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EU Life Sciences Reforms: The Evolving Landscape for Clinical Development, Market Access and Manufacturing

Client Update – July 2026

Dear Clients,

The EU is pursuing a coordinated set of legislative and policy reforms intended to strengthen its life sciences sector, accelerate regulatory pathways and incentivise EU-based research, clinical development and manufacturing. The measures span clinical trials, medicinal-product marketing authorisations, medical devices and in vitro diagnostic medical devices, combined studies, regulatory sandboxes and incentives for certain biotechnology products. If adopted and implemented as proposed, they may affect development timelines, regulatory strategy, manufacturing planning and market-access pathways for Israeli companies operating in the EU life sciences sector.

The reforms may create meaningful strategic opportunities, but also reinforce the need to integrate EU regulatory, clinical, IP and manufacturing considerations earlier in product development. The reforms are particularly relevant to pharmaceutical, biotechnology and medical device companies conducting EU clinical studies, seeking EU market access or working with EU manufacturing and supply chain partners, including Israeli companies with material EU activities. Most measures remain proposed or are being implemented progressively, and their final scope and practical impact will depend on the legislative process and operational practice.

1. Faster approvals and less regulatory friction

Clinical trials

The proposed European Biotech Act would simplify aspects of clinical development in the EU. Among other measures, it would reduce the maximum authorisation period for initial multinational clinical trial applications from 106 to 75 days, or to 47 days where no request for information is issued to the sponsor.

It would also remove the additional 50-day review period currently applicable to clinical trials involving advanced therapy medicinal products (ATMPs), and permit sponsors to use a single dossier as the basis for multiple trials involving the same investigational medicinal product.

For Israeli biotech and pharma companies, these changes could make EU multinational studies more predictable and potentially improve the feasibility of including EU sites in global development programmes.

Medicinal-product marketing authorisations

The proposed reform of the EU's general pharmaceutical legislation would shorten the EMA's standard assessment period for centralised marketing-authorisation applications from 210 to 180 days, and to 150 days for medicines of major public-health interest. The European Commission's decision-making period would also be reduced.

This may be particularly relevant to Israeli companies developing innovative medicines, biologics or ATMPs that intend to pursue an EU centralised authorisation alongside, or shortly after, US regulatory submissions.

Medical devices and IVDs

For medical devices and IVDs, conformity assessment capacity and timelines at notified bodies remain a practical barrier to EU market access. Commission Implementing Regulation (EU) 2026/977 introduces more harmonised procedural requirements for

notified bodies under the MDR and IVDR, including rules on quotations, assessment timing, interruptions, recertification and performance reporting.

The Regulation also establishes maximum timelines for certain assessment stages, including 120 days for quality-management-system auditing and 90 days for product or technical documentation assessment. For Israeli manufacturers seeking EU market access, these measures may improve visibility over anticipated certification timing and costs, although the practical benefit will depend on notified-body capacity and implementation.

Combined medicinal product, device and IVD studies

Sponsors of combined studies currently face overlapping requirements under the Clinical Trials Regulation, MDR and IVDR. The COMBINE pilot is testing a more coordinated process through CTIS for selected combined-study applications.

The proposed European Biotech Act seeks to establish a permanent single-assessment procedure for such studies, supported by corresponding MDR and IVDR amendments. This could be significant for Israeli companies developing drug-device combinations, companion diagnostics or integrated therapeutic and diagnostic platforms.

Regulatory sandboxes

The EU is also proposing regulatory sandboxes for innovative medicinal products, clinical trial designs, health-biotechnology products and medical devices. These controlled environments are intended to allow targeted regulatory adaptations where standard requirements could otherwise materially delay development of innovations addressing unmet medical needs.

Israeli innovators should monitor the eligibility criteria and practical operation of these sandboxes, particularly where novel technology does not fit comfortably within established EU regulatory pathways.

2. Incentives for EU-based R&D and manufacturing

The reforms also seek to encourage clinical development and manufacturing activity within the EU.

Proposed SPC extension for certain biotechnology medicines

The proposed European Biotech Act would introduce a potential 12-month supplementary protection certificate extension for eligible biotechnological medicinal products, including certain ATMPs. The proposed extension remains subject to the final legislative text and the detailed eligibility framework.

Eligibility depends on conditions including:

1. The product must contain a new active substance distinct from authorised EU medicines.
2. The product must have a distinct mechanism of action, with safety and efficacy at least equivalent to authorised EU products for the same disease.
3. Supporting efficacy trials must be conducted in more than two EU Member States.
4. At least one manufacturing step must be performed in the EU, excluding packaging, quality testing and certification.

This proposal is strategically relevant to Israeli life sciences companies with EU commercial ambitions. It may affect decisions regarding EU trial site selection, manufacturing footprint, technology transfer arrangements and supply chain structuring. Companies should assess early whether their anticipated development and manufacturing model could meet the proposed conditions.

Additional market-protection incentive

The proposed general pharmaceutical legislation would also offer an additional year of market exclusivity where qualifying efficacy trials are conducted in more than one EU

Member State, subject to further conditions, including either a comparative clinical trial or timely EU filing relative to filings outside the EU.

For Israeli originator companies, this may create an additional reason to consider EU clinical development and EU-first or near simultaneous filing strategies at an early stage.

3. Targeted incentives for priority innovation areas

Priority antimicrobials

The proposed pharmaceutical reform includes a transferable exclusivity voucher for qualifying priority antimicrobials. The voucher would provide one additional year of regulatory data exclusivity against generic and biosimilar competition.

This may be relevant to Israeli companies active in anti-infectives, antimicrobial resistance technologies and related platforms. However, the commercial value will depend on the final eligibility framework, transferability conditions and the ultimate structure of the wider pharmaceutical package.

Breakthrough and orphan devices

Proposed MDR and IVDR reforms would introduce an adaptive pathway for breakthrough and orphan or niche devices, including IVDs. Where the relevant status is confirmed, notified bodies would be expected to prioritise certification and may use rolling review. Manufacturers could also obtain expert-panel input on clinical development or performance-evaluation strategy.

The EMA's April 2026 pilot on breakthrough device eligibility and scientific advice is therefore particularly relevant to Israeli medical device and diagnostic companies developing novel products for serious conditions, small patient populations or unmet medical needs.

Practical implications for Israeli companies

The reforms may improve the case for including EU sites in global clinical-development programmes. Shorter authorisation timelines, a potential streamlined pathway for

combined studies and incentives linked to trials conducted in multiple EU Member States could make EU clinical development more attractive for Israeli sponsors, particularly in programmes involving ATMPs, drug device combinations or companion diagnostics.

For companies pursuing EU market access, the notified body reforms may offer greater predictability in MDR and IVDR certification planning. Nonetheless, manufacturers should continue to account for notified body capacity, the quality and completeness of their technical documentation, and the potential for interruptions during conformity assessment.

Companies developing biotechnology medicines, biologics and ATMPs should assess their proposed EU manufacturing and supply chain model at an early stage. The proposed SPC extension could make an EU manufacturing step commercially valuable for qualifying products, while product development and technology transfer choices made before pivotal trials may later determine whether the relevant conditions can be satisfied.

Israeli originator companies should also consider the interaction between EU clinical development, filing strategy and regulatory exclusivity incentives. The proposed additional market protection period may favour efficacy trials conducted in multiple EU Member States and EU-first, or closely timed, marketing-authorisation submissions.

Finally, developers of novel medical devices, IVDs and digital-health-enabled technologies should monitor the proposed breakthrough and orphan-device pathways, as well as regulatory sandbox initiatives. These programmes may provide an opportunity for earlier regulatory engagement, targeted expert input and, potentially, a more tailored route to EU market access.

Israeli companies with material EU clinical, commercial or manufacturing activities should consider these developments as part of their broader EU regulatory and product development strategy.

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As always, the team at Agmon with Tulchinsky remains at your disposal.

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