at ₹7,833 — against roughly ₹345–453 for 70 units of currently marketed daily basal insulin. Prices and pack availability move quickly; verify locally before quoting to patients.

Broadcast-ready summary (WhatsApp / group post)

Once-weekly insulin icodec — missed dose, India label:

TYPE 2: ≤ 3 days late → inject now, keep the usual day. > 3 days late → inject now, that day becomes the new weekly day.

TYPE 1: Inject now. The day always changes to the day you injected. Monitor closely.

NEVER: double the dose, or inject twice within 4 days.

To get back to a preferred day, lengthen the next interval — never shorten it.

The US label differs (4-day window; skip the dose if later). It applies to type 2 only and is not the label in force in India.

References

1. Awiqli 700 units/mL solution for injection in pre-filled pen (insulin icodec). Summary of Product Characteristics. Amsterdam: European Medicines Agency; 2024. Available from: https://www.ema.europa.eu/en/documents/product-information/awiqli-epar-product-information_en.pdf
2. Awiqli (insulin icodec-abae) injection, for subcutaneous use. Highlights of Prescribing Information. Plainsboro (NJ): Novo Nordisk Inc.; revised March 2026. Available from: https://dailymed.nlm.nih.gov
3. European Medicines Agency. Educational materials for healthcare professionals and patients using the diabetes medicine Awiqli: measures intended to reduce risk of confusion with dosing requirements. EMA/137463/2024. Amsterdam: EMA; 2024.
4. European Medicines Agency. Awiqli: EPAR – risk management plan, version 2.1. Amsterdam: EMA; 2025.
5. Novo Nordisk launches once-weekly basal insulin Awiqli in India. Medical Dialogues. 2026 Jul.

Prepared for CME India. Educational content for registered medical practitioners. Dosing must follow the CDSCO-approved package insert in force at the time of prescribing; verify the missed-dose section of the Indian pack insert, which follows the EU-type indication.