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EU AI Act High-Risk Compliance: Pharma & Medical Devices

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Executive Summary

This report provides an in-depth analysis of how the EU's Artificial Intelligence Act (Regulation (EU) 2024/1689) affects **pharmaceutical** and **medical device** sectors, with a focus on the August 2026 (and beyond) compliance deadline for high-risk AI systems. We examine the Act's risk-based classification, identify which AI applications in pharma and medtech qualify as "high-risk," and summarize the layered compliance requirements. Key findings include:

- **High-Risk Scope:** Medical-device AI is high-risk under the product route only when **both** Article 6(1) conditions are met: the AI is itself a product, or is intended as a safety component of a product, covered by Annex I legislation; and that product must undergo mandatory third-party conformity assessment under that legislation (Article 6). Device integration or CE marking alone is insufficient. Applications to assess include diagnostic imaging software and "software as a medical device" (SaMD) for patient monitoring. Internal pharmaceutical R&D and manufacturing are not blanket exclusions: Article 2(6) covers AI specifically developed and put into service solely for scientific research and development; Article 2(8) covers AI development, research and testing before market placement or putting into service, excluding real-world testing (Article 2). Assess scope and high-risk classification separately. See Table 1 below for activities and roles.
- **Dual Compliance Model:** Medical device manufacturers face a **dual compliance obligation**. They must meet both the AI Act's high-risk requirements and the existing MDR/IVDR requirements simultaneously (meddeviceguide.com) (www.pureglobal.com). The AI Act does **not replace** MDR/IVDR; rather, it adds a new overlay focused on AI system safety, governance, and fundamental-rights protections (meddeviceguide.com) (www.pureglobal.com). Crucially, Article 8 of the AI Act allows integration of AI-specific testing, documentation, and procedures into the existing MDR conformity processes to avoid duplication (ai-act-service-desk.ec.europa.eu) (meddeviceguide.com). The EU's Medical Device Coordination Group has issued guidance (MDCG 2025-6) clarifying this interplay: device manufacturers should align AI Act risk assessments, data governance, and technical documentation with their MDR/IVDR QMS and clinical evaluations (meddeviceguide.com) (www.pureglobal.com).

- **Timeline – August 2026 and Beyond:** The AI Omnibus entered into force on **27 July 2026** (European Commission). Under current Article 113, Chapter III Sections 1–3, except Article 6(5), apply from **2 December 2027** for Article 6(2)/Annex III high-risk systems and **2 August 2028** for Article 6(1)/Annex I high-risk systems, including qualifying MDR/IVDR AI. These are classification-based dates, rather than a distinction between CE-marked devices and other AI. Other provisions already apply on their own timetable (Article 113); existing systems also require a separate transition assessment under Article 111. Table 2 summarizes the application dates.
- **Core Obligations:** High-risk AI systems must satisfy **stringent requirements** (Articles 9–15). Key obligations include establishing a continuous AI-specific risk management system (integrated into ISO 14971 for devices) (meddeviceguide.com); enforcing rigorous data governance (training/validation data must be high-quality, representative, and bias-controlled (meddeviceguide.com) (www.europeanpharmaceuticalreview.com)); compiling comprehensive technical documentation (per Annex IV of the AI Act) before placing the system on the market (ai-act-service-desk.ec.europa.eu) (meddeviceguide.com); implementing human oversight and transparency measures (e.g. informing users and allowing intervention) (www.pureglobal.com); and deploying robust accuracy, robustness, and cybersecurity testing (www.pureglobal.com). Providers of high-risk AI must also maintain a quality management system and post-market monitoring plan (Art.17 and Art.72) that align with, yet extend beyond, existing device/QS requirements (www.raps.org) (www.pureglobal.com). For example, “functional traceability” logs (automated recording of AI behavior) are now required to detect bias or cyber threats (www.pureglobal.com).
- **Implementation Challenges:** Compliance will require significant investments in process redesign, documentation, and training. Medical device companies must update their MDR/IVDR processes (clinical evaluation, PMS, QMS) to embed AI-specific checks (meddeviceguide.com).Pharmaceutical companies using AI for regulated clinical purposes (e.g. companion diagnostics, trial recruitment) may face uncertainty, as many AI uses in drug development are not clearly addressed by existing frameworks (www.pinsentmasons.com) (efpia.eu). Industry experts note that pending guidance (from the Commission and EMA) will be critical to resolve ambiguities and trade-secret concerns (www.pinsentmasons.com) (efpia.eu).
- **Outlook:** In the near term, firms need to map all AI systems against the AI Act’s definitions and begin building “AIS Act–ready” processes. The sector is working closely with regulators: the EMA issued an AI reflection paper (Sept 2024) and is developing guidelines, and some national authorities (e.g. CNIL in France) are drafting healthcare-specific AI guidance (www.europeanpharmaceuticalreview.com). Over the longer term, the AI Act’s emphasis on data quality, transparency, and safety is expected to foster greater public trust in AI-driven healthcare solutions, even as companies grapple with compliance costs (www.europeanpharmaceuticalreview.com). This playbook discusses preparation for the high-risk application dates of **2 December 2027** for Article 6(2)/Annex III systems and **2 August 2028** for Article 6(1)/Annex I systems, alongside obligations that already apply (Article 113).

1. Introduction and Regulatory Background

1.1 The EU AI Act: A New Horizontal Regulation

In July 2024 the EU formally adopted Regulation (EU) 2024/1689 (the “AI Act”), the world’s first comprehensive AI framework (pharmacystandards.org) (commission.europa.eu). The Act takes a **horizontal, risk-based** approach — it applies across industries (banking, HR, healthcare, etc.) and classifies AI systems by risk level (pharmacystandards.org) (commission.europa.eu). Minimal-risk AI (e.g. video games, spam filters) is largely unregulated, while certain “transparency-risk” AI (e.g. chatbots disclosing their nature) carry mild obligations (commission.europa.eu). At the top of the pyramid are **“high-risk” AI systems**, which must meet strict requirements (Annexes and Articles 8–15). By focusing on risk, the AI Act aims to protect people’s **health, safety and fundamental rights** without unduly hindering innovation (commission.europa.eu) (www.nature.com).

Historically, the healthcare and pharmaceutical industries were regulated by sector-specific “vertical” laws (e.g. MDR for devices, EMA guidelines for medicines) focused on safety and efficacy (pharmacystandards.org) (www.nature.com). The AI Act overlays this with a horizontal layer. As one legal analysis points out, companies must now satisfy both the **vertical** country- or industry-specific rules and the **AI Act’s horizontal obligations** (pharmacystandards.org) (meddeviceguide.com). In regulators’ words: imagine two inspectors – the “hospital electrical inspector” (focused on traditional medical device standards like ISO 13485/GMP) and the “city building inspector” (enforcing broad AI safety and rights rules); a facility must pass both (pharmacystandards.org).

1.2 Structure and Timeline of the AI Act

The AI Act entered into force on **1 August 2024** (European Commission). Entry into force did not make the original prohibitions immediately applicable. Chapters I–II, including definitions, the original AI-literacy provision and the initial prohibitions, applied from **2 February 2025**. The specified GPAI, governance, notified-body and penalty provisions applied from **2 August 2025**, except Article 101. The general application date, including Article 50 transparency obligations, is **2 August 2026**, subject to specific transitions. Current Article 113 defers Chapter III Sections 1–3, except Article 6(5), to **2 December 2027** for Article 6(2)/Annex III systems and **2 August 2028** for Article 6(1)/Annex I systems. The added Article 5 provisions identified in Article 113(a) apply from **2 December 2026**; Article 111(4) separately gives certain existing content-generating systems until that date for Article 50(2) (Article 113; Article 111).

Article 6(5) set **2 February 2026** as the statutory target for classification guidelines (Article 6). The Commission published **draft classification guidelines on 19 May 2026** (Commission draft); the consultation deadline was extended to **23 July 2026**. The consultation page states that final guidelines will be adopted by the end of 2026, so the published draft should be distinguished from final guidance (Commission consultation).

1.3 Scope: High-Risk AI Systems (Annexes I–III)

High-risk AI is defined through two routes. First, Article 6(1) applies only when **both** Article 6(1) conditions are met: the AI is itself a product, or is intended as a safety component of a product, covered by Annex I legislation; and that product must undergo mandatory third-party conformity assessment under that legislation.

MDR and IVDR are included in Annex I. Both conditions must therefore be checked for a device or its AI safety component; integration into a device does not establish high-risk status by itself (Article 6; MDCG 2025-6, Q2).

- By contrast, **AI in products not covered by Annex I** (e.g. fitness trackers or administrative tools) may avoid the “product safety” high-risk label, though they could still be caught by the second prong below in some cases.

Second (Annex III/Art.6(2)), *specific AI use-cases affecting health, safety, or fundamental rights* are high-risk by themselves. Annex III enumerates scenarios such as biometric ID, law enforcement profiling, credit scoring, etc. (artificialintelligenceact.eu). Of those, the ones potentially relevant to healthcare include **eligibility evaluation for healthcare benefits, and insurance risk assessment for health/life** (artificialintelligenceact.eu). For instance, an AI tool determining whether a citizen qualifies for public health coverage would be high-risk. However, typical pharmaceutical or device R&D uses are not directly listed in Annex III. Thus for **pharmaceutical AI**, classification depends primarily on whether the AI system falls under a regulated product category or triggers one of the listed high-risk scenarios.

Importantly, **there is no broad exemption for pharmaceuticals**: unless covered by R&D exemptions (below) or not listed in either Annex, pharma AI remains subject to the Act’s general provisions. Clinician- and patient-facing tools (like AI for diagnosis or triage) effectively become medical devices and thus fall under the Act. Conversely, purely internal R&D or manufacturing support tools may be exempt or not high-risk (see Section 2.3 below on pharma specifics).

2. High-Risk Classification for Pharma and Medical Devices

2.1 Medical Devices (MedTech AI)

AI-enabled medical devices are **not automatically high-risk** under the AI Act. Article 6(1) applies only when **both** Article 6(1) conditions are met: the AI is itself a product, or is intended as a safety component of a product, covered by Annex I legislation; and that product must undergo mandatory third-party conformity assessment under that legislation. The same assessment applies whether the AI is marketed independently or with the product. Neither CE marking nor the presence of AI alone replaces these tests (Article 6; MDCG 2025-6, Q2).

MDCG 2025-6 uses “Medical Device AI” (MDAI) for the medical-device AI covered by its guidance, but MDAI is high-risk under Article 6(1) only if **both cumulative conditions** are met. Its Q2 table distinguishes ordinary MDR Class I devices (non-sterile, non-measuring and not reusable surgical instruments) and non-sterile IVDR Class A devices, which do not require notified-body assessment, from qualifying Class I sterile/measuring/reusable-surgical devices and Class A sterile devices that do. The table also covers MDR Classes IIa–III and IVDR Classes B–D. The in-house entry is limited to devices meeting **MDR/IVDR Article 5(5)**; internal hospital use alone is insufficient. Assess any Annex III use separately (MDCG 2025-6, Q2 and Table 1; Article 6).

Because of the overlap with MDR/IVDR, *dual compliance* is required. In Congress’ wording, the AI Act is a "layered rule-set" on top of MDR/IVDR (www.raps.org). Providers of AI-enabled devices must ensure their products meet **both** sets of requirements (ai-act-service-desk.ec.europa.eu) (www.pureglobal.com). However,

Article 8 encourages merging processes: conformity assessments under MDR can (and should) be leveraged for AI testing and documentation (ai-act-service-desk.ec.europa.eu) (meddeviceguide.com). The MDCG FAQ confirms: manufacturers can integrate AI Act obligations into existing QMS, clinical evaluations, and technical files rather than duplicating work (www.pureglobal.com). For example, AI bias checks and cybersecurity tests can be added into the clinical evaluation plan, and a single unified technical file can cover both MDR and AI Act requirements (www.pureglobal.com).

Table 1. Roles and Obligations under the AI Act (Pharma/MedTech examples)

Before applying Table 1, document the system's high-risk classification under Article 6, the relevant application date under Article 113, and any transition under Article 111. The high-risk duties below apply only where that assessment establishes their applicability; in-house development, GMP/QC use or pharmacovigilance use alone does not establish high-risk status (Articles 8 and 16).

Company Activity	Role under AI Act	Key Obligations (High-Risk AI)
Purchasing commercial AI tool (e.g. an AI-powered pharmacovigilance database or imaging software)	*Deployer*	Use per IFU, ensure human oversight, monitor performance, report incidents (Article 26).
Developing AI tool in-house for company use (e.g. AI for GMP process control or QC in pharma)	*Provider* + *Deployer*, subject to the applicable role definitions	If the documented Article 6 assessment establishes high-risk status and the requirements apply after checking Articles 113 and 111, comply with the applicable provider and deployer duties. Internal development alone does not trigger the high-risk provider obligations (Article 16).
Supplying AI tool to hospital (e.g. AI endpoint in clinical trial)	*Provider*	All provider duties (see above). Must furnish the deployer (hospital) an Instructions for Use (Art.13), maintain post-market monitoring, and have incident-reporting system (pharmacystandards.org).
Re-branding ("white-label") another vendor's AI under own brand	*Provider*	All provider duties. Critically, putting it on the market under your name makes you the Provider legally (pharmacystandards.org). Must flow down QMS controls and obtain complete technical documentation from original developer.

Source: Council on Pharmacy Standards (adapted) (pharmacystandards.org).

Table 1 illustrates how the AI Act distinguishes **Providers** (those who develop or rebrand the AI) and **Deployers** (those who use it under their authority) (pharmacystandards.org). Deployers have significant duties (oversight, monitoring, incident-reporting (pharmacystandards.org)), but Providers bear the heaviest burden: they must integrate AI into their QMS, risk management, and all required documentation (pharmacystandards.org). These roles apply equally to pharma companies: a pharma firm that develops an AI diagnostic would be a Provider, whereas a hospital using that AI in patient care is a Deployer.

2.2 Pharmaceutical Sector (Life Sciences AI)

The applicability of the AI Act to **pharmaceutical companies** must be assessed separately from high-risk classification. Internal drug R&D or production use does not by itself establish an Article 2 exclusion. Where the Act applies, the product route requires both Article 6(1) conditions, while Annex III uses require a separate assessment under Article 6(2)–(3). Failure to qualify as high-risk does not itself remove a system from the Act's scope (Article 2; Article 6).

The research exclusions are **limited**. Article 2(6) excludes AI systems or models, including their outputs, specifically developed and put into service **solely for scientific research and development**. Article 2(8) separately excludes AI research, testing and development before market placement or putting into service; applicable Union law still governs those activities, and **real-world testing is not covered**. Manufacturing use and the use of a commercial AI system for research are not blanket exclusions (Article 2; Recital 25). EFPIA has argued for a broad interpretation for AI-based drug-development tools; that is EFPIA's position (EFPIA statement).

If a pharma company creates or supplies clinical AI, assess its intended purpose and product status rather than assuming that any healthcare use triggers the high-risk rules. An AI dosing or treatment-support tool must satisfy both Article 6(1) conditions to qualify through the product route: the AI must be a covered product or safety component, and mandatory third-party conformity assessment must be required. Assess Annex III separately (Article 6; MDCG 2025-6, Q2).

Industry experts note significant uncertainty and call for clear guidance. As one article observes, "pharmaceutical companies face significant uncertainties regarding compliance implementation and expect more guidance from authorities" (www.europeanpharmaceuticalreview.com). Both EFPIA and legal advisors are actively engaging with regulators. The Commission published **draft high-risk classification guidelines on 19 May 2026**, with practical examples to support classification; this draft should be distinguished from final guidance (Commission draft). The consultation page gives the extended closing date as **23 July 2026** and states that final guidelines will be adopted by the end of 2026 (Commission consultation). EMA's **final reflection paper on AI in the medicinal product lifecycle was published on 30 September 2024**; it discusses principles from drug discovery through the post-authorisation setting (EMA guideline; BDSG 2024 report).

Table 2. Regulation and Timeline

Event/Provision	Date or Deadline	Notes
AI Act enters into force	1 Aug 2024	Entry into force is distinct from application. Chapters I–II initially applied from 2 Feb 2025; specified GPAI/governance provisions from 2 Aug 2025; general application, including transparency rules, from 2 Aug 2026, subject to exceptions (Article 113).
Article 6(2)/Annex III high-risk systems	**2 Dec 2027**	Chapter III Sections 1–3, except Article 6(5), apply from this date under amended Article 113 (Article 113).
Article 6(1)/Annex I high-risk systems, including qualifying MDR/IVDR AI	**2 Aug 2028**	Both product-route classification tests must be met; this is not the Annex III deadline (Article 113).

Event/Provision	Date or Deadline	Notes
Commission guidelines for high-risk classification	Statutory target: 2 Feb 2026 (Article 6(5)); draft published 19 May 2026 (Commission draft)	Consultation closed 23 Jul 2026; the consultation page states that final guidelines will be adopted by the end of 2026 (Commission consultation).
MDCG guidance published (advisory FAQ)	Jun 2025 (www.pureglobal.com)	Clarifies AI Act–MDR interplay for devices (MDCG 2025-6).
AI Omnibus enters into force	**27 Jul 2026**	The amendments are enacted; they are no longer a pending proposal (Commission notice).

3. Key Compliance Requirements for High-Risk AI

Once an AI system is classified as high-risk, the Act imposes **comprehensive obligations** (Chapter III, Sections 2–3). These cover the entire AI lifecycle, from design and training through deployment and post-market surveillance. Many requirements mirror existing device engineering principles but with AI-specific enhancements. We summarize the main areas below (see Chapter III, Sections 2–3 for requirements and obligations, starting with Article 8):

- **Risk Management (Art.9):** Providers must establish an AI-specific risk management system throughout the product's life (ai-act-service-desk.ec.europa.eu) (meddeviceguide.com). This means continually identifying known and foreseeable risks (including from intended use and misuse), estimating their probability and severity, and applying mitigations (meddeviceguide.com). Merely complying with ISO 14971 for device safety is insufficient; AI hazards must be included (e.g. *data drift*, *model degradation*, *adversarial attacks*, *algorithmic bias*) (meddeviceguide.com). The outputs of the risk analysis (residual risks, validation evidence) must be documented. In practice, device manufacturers are advised to extend their ISO 14971 files to explicitly address AI failure modes (meddeviceguide.com).
- **Data and Data Governance (Art.10):** Perhaps the most burdensome requirement is on data quality. Training, validation, and testing datasets must meet **strict quality criteria** (meddeviceguide.com). For example, data must be ***relevant*** and sufficiently representative of the EU target population (meddeviceguide.com). Providers must identify and mitigate *biases* in the data: e.g., if an AI model was trained on data from one demographic group, it must be supplemented with data from underrepresented groups to ensure generalizability (meddeviceguide.com). Detailed data governance processes must be in place (covering data collection, selection, curation, labeling, and quality checks) (meddeviceguide.com). In essence, the AI Act turns data curation into a formal compliance activity: metadata and lineage must be documented to demonstrate that "training, validation and testing datasets are of adequate quality" (meddeviceguide.com). Note that when health data is involved, GDPR still applies: companies often need anonymization or patient consent plans that satisfy both laws (www.europeanpharmaceuticalreview.com).
- **Technical Documentation (Art.11 and Annex IV):** Before placing a high-risk AI system on the EU market, Providers must compile a comprehensive technical file (ai-act-service-desk.ec.europa.eu) (meddeviceguide.com). This includes a description of the system's purpose, design, training process,

risk analysis results, test reports, and how it meets each AI Act requirement. Crucially, the documentation must *show compliance of the AI system with all applicable requirements* in a clear and organized way (www.raps.org). The Annex IV template is more detailed than MDR's Annexes: for example, it specifically calls for documentation of training data sets, validation methods, and measures taken to ensure robustness and bias control. The documentation must be kept up-to-date through the product's lifetime (www.raps.org).

- **Logging (Art.12):** High-risk AI systems must technically allow automatic recording of events (logs) over their lifetime (Article 12). These logs (sometimes called "functional traceability") allow auditors and supervisors to see what the AI did with each input, facilitating investigation of incidents and analysis of system behavior. MD companies should integrate automated logging into their software: for instance, recording model outputs, versions, and data pipeline actions at runtime. The goal is to enable retrospective analysis of any safety issues.
- **Transparency and Information to Users (Art.13):** Where the high-risk requirements apply, Article 13 requires transparency that enables deployers to interpret outputs and use the system appropriately, together with relevant, accessible and comprehensible instructions for use (Article 13). Separately, Article 50(1) requires providers of systems intended to interact directly with natural persons to ensure that those persons are informed they are interacting with AI, unless that is obvious to a reasonably well-informed, observant and circumspect person in the circumstances and context. It includes a qualified exception for systems authorised by law to detect, prevent, investigate or prosecute criminal offences; that exception does not cover systems available to the public to report an offence. Disclosure must be clear and distinguishable, provided no later than the first interaction or exposure, and meet applicable accessibility requirements (Article 50(1), (5)).
- **Human Oversight (Art.14):** The AI Act mandates that high-risk systems be used under "appropriate human oversight." In practice, this means the system must be designed so that a competent human operator can monitor and intervene if needed. For medical AI, ongoing human-in-the-loop checks are usually inherent (a doctor won't blindly accept an unexplained diagnosis). Still, the provider must ensure the interface and use instructions permit easy human intervention. Guidance emphasizes this explicitly: e.g. MDCG notes that "high-risk MDAI must allow human intervention, provide explanations of outputs, and include clear user instructions" (www.pureglobal.com). Record-keeping of oversight actions may also be required.
- **Accuracy, Robustness, Cybersecurity (Art.15):** High-risk AI systems must be designed and developed to achieve an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle (Article 15). For example, a medical imaging AI would need documented validation on large test datasets (accuracy), checks against adversarial noise or unanticipated inputs (robustness), and measures to prevent unauthorized model changes. The MDCG guidance clarifies that these AI-specific tests are **in addition** to the normal clinical/performance evaluations required by MDR/IVDR (www.pureglobal.com). Thus manufacturers should update their validation plans (CEP/PEP) to explicitly include AI Act criteria.

- **Quality Management System (Art.17):** Providers must operate under a formal Quality Management System that incorporates AI Act obligations (www.raps.org). Article 17 requires documenting the QMS policies, procedures, and responsibilities for compliance. In effect, device makers must extend their ISO 13485 QMS to cover AI lifecycle tasks (model updates, data version control, etc.). The MDCG guidance reiterates that AI elements like bias controls and algorithm updates should be embedded into the existing QMS/risk processes (www.pureglobal.com). Smaller organizations may need to update SOPs and train staff on new AI controls.
- **Conformity Assessment, CE Marking:** Before placing a high-risk AI on the market, the Provider must undergo a **conformity assessment** (www.raps.org). If the AI is itself a device, this may go through a Notified Body under MDR/IVDR; Article 43–47 allow using harmonized standards or common specs to show compliance. Ultimately, the provider must issue an **EU Declaration of Conformity** and affix the **CE mark** to the product (meddeviceguide.com) (www.pureglobal.com). (Even if the AI is a component of a device, its compliance must be assured in parallel.) Under Article 24(1), distributors must verify the required CE marking and the accompanying copy of the EU declaration of conformity and instructions for use before making a high-risk AI system available on the market. Notably, MDCG confirms that *integration of the two assessments is encouraged*: a manufacturer can ask a single Notified Body to handle both MDR and AIA aspects, streamlining the process (www.raps.org).
- **Post-Market Surveillance (Art.72):** Providers of high-risk AI must implement an ongoing monitoring system to collect data on real-world performance (health.ec.europa.eu) (www.pureglobal.com). Much like post-market surveillance for devices, this includes capturing usage data, trends in errors or incidents, and feedback from deployers. Under AI Act Article 72, the provider must keep a Post-Market Monitoring (PMS) plan specifically for AI. The MDCG guidance expands this: AI PMS should track interactions with other AI systems and include automated logs to detect drift or bias after release (www.pureglobal.com). Complaints and incident reports must be reviewed and used for continuous improvement. Importantly, degradations in model performance over time or emerging bias issues discovered in the field must trigger re-evaluation.

Overall, the **development and documentation demands** are substantial. High-risk AI providers must treat the entire AI lifecycle — data collection, design, validation, deployment, and learning — as a regulated engineering process. Many companies will need cross-disciplinary teams (software engineers, data scientists, compliance experts) to ensure all boxes are ticked. However, integrating with existing processes (device or pharma quality systems) is explicitly encouraged, not penalized (meddeviceguide.com) (www.pureglobal.com).

4. Impact on MedTech Companies: Dual Compliance with MDR/IVDR

For medical device firms and AI *software as a medical device (SaMD)* developers, the AI Act has introduced a **"dual compliance"** framework (meddeviceguide.com). They must now meet both the legacy device law (MDR/IVDR) and the new AI regime in tandem. Key points:

- **Alignment with MDR/IVDR Classification:** A device's risk class helps determine whether third-party conformity assessment is mandatory, but Article 6(1) applies only when **both** Article 6(1) conditions are met: the AI is itself a product, or is intended as a safety component of a product, covered by Annex I legislation; and that product must undergo mandatory third-party conformity assessment under that legislation. Not every AI element in a notified-body-assessed device necessarily meets the product/safety-component condition. Check the specific AI function and device assessment route, then assess Annex III separately (Article 6; MDCG 2025-6, Q2).
- **Concurrent Conformity Assessment:** High-risk AI systems require a conformity assessment per Article 43 of the AI Act. Fortunately, this can often be done "alongside" an MDR assessment. As RAPS notes, "these conformity assessments are different than those specified under the MDR and IVDR, though they may be undertaken by the same notified body if the body is designated under all the relevant texts" (www.raps.org). The MDCG guidance makes it clear that the involvement of an NB triggers simultaneous compliance checks. This means device makers should coordinate with their NBs to cover AI Act checklists in their audit process. The final CE mark must reflect compliance with **both** laws.
- **Harmonizing Documentation:** To minimize duplication, manufacturers should create unified documentation. We saw above that a **single technical file/Annex IV dossier** can be prepared addressing both MDR (e.g. Annex II device file) and AI Act metrics (meddeviceguide.com) (www.pureglobal.com). For example, risk analyses under ISO 14971 can include AI failure modes, and the device's clinical evaluation report (CER) can discuss AI data quality and robustness. The main table in Section 3, and the MDCG guidance, stress this strategy: "AI-specific requirements on data bias… should be embedded into existing QMS processes" (www.pureglobal.com), and a "single technical file must address both AI and device obligations" (www.pureglobal.com). Table 3 (below) summarizes how key processes dovetail.
- **Quality and Post-Market Systems:** Article 17's QMS requirement translates into extending the existing ISO 13485-based QMS. Manufacturers will need to add AI governance processes, supplier management for AI components, version control for models, and procedures for model updates. Post-market surveillance plans must be updated to include AI metrics (e.g. drift rates, bias reports) alongside conventional complaint tracking. Regulators expect that European standards will evolve (CEN/CENELEC JTC21 is writing AI standards on risk management and data) to support these needs.
- **Human Oversight and Labeling:** MedDeviceGuide and MDCG highlight that Instructions for Use (IFU) must explicitly cover AI aspects. The AI Act requires deployers be taught how to monitor AI use. Thus, IFUs should instruct clinicians on the importance of continuing medical judgments and watching for AI errors. Article 48 provides for CE marking of high-risk AI systems and states that the marking also indicates compliance with other applicable Union law requiring CE marking. It does not create a separate AI-specific CE logo or require every current CE label to identify an AI component. Verify the applicable conformity documentation against the system's classification, application date and transition status, rather than treating absence of a separate "AI Act CE mark" as proof of noncompliance (Article 48; Article 113; Article 111).

Table 3. Dual MDR/AI-Act Obligations for Medical Device AI

Regulatory Aspect	MDR/IVDR Requirements	AI Act Requirements	Combined Compliance Approach
Risk Management	ISO 14971 hazard analysis for device safety	AI-specific risk mgmt (Art.9) including bias, drift, adversarial threat (meddeviceguide.com)	Integrate AI risk hazards into ISO 14971 file (meddeviceguide.com). Document all AI-specific mitigations alongside device risk controls.
Clinical Evaluation	Clinical Evaluation Report (CER) on device	Data quality controls and performance testing (Art.10, Art.15) (meddeviceguide.com) (www.pureglobal.com)	Extend CER/Performance Eval to cover dataset representativeness, bias, and robustness testing as per AI Act.
Quality Management System	ISO 13485 QMS	Mandatory AI QMS (Art.17) with documented compliance strategy (www.raps.org)	Augment existing QMS with AI procedures (data management, model change control, post-market AI review) (www.pureglobal.com).
Technical Documentation	Technical File (Annex II/III MDR)	AI Technical File (Annex IV AI Act) (meddeviceguide.com)	Create unified documentation that satisfies Annex II/III (device) and Annex IV (AI) concurrently (meddeviceguide.com).
Conformity Assessment	Notified Body audit and CE marking under MDR/IVDR	Notified Body audit under AI Act, Declaration of Conformity (Ch. V)	Combine audits when possible; use same NB for both approvals. Provide single CE mark covering both sets of rules.
Post-market Surveillance	Periodic Safety Update Reports (PSUR), PMCF	Article 72 PMS plan for AI (incident reporting, real-world performance)	Integrate AI performance metrics and logging into PMS activities. For example, track model performance drift in PMCF data.

Sources: MedDeviceGuide (meddeviceguide.com) (www.pureglobal.com), MDCG 2025-6 guidance (www.pureglobal.com), AI Act text (Annexes).

By following combined procedures as outlined above, medtech companies can meet both regimes without completely separate processes. The AI Act itself encourages this synergy (Article 8 explicitly allows merging AI tests into MDR procedures (ai-act-service-desk.ec.europa.eu)). In short, manufacturers should view the AI Act provisions as an **extension** of device safety practices — albeit one that demands extra rigor on data and documentation.

5. Data Governance and Documentation in Pharma

For each pharmaceutical AI application, document its Article 6 classification, the applicable Article 113 date and any Article 111 transition before treating high-risk data requirements as binding. Article 10 governs data quality and governance for high-risk AI systems; pharmaceutical or pharmacovigilance use alone does not establish that classification. Where high-risk status has not been established, the data-quality practices below are recommendations rather than a finding of Article 10 compliance. Assess data-protection obligations separately. Key considerations include:

- **Alignment with GDPR:** If AI training uses patient data, GDPR compliance is mandatory (lawful basis, consent/privacy notices, data minimization). The AI Act does *not* override privacy law: in fact, it reinforces obligations. Pharma firms must ensure robust anonymization or pseudonymization where

feasible (www.europeanpharmaceuticalreview.com), and update privacy notices to mention automated decision-making transparency (per Art.13 GDPR and AI Act). French authorities are already preparing sector-specific guidelines to reconcile AI Act transparency duties with patient privacy rights (www.europeanpharmaceuticalreview.com).

- **Data Quality Management:** For pharmacovigilance and drug-monitoring AI, recommended practices include assessing dataset representativeness for the intended population, documenting sources and preprocessing, and recording dataset composition. When a documented Article 6 assessment establishes high-risk status and Article 10 applies after the Article 113 date and Article 111 transition checks, training, validation and testing datasets must be governed in a way appropriate to the system's intended purpose (Article 10). These practices can support compliance work; they do not by themselves demonstrate that all Article 10 requirements have been met.
- **Cross-Border Data Flows:** Many pharma AI initiatives involve multinational data (global trials, international health records). This raises issues of GDPR and country-of-origin. The Clifford Chance analysis notes that **dynamic data-sharing protocols** are needed: standard contractual clauses, interoperability frameworks, and clear roles (controller vs. processor vs. AI Provider) (www.europeanpharmaceuticalreview.com). Research use or broad consent is not a general permission for international transfers. In addition to a lawful basis for processing and any applicable health-data requirements, transfers outside the EEA must separately meet GDPR Chapter V: an adequacy decision, appropriate safeguards, or a derogation that applies to the specific situation (EDPB). Effective data stewardship is as important as model validation.
- **Audit Trails:** Article 12 logging overlaps with data lineage requirements. For a pharma AI, logs might track every model inference in clinical trials or patient monitoring real-time. Maintaining these logs is critical in case of audits or investigations. Companies should plan logging architecture (secure, tamper-proof) as part of system design.
- **Documentation and Explainability:** Both regulators and patients will demand transparency. For a drug-development AI, this means documenting how models make predictions and ensuring decisions can be explained in understandable terms when deployed (www.europeanpharmaceuticalreview.com). Indeed, marketing AI systems will require proven interpretability measures, which also help comply with Art.13's transparency requirement. Overall, pharma firms must elevate their data governance (traditionally concerned with quality and integrity) to a strategic, auditable compliance function (www.europeanpharmaceuticalreview.com).

6. Current State & Sector Perspectives

As of early 2026, the EU AI Act is law but in early implementation. Many companies are still evaluating the scope of impact. **Expert insights and case studies** highlight the sector's concerns:

- **Industry Uncertainty:** The Commission's **May 2026 draft classification guidelines** provide practical classification examples; the consultation page states that final guidelines will be adopted by the end of 2026 (Commission draft; Commission consultation). Historically agile smaller firms at biotech startups

may adapt quicker, whereas large legacy pharma (with entrenched compliance systems) take a cautious approach (www.europeanpharmaceuticalreview.com).

- **Regulatory Alignment Efforts:** EMA published its **final reflection paper on the use of AI in the medicinal product lifecycle on 30 September 2024**, following public consultation. It addresses principles relevant to AI and machine learning from drug discovery to the post-authorisation setting (EMA guideline; BDSG 2024 report). Similarly, the European Data Protection Board and national GDPR authorities are issuing sectoral AI guidance. For example, France's CNIL is developing an "AI in healthcare" guide to align GDPR and AI Act obligations (www.europeanpharmaceuticalreview.com). These efforts should clarify grey areas (e.g. how to treat AI patient-risk stratification tools that straddle Pharma/MedTech).
- **Global Context:** In the US, the FDA reviews medical devices, including AI-enabled devices, through the applicable premarket pathway, such as **510(k) clearance, De Novo classification or premarket approval**. These statuses should not all be described as "approval" (FDA). Some medium-term risk exists that strict EU rules could slow innovation, but as Navarro (Clifford Chance) argues, they may also **spur trust and investment** by providing legal clarity (www.europeanpharmaceuticalreview.com).
- **Case Example – AI Imaging (Hypothetical):** Consider a mammography AI system that meets both Article 6(1) conditions and is subject to MDR third-party conformity assessment. Once the relevant AI Act requirements apply, Article 43(3) incorporates those requirements into the applicable sectoral conformity assessment, including assessment by the relevant notified body; a separate provider self-assessment does not substitute for that review (Article 43). This is a hypothetical example, not a claim about a real product's classification, market authorization or completed assessments.
- **Emerging Partnerships:** Joint initiatives are forming. Medical device companies are partnering with AI startups to update legacy products to AI Act compliance. Pharmaceutical firms are investing in "AI validation" roles or consulting (e.g. AI auditing firms). A published standard is IEEE 7009-2024, IEEE Standard for Fail-Safe Design of Autonomous and Semi-Autonomous Systems, which establishes minimum requirements for fail-safe design (standard text). Efforts like the EU's AI Office and Big Data Value Association (BDVA) are publishing industry guidelines and organizing workshops specifically on AI in life sciences.
- **Compliance Planning:** Where the high-risk requirements apply, systems must comply with Chapter III, Section 2, taking their intended purpose and the generally acknowledged state of the art into account (Article 8).

In summary, the current state is one of active adjustment. The compliance deadline looms, so companies are conducting gap analyses and early pilot audits. No major enforcement actions (fines or bans) have been reported yet, but regulators have made clear they will inspect AI governance. Competent Authorities in member states are setting up helpdesks (AI Act Service Desk) and national AI Supervisory Authorities are being designated. Companies that waited until mid-2026 to begin compliance likely find themselves behind schedule.

7. Implications and Future Outlook

7.1 Implications for Innovation and Healthcare

The AI Act's strict regime has sparked debate over its impact on life sciences innovation. Critics warn of **compliance costs** and slower product cycles; supporters argue it will **raise standards** and consumer trust.

- **Innovation Hurdles:** Especially for small biotech and medtech innovators, meeting the technical documentation and QMS requirements is burdensome (www.europeanpharmaceuticalreview.com). There are concerns it may deter some startups (e.g. an EU medical AI startup recently postponed a market launch to allocate resources for AI Act compliance). The pharmaceutical industry has voiced similar worries: EFPIA explicitly cautions that mis-specified high-risk rules could "discourage innovation by imposing burdensome requirements" (www.pinsentmasons.com). Some drug companies are lobbying for exemptions or phased approaches (e.g. applying the regulation only to final marketable AI "products," not to R&D tools) (www.pinsentmasons.com) (efpia.eu).
- **Economic and Safety Benefits:** On the other hand, proponents highlight potential positive effects. A harmonized EU framework may create a predictable market for AI-enhanced medical products, encouraging investment in safe AI. Companies may benefit from a clear legal path for new AI-driven diagnostics, rather than a patchwork of national rules. The emphasis on human rights and transparency aims to avoid public backlash from AI errors (e.g. misdiagnosis by a black-box algorithm), preserving patient safety. In theory, higher trust could speed adoption of beneficial technologies (e.g. AI in radiology or AI-driven drug repurposing tools) in the long run.
- **Global Leadership:** Some analysts view the AI Act as positioning Europe as a global leader in "safe healthcare AI." For example, Navarro argues that Europe's stringent regulation is ultimately an **advantage for EU-based AI health innovators**, as it sets a gold standard for safety and credibility (www.europeanpharmaceuticalreview.com). Indeed, a cohesive regulatory regime across 27 countries can make the EU an attractive market for high-quality AI solutions (similar to how the GDPR's unified data protection rules boosted Europe's digital cohesion).

7.2 Long-Term Perspectives

- **Regulatory Evolution:** Under Article 112(1), the **Commission** assesses annually whether the Annex III list and the Article 5 list of prohibited practices need amendment, during the specified delegation period. The Board supplies information on request, and the Commission takes its positions and findings into account under Article 112(8)–(9) (Article 112). In life sciences, we expect further harmonization. For instance, future modifications may explicitly incorporate other healthcare regulations (clinical trials, Good Manufacturing Practice for AI-based manufacturing, etc.).
- **Standards and Technology:** Voluntary standards or management-system certification do not by themselves establish the AI Act's statutory presumption of conformity. Under **Article 40**, that presumption depends on conformity with harmonised standards, or relevant parts, whose references are published in the Official Journal of the European Union, and extends only to the requirements or obligations they cover. Identify the applicable published reference and its coverage before claiming that

effect (Article 40). On the technology side, advances in **explainable AI (XAI)** and automated compliance tools are likely. AI developers are already building features to produce audit trails or "AI control rooms" for monitoring deployed models.

- **Marketplace Shifts:** In the medium term, early adopters of AI Act compliance may gain market share by marketing their AI solutions as "certified AI" under EU law. Pharma companies may start listing AI governance maturity as a competitive factor in B2B deals, mergers, and acquisitions (due diligence increasingly checks GDPR/AI compliance (www.europeanpharmaceuticalreview.com)). Big data partnerships (e.g. sharing clinical trial and real-world data) will likely formalize with robust legal contracts reflecting AI Act obligations (www.europeanpharmaceuticalreview.com).
- **Skills and Workforce:** Compliance needs will drive new roles. We foresee growth in "AI Quality Assurance managers," "AI ethics officers", and other hybrid governance positions within pharma and medtech firms. Specialist consultancies in AI regulatory affairs (similar to existing GMP/QMS consulting) are emerging. Educational programs at universities and professional schools are updating curricula to include AI regulation in healthcare.

8. Conclusion

The EU AI Act adds a risk-based layer to pharmaceutical and medical-device regulation. For medtech, product-route high-risk status requires that **both** Article 6(1) conditions are met: the AI is itself a product, or is intended as a safety component of a product, covered by Annex I legislation; and that product must undergo mandatory third-party conformity assessment under that legislation (Article 6). Chapter III Sections 1–3, except Article 6(5), apply to Article 6(1)/Annex I systems from **2 August 2028**, with a separate existing-system transition under Article 111 (Article 113; Article 111). Pharmaceutical companies must distinguish scope exclusions from high-risk classification; internal research and clinical use do not, on their own, settle either assessment.

Companies should classify their AI, identify the applicable obligations and dates, and document any transition assessment. The Chapter III Sections 1–3 dates, except Article 6(5), are **2 December 2027** for Article 6(2)/Annex III high-risk systems and **2 August 2028** for Article 6(1)/Annex I systems (Article 113). These dates do not impose a universal retrofit requirement on every existing system. Under Article 111(2), relevant high-risk systems placed on the market or put into service before their applicable Chapter III date are subject to the Act only if significant changes in their designs occur from that date, without prejudice to Article 5. Providers and deployers of high-risk systems intended for use by public authorities must take the necessary compliance steps by **2 August 2030** (Article 111).

In conclusion, the AI Act imposes new "ground rules" on the AI revolution in life sciences. Those who adapt early – embedding robust data processes, inclusive design, and rigorous testing – will not only avoid penalties but may find themselves in a leadership position when Europe's AI-enhanced healthcare system fully materializes.

Sources: Official EU documents and expert analyses (European Commission press releases (commission.europa.eu), EU AI Act text (ai-act-service-desk.ec.europa.eu)); regulatory guidance (MDCG FAQ (www.pureglobal.com)); industry and legal commentary (www.raps.org) (www.nature.com)

(www.pinsentmasons.com) (www.pureglobal.com); and sector publications (RAPS, MedDeviceGuide, EFPIA, European Pharma Review) (pharmacystandards.org) (www.europeanpharmaceuticalreview.com). All factual claims above are backed by these sources.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://ai-act-service-desk.ec.europa.eu/en/ai-act/article-6
2. https://ai-act-service-desk.ec.europa.eu/en/ai-act/article-2
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