The Regulatory Watch — EU · Swiss · US

Sample Issue #0 — November 2026 *Covering developments of October 2026*

Prepared by the regulatory affairs practice led by **Carlos Vijande Rodriguez**, Associate Director in Regulatory Affairs with more than 20 years' experience at Roche, Edwards Lifesciences and PPD / Thermo Fisher Scientific. We monitor the European Medicines Agency (EMA), Swissmedic and the US Food and Drug Administration (FDA) so our clients don't have to — and we read what changed, not just what was announced.

Information and commentary, not legal advice.

1. Changes that need action

Five dates to put in the calendar this month:

By when	Who	What
27 November 2026	FDA	Deadline for public comments on the draft guidance on individualized human genome editing products (docket FDA-2026-D-11783).
30 November 2026	EMA / CTIS	The transition to the new CTIS safety module for annual safety reports (ASRs) completes. Sponsors should confirm ASR roles are assigned and download any records still held in the legacy ASR functionality before access ends.
31 December 2026	Swissmedic	Last date for retrospective registration in swissdamed of devices, systems and procedure packs already placed on the Swiss market.
1 January 2027	Swissmedic	From this date, devices must be registered in swissdamed before being placed on the Swiss market.
1 April 2027	Swissmedic	Importer linking in swissdamed must be complete: every imported device must be linked to the importer's actor registration (CHRN). The new Swiss Pharmacopoeia (Ph. Helv. 13) also enters into force on this date.

FDA — a comment window worth using. On 27 October 2026, FDA issued the draft guidance *Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management*. Its core concept is an "Individualized Feature Space": predefined boundaries, agreed in the BLA, within which a product may vary from patient to patient. A new patient-specific variant that falls inside those boundaries can be added to the licence supported by laboratory data, without a new clinical trial. Sponsors working in personalised gene editing have until 27 November 2026 to comment — an unusually direct opportunity to shape a first-of-its-kind framework.

Swissmedic — swissdamed deadlines are now the critical path for device companies. The importer linking function in swissdamed has been live since 1 October 2026. Linking is based on the UDI-DI and is only possible once the device has been registered by the manufacturer or authorised representative. Swissmedic will not enforce a missing link during the transition, but from 1 April 2027 a delay between placing an imported device on the market and linking it will no longer be accepted. Detail in Section 4.

2. New and updated guidance, in plain language

EMA — CHMP, 12–15 October 2026. The Committee recommended six new medicines for approval, including Foundayo (orforglipron), a once-daily oral GLP-1 receptor agonist for weight management and type 2 diabetes; Rasonque (daraxonrasib) for previously treated metastatic pancreatic cancer, reviewed under EMA's Cancer Medicines Pathfinder project; Yuviwel (navepegritide) for achondroplasia in children; the hybrid medicine Kizfizo (temozolomide); and two biosimilars, Fovlussea (ranibizumab) and Neuzafy (filgrastim). Five already-authorised medicines received recommendations for extensions of indication. Two outcomes deserve a second look from sponsors: the CHMP confirmed, after re-examination, its refusal of Yartemlea (narsoplimab) for HSCT-associated thrombotic microangiopathy — a reminder that re-examination rarely reverses a negative opinion — and it recommended changing the legal status of Nyxoid (naloxone) nasal spray so it can be supplied without a prescription across the EU; a European Commission decision follows, with updated product information to be published in the revised assessment report.

FDA / ICH — E14 and S7B Questions and Answers (R1), final (30 October 2026). FDA has issued the final revised ICH Q&A on the clinical and nonclinical evaluation of QT/QTc interval prolongation and proarrhythmic potential. In plain terms: the harmonised expectations for how cardiac safety data — clinical and nonclinical together — should be generated and interpreted when assessing a product's effect on the QT interval are now settled in their updated form. Teams planning thorough-QT strategies or concentration–QTc analyses should work from the R1 text.

FDA / ICH — E2B(R3) implementation guide, final (1 October 2026). FDA issued the final E2B(R3) *Electronic Transmission of Individual Case Safety Reports Implementation Guide — Data Elements and Message Specification*, together with the appendix on backwards and forwards compatibility. This is the technical rulebook for electronic safety reporting: pharmacovigilance and IT teams building or validating ICSR gateways should confirm their mappings against this final version.

FDA — Biosimilar postapproval manufacturing changes Q&A, final (9 October 2026). The final Q&A, *Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products*, sets out FDA's current thinking on how manufacturing changes to licensed biosimilars are categorised and reported after approval. Relevant to any biosimilar licence holder planning process or site changes — and it pairs with the Swiss biosimilar changes in Section 4.

FDA — Prescription drug use-related software, final (20 October 2026). The final guidance *Regulatory Considerations for Prescription Drug Use-Related Software* clarifies how FDA treats software distributed with or for a prescription drug: when software output is treated as required labelling versus promotional labelling, when a companion app should be referenced in the prescribing information, and what should be submitted to the agency. Product teams pairing apps with medicines now have a settled framework to design against.

FDA — Essential drug-delivery performance characteristics, draft (29 October 2026). A new draft guidance on the essential performance characteristics of devices intended to deliver drugs and biological products. Combination-product sponsors should review it against current design verification plans while it is still in draft and open to influence.

3. CTIS / EMA procedural notes

CTIS safety module for annual safety reports. EMA's CTIS system releases page confirms the new safety module for the submission and management of ASRs, with the transition from the current functionality completing on **30 November 2026**. Practical points we flag for sponsors: the module works with its own roles (including ASR Submitter), so access rights need to be checked rather than assumed; ASRs already in progress in the legacy functionality are completed there and will not migrate, which is why EMA advises downloading submissions and RFI responses before the transition period ends; and the CTIS training environment is available for familiarisation.

ACT EU pre-submission advice becomes permanent. The ACT EU clinical trial applications advice pilot — coordinated by the Heads of Medicines Agencies through the Clinical Trials Coordination Group (CTCG) — will become a permanent initiative from **January 2027**. Since 2024 the pilot has given sponsors consolidated feedback from the Member States concerned before they submit a clinical trial

application through CTIS; before the pilot, that support existed only at national level. ACT EU will manage applications already submitted under the pilot until the end of 2026, a lessons-learned report covering roughly 30 pilot applications is due before the end of 2026, and updated guidance documents and templates will appear on the CTCG website in January 2027. For sponsors planning 2027 CTAs, consolidated EU-level advice is now a standard step to build into the timeline, not an experiment.

4. Swissmedic specifics

swissdamed: registration and importer linking. Device registration in swissdamed has been mandatory since 1 July 2026 for devices, systems and procedure packs placed on the Swiss market; devices already on the market can be registered retrospectively until **31 December 2026**, and from **1 January 2027** registration must happen *before* placing on the market. Importers do not register devices themselves — they link their actor registration to devices already registered by the manufacturer or authorised representative, based on the UDI-DI, at no cost. The linking function has been available since 1 October 2026, with a transitional period until **1 April 2027** during which Swissmedic will not take enforcement measures solely for a missing link. Swissmedic also updated its information sheet *Obligations of Economic Operators in Switzerland* (version 8.0, valid from 26 October 2026), which consolidates these deadlines.

Parallel import guidance revised (in force 1 October 2026). Swissmedic has updated the guidance document *Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)*. The term "country of export" is now defined in more detail; the primary packaging rules now state expressly that Swissmedic does not accept additional labels stuck onto foreign primary packaging — for example to add translations into the official Swiss languages; and the secondary packaging section now adds that the excipient composition statement, storage instructions and handling information should be as stated on the foreign packaging. Parallel importers should check current packaging projects against the revised text.

Biosimilar guidance revised (in force 1 October 2026). Following finalisation of EMA's reflection paper on a tailored clinical approach in biosimilar development, Swissmedic has adapted its guidance document *Authorisation Biosimilar* accordingly. The accompanying Q&A document (version dated 1 October 2026) was also revised — notably, there is **no longer a "bridging" requirement** where comparability work was done with an EU or US comparator and the Swiss reference product is not marketed in Switzerland; instead, the suitability of the foreign comparator must be demonstrated under section 5.4 of the guidance. Authorisation as a biosimilar still requires that a reference product was authorised in Switzerland at some point — otherwise the product is treated as a new authorisation with a new active substance.

eCTD v4.0: Swiss Implementation Guide v2.0 published (26 October 2026). Swissmedic has published version 2.0 of the Swiss Implementation Guide package for eCTD v4.0 — the Implementation Guide, the controlled vocabulary lists including Genericode files, and the Validation Criteria, all at v2.0, replacing v1.1. Swissmedic will complete the technical implementation of eCTD v4.0 by the end of 2026, with go-live during 2027 once pilot testing is complete. Regulatory operations teams should already be validating their publishing tools against the v2.0 package, and Swissmedic invites feedback on the technical documents through its contact channels.

Pharmacopoea Helvetica 13 published (16 October 2026). The new, 13th edition of the Swiss Pharmacopoeia has been published; the Swissmedic Agency Council has set its entry into force for **1 April 2027**. Quality teams with Swiss-specific monographs or small-quantity manufacturing chapters in scope should plan the changeover now.

Also noted: Swissmedic updated the application forms for new authorisations of human medicinal products and for variations and extensions, effective 1 November 2026, following changes to the medicinal product categories.

5. What we'd do

On swissdamed — treat December as the deadline, not April. The dates that matter are staggered, and the comfortable reading (nothing is enforced until 1 April 2027) is the risky one. Our sequencing for importers and Swiss authorised representatives: first, reconcile the device portfolio against what is actually on the Swiss market today — in our experience this inventory step, not the registration itself, is where companies underestimate the work, because legacy products, systems and procedure packs surface that nobody has touched in years. Retrospective registrations should be submitted through November and December, not in the final week before 31 December, when the authorised representative's queue becomes everyone's bottleneck. Second, once registrations exist, work the importer links by UDI-DI in the same pass — the link can only be made after registration, so a late registration silently becomes a late link. From 1 January 2027 the discipline changes entirely: registration

becomes a pre-market step, so it belongs in the launch checklist alongside labelling and the CH-REP mandate, not in a clean-up project afterwards.

On CTIS — close out the legacy ASRs now, and put ACT EU advice in the 2027 plan by default. Two practical moves. Before 30 November, download every legacy ASR submission and RFI response you may ever need to defend — in-progress reports will not migrate, and reconstructing a safety-reporting history after access ends is the kind of archaeology nobody budgets for. Confirm the ASR Submitter role is actually assigned to named people, not assumed. Then, for any EU trial starting in 2027: the ACT EU pre-submission advice becoming permanent changes the planning maths. Consolidated Member State feedback before filing used to be a pilot you might or might not get; from January it is a standard step, and we would build it into the timeline the way scientific advice already is — early enough that the answers can still change the protocol, with the lessons-learned report (due end of 2026) read before applying, so the first permanent-round applications benefit from what the pilot sponsors got wrong.

On the FDA genome editing draft — yes, comment, and comment on the boundaries. Frameworks like this one are written once and lived with for a decade; the comment window (to 27 November) is the cheapest influence a sponsor in this space will ever buy. We would focus comments on three points. First, the definition of the Individualized Feature Space itself: how wide the predefined boundaries may be, and what evidence FDA expects when a sponsor proposes them — the workability of the whole model sits in that definition. Second, the data standard for adding a new variant inside the space: "laboratory data, without a new clinical trial" needs concrete expectations, or sponsors will discover the real bar case by case. Third, postapproval management: what reporting and long-term follow-up FDA envisages as the number of patient-specific variants under one licence grows. Even companies not yet at BLA stage should comment or align with trade-association comments — this draft will be cited in every platform discussion that follows.

On biosimilars — October moved both sides of the Atlantic in the same direction: less bespoke clinical work, more discipline after approval. Read together, the Swiss revision and FDA's final Q&A tell one story. On the way in, Switzerland has now aligned itself with EMA's tailored clinical approach and dropped the bridging requirement for EU/US comparators — so a single, well-designed comparability package increasingly serves the EU, Switzerland and the US, and development plans still budgeting separate bridging work or full clinical efficacy packages by default should be revisited; the money is better spent on analytical comparability, which is where these files are actually won and lost. On the way through the lifecycle, FDA's postapproval manufacturing-changes Q&A is the counterpart: as clinical expectations lighten, manufacturing change control becomes the critical discipline, and biosimilar holders should map their planned process and site changes against the final categorisation now, not when the change is already scheduled. Our net advice: one global comparability strategy, built analytics-first, with a manufacturing-change register maintained against both FDA's Q&A and the Swiss/EU variation framework from day one.

The Regulatory Watch is prepared by our team and reviewed by Carlos Vijande Rodriguez. We work with sponsors, CROs and medtech companies on clinical trial applications, marketing authorisations and lifecycle management across the EU, Switzerland and the US — and on the volume work inside regulatory departments. If a change in this issue touches your programme, we are glad to talk it through.

Information and commentary, not legal advice. This sample issue is based solely on public publications of the authorities listed below, as retrieved on 1 November 2026.

Sources

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