iFeed | WEEKLY SIGNALS · W25 · 15 – 21 JUN 2026

9 signals this week: 4 Quality, 1 Clinical trials, 4 Regulatory

Nine developments across quality, clinical trials and regulatory, each traced to its primary source and selected by iFeed. Covering 15 – 21 Jun 2026.

Nine signals • traced to primary sources • selected by iFeed

1 SIG Regulatory 2026-06-18

FDA VRBPAC votes 9-0 to recommend Moderna mFlusiva mRNA flu vaccine for adults 50+

FDA's Vaccines and Related Biological Products Advisory Committee voted unanimously 9-0 on June 18 that the benefits of Moderna's mFlusiva (mRNA-1010) outweigh its risks for adults 50+, making it the first mRNA-based seasonal influenza vaccine to reach this regulatory threshold. Phase 3 data showed 26.6% relative vaccine efficacy against influenza-like illness and 47.9% against healthcare outcomes. FDA approval decision is due by August 5, 2026, with EU regulatory submissions already active.

WHY IT MATTERS

NIAC and JCVI will need to evaluate mFlusiva once FDA rules by 5 August, since a positive US approval puts an mRNA option in front of national immunisation committees that have only ever assessed egg- or cell-based flu vaccines for routine seasonal use.

WHAT TO CHECK

BLA licensure under 21 USC 351; accelerated-approval pathway under 21 CFR 601.41-44 applies to the 65+ population and carries a Phase IV confirmatory-trial requirement FDA will need to enforce post-approval.

Source · FDA Center for Biologics Evaluation and Research (CBER) / VRBPAC ↗

2 SIG Regulatory 2026-06-16

CMS proposes rule codifying Medicare Drug Price Negotiation Program and Part D policies

CMS published a proposed rule to codify Medicare Drug Price Negotiation Program policies in the Code of Federal Regulations, moving IRA drug pricing from operational guidance into permanent regulatory text. The rule also proposes new policies including treatment of fixed-combination drugs and updates Medicare Part D provisions.

WHY IT MATTERS

Codifying negotiation into the CFR means the program's mechanics survive a change in administration, not just an executive term, and the rule's proposed treatment of fixed-combination drugs, which iFeed flagged as unresolved in prior weeks, is now written down for comment. Irish and EU teams with combination products on the Medicare formulary should read that section specifically before 17 August.

WHAT TO CHECK

42 CFR Part 429 (proposed); Medicare Drug Price Negotiation Program under Sections 1191-1198 of the Social Security Act, as required by the Inflation Reduction Act of 2022.

Source · Federal Register / CMS ↗

3 QMS Quality 2026-06-17

FDA codifies Class II pathway for ML-based radiology software with PCCP

FDA classified radiological machine learning–based quantitative imaging software with a predetermined change control plan into Class II with special controls, effective 2026-06-17. ([Federal Register][1])

WHY IT MATTERS

SaMD teams building radiology AI without a PCCP-based change-control process are now working against a codified special control, not just an FDA preference, algorithm retraining, threshold changes, and dataset expansion all need PCCP documentation before deployment under this classification.

WHAT TO CHECK

21 CFR classification (91 FR 36522, Doc. 2026-12166); manufacturers of ML-based radiology quantitative imaging software fall under this Class II special-controls framework, including the PCCP documentation requirement, design verification/validation, and version-history labeling.

Source · federalregister.gov ↗

4 QMS Quality 2026-06-11

EMA PRAC restricts Ixchiq chikungunya vaccine to individuals at high risk of infection

EMA PRAC recommended restricting Ixchiq to individuals at high risk of chikungunya infection following review of serious adverse-event reports. The committee also endorsed a direct healthcare professional communication (DHPC) to inform prescribers immediately. This is a live benefit-risk restriction with immediate clinical implications.

WHY IT MATTERS

HPRA will relay the DHPC to Irish prescribers, and travel medicine practitioners need to apply the high-risk restriction now, before the label text itself is updated, since PRAC's guidance is that Ixchiq "should only be given to individuals 12 years of age and older who are at high risk of acquiring chikungunya infection and after careful consideration."

WHAT TO CHECK

EMA PRAC benefit-risk review under GVP Module IX; DHPC dissemination to prescribers; the label itself has not yet caught up, so the DHPC is the operative document until it does.

Source · European Medicines Agency, PRAC ↗

5 CT Clinical trials 2026-06-18

NEJM trial: cefazolin noninferior to flucloxacillin for MSSA bacteremia with fewer nephrotoxic effects

The New England Journal of Medicine published an RCT demonstrating that cefazolin was noninferior to flucloxacillin/cloxacillin for 90-day mortality in MSSA bacteremia and was associated with significantly fewer nephrotoxic adverse effects. The trial provides practice-ready evidence for a lower-toxicity standard-of-care shift in one of the most common and serious hospital infections.

WHY IT MATTERS

MSSA bacteremia is common and carries meaningful mortality risk, so a trial-backed case for a lower-toxicity first-line agent is the sort of result Irish hospital empirical-prescribing guidelines tend to adopt within a cycle or two, not something that sits in the literature unused.

WHAT TO CHECK

Peer-reviewed RCT evidence (NEJM, SNAP trial); hospital antimicrobial stewardship committees and formulary bodies are the relevant governance layer for adopting the finding into treatment protocols.

Source · New England Journal of Medicine ↗

6 SIG Regulatory 2026-06-18

NICE TA1167 recommends serplulimab with chemotherapy for extensive-stage small-cell lung cancer

NICE published TA1167 recommending serplulimab with carboplatin and etoposide as an option for previously untreated extensive-stage small-cell lung cancer in adults. The guidance provides NHS technology appraisal recommendations and supporting evidence.

WHY IT MATTERS

NICE decisions in SCLC get watched as comparator benchmarks well outside England, and NCPE and other EU HTA teams will inherit the same indirect-comparison uncertainty NICE's committee flagged when they model this indication.

WHAT TO CHECK

NICE technology appraisal TA1167; NHS bodies in England and Wales have a statutory duty to fund and resource the recommended treatment once published.

Source · NICE ↗

7 QMS Quality 2026-06-16

WHO alert: falsified Jakavi (ruxolitinib) identified in European and Eastern Mediterranean regions

WHO issued Medical Product Alert N°2/2026 identifying falsified Jakavi (ruxolitinib, a specialist oncology/myelofibrosis therapy) in the Eastern Mediterranean and European regions. Falsified products were found to be illicitly sold via online platforms and, in at least one instance, supplied from a pharmacy. WHO urges healthcare providers and patients to verify product authenticity.

WHY IT MATTERS

Ruxolitinib for myelofibrosis has a narrow therapeutic margin, and WHO's own warning is blunt: use of a falsified product "may lead to treatment failure, resulting in progression of serious disease and an increased risk of death due to lack of therapeutic effect." HPRA and other national regulators will relay this alert to prescribers and pharmacies directly.

WHAT TO CHECK

WHO substandard and falsified medical products surveillance; national pharmacovigilance and supply-chain controls

Source · World Health Organization ↗

8 SIG Regulatory 2026-06-09

NCPE recommends full HTA for pembrolizumab in resectable locally advanced head and neck cancer

NCPE recommended a full health technology assessment after rapid review to assess the clinical and cost effectiveness of pembrolizumab for resectable, locally advanced head and neck squamous cell carcinoma. The full HTA submission was received from the applicant on June 9, 2026. This signals that Irish reimbursement review is now formally underway for this indication.

WHY IT MATTERS

Irish oncology market-access teams tracking NCPE now have a concrete timeline to work against: submission received 9 June, preliminary review out 16 July, with the full assessment still to come, plan evidence and pricing strategy around that clock, not a general expectation of review.

WHAT TO CHECK

NCPE HTA pathway (rapid review to full HTA escalation); HSE reimbursement decision follows the completed assessment.

Source · NCPE ↗

9 QMS Quality 2026-06-22

India prohibits manufacture, sale and distribution of 16 fixed-dose combinations

India's Union Ministry of Health and Family Welfare announced prohibition of manufacture, sale, and distribution of 16 fixed-dose combinations in public interest under the Drugs and Cosmetics Act. The action targets FDCs without demonstrated clinical advantage and with potential safety concerns.

WHY IT MATTERS

Global pharma with Indian manufacturing or export exposure in dermatology, pain, antispasmodic, or antibiotic FDCs should check whether their portfolio includes a chemically similar combination, this is a standing India Watch category for iFeed, and DTAB's committee-review approach here is the template it's likely to keep using.

WHAT TO CHECK

Drugs and Cosmetics Act (Section 26A); DTAB expert-committee clinical review preceding the MoHFW prohibitory order.

Source · Press Information Bureau / Ministry of Health and Family Welfare, India ↗