

Chapter 18 / Capítulo 18

Primum non nocere: Software engineering
for medicine
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Chapter 18. Comparative Regulatory Landscape

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“Medical software is not a global product simply because it is written in binary code. What is safe and effective in one country may not be in another, not because the software changes but because laws, criteria, and expectations change. Navigating the international regulatory maze is not an option for those who aspire to bring their products to patients around the world; it is a condition for survival.”

Let us imagine that we developed an algorithm to detect diabetic retinopathy with exceptional performance. We’ve validated it in thousands of patients, obtained certification in our country, and are ready to bring it to market. Then, someone asks us: what about the FDA? What about the CE mark? What about Brazil’s ANVISA? What about Mexico’s COFEPRIS? We discover that every country has its own regulatory body, its own requirements, and its own timelines. What is a simple procedure in one place can be a long and costly process in another. The low-risk product in one country may require additional clinical trials in another. Regulatory harmonization is still a distant dream, and those who want to operate internationally must learn to navigate this complexity.

The regulatory landscape for medical software is a mosaic of standards, institutions, and procedures that reflect the diversity of healthcare systems, legal traditions, and political priorities. In the United States, the FDA has a well-established system with decades of experience. In Europe, the new Medical Device Regulation (MDR) has tightened requirements and centralized evaluation. In Latin America, each country has its own agency, with varying levels of maturity and stringency. Added to this is the recent regulation of artificial intelligence, such as the European AI Act, which adds an additional layer of complexity. Understanding this landscape is not a luxury; it is a strategic necessity.

In this chapter, we explore the main regulatory frameworks for medical software around the world. We will begin with the U.S. FDA, its product classification, and its approval pathways. We will continue with the European Medical Device Regulation (MDR) and its counterpart for in vitro diagnostics (IVDR). We address the AI Act, the first regulation specifically targeting artificial intelligence, and how it affects medical software. Finally, we provide an overview of regulations in Latin America and Spain, including their specific characteristics and challenges. This is not an exhaustive legal guide but rather an introduction to the questions every developer should ask and the resources they should consult.

18.1. FDA: CLASSIFICATION AND APPROVAL PATHWAYS

“In the world of digital health, the FDA is not just another agency: it is the beacon that many other regulators follow, and its approval can mean the difference between a product that changes lives and one that never leaves the drawer.”

The U.S. Food and Drug Administration, known simply as the FDA, exerts a disproportionate influence on the global regulatory landscape. This is no exaggeration: when the FDA makes a decision regarding a new medical device—from a diagnostic algorithm to a chronic monitoring app—its criteria resonate with those of agencies across the globe.⁽¹⁾ Many countries, especially in Latin America and Asia, view FDA approval as a seal of quality that facilitates their own authorization processes. For any development team with international ambitions, understanding how this agency works is not an academic luxury but a business survival skill. However, the FDA is not a monolithic, immutable entity; it is a complex organization with multiple centers, specialized divisions, and, most importantly, different regulatory pathways tailored to the risk level and nature of each product.

The relationship between the FDA and medical software has been a story of constant adaptation. It began in the 1980s, when the first programmable devices began appearing in U.S. hospitals. For years, the agency applied the same criteria to these new products as it did to traditional physical devices, which often led to confusing and inappropriate outcomes. A turning point came in 2017 with the publication of specific guidance on Software as a Medical Device (SaMD), which finally recognized that code is not a screw or a circuit but rather something with its own characteristics that requires a different framework. Since then, the FDA has continued to evolve, attempting to keep pace with rapid advances in artificial intelligence and machine learning, although technology sometimes advances faster than the regulatory capacity to adapt.⁽²⁾

18.1.1. THREE RISK CLASSES: THE FIRST STEP IN NAVIGATING THE SYSTEM

The absolute starting point for any developer looking toward the U.S. market is understanding how the FDA classifies medical devices. The agency organizes all products into three categories on the basis of their level of potential risk to the patient, and this classification determines everything that follows: the necessary documentation, timelines, costs, and business strategy. Class I encompasses the lowest-risk products—those that, if they fail, would cause minimal or no harm. In the world of software, this category includes administrative management systems, basic electronic health records, and appointment scheduling applications. These products are subject to general quality controls and good manufacturing practices but rarely require a comprehensive review by the FDA before being marketed, provided that they meet basic safety and privacy standards.⁽³⁾

Class II represents the category where most of the medical software currently being developed falls. This includes moderate-risk products—those that can influence important clinical decisions but do not sustain vital functions on their own. Diagnostic imaging support algorithms, applications that calculate drug doses on the basis of patient parameters, and clinical alert systems fall into this category. For these products, the FDA requires a premarket notification known as a 510(k), a process that requires demonstrating that the new device is substantially equivalent to another device already authorized and legally marketed in the United States. This equivalence refers not only to appearance or branding but also to safety and clinical efficacy under the same intended conditions of use.

Class III is the highest-risk category and, therefore, is subject to the most scrutiny. This class includes devices that sustain or maintain human life, implants, diagnostic products for life-threatening diseases with no alternative treatments, and those whose failure could cause serious injury or death. This class of medical software is relatively rare but not nonexistent: an algorithm that directly controls an insulin infusion pump or a fully autonomous diagnostic system for cancer could fall into this category. These products require a premarket approval (PMA), a rigorous process that demands robust clinical evidence, typically through randomized controlled trials, and can take years and millions of dollars to prepare.

Class determination is not a theoretical exercise that the developer undertakes alone; it is a decision that must be documented and that the FDA may challenge or modify. The manufacturer must carefully analyze the intended use of its product, the specific indications for which it is designed, and the risks associated with its normal operation as well as its potential failures. To facilitate this task, the FDA maintains an extensive public database of previously classified products, known as “predicates” or reference devices. These predicate devices serve as the compass guiding the regulatory strategy: if your product is substantially equivalent to one already on the market, you can follow the 510(k) pathway. If no suitable predicate exists or if your product is highrisk, you will face more complex processes.

18.1.2. APPROVAL PATHWAYS: FROM EQUIVALENCE TO RADICAL INNOVATION

Once the product class has been determined, the developer must choose and prepare the appropriate regulatory pathway, and this is where experience and specialized advice make the difference between a smooth process and a tortuous one. The 510(k) pathway is by far the most commonly used for Class II medical software, and its logic is relatively simple to understand, although complex to execute: You must demonstrate that your new product is substantially equivalent to a predicate device already on the market in terms of safety and effectiveness. This equivalence encompasses multiple dimensions: the indications for use must match or be more restrictive, the underlying technology must be comparable, and the clinical performance must demonstrate that it does not introduce significant new risks. New clinical trials are not always required for this pathway, but sufficient evidence is required—generally through concordance studies, analytical validation, or, in some cases, real-world performance data—to demonstrate that the equivalence is genuine and not merely declarative.

The 510(k) process has a variable duration that typically ranges from three to twelve months, depending on the product’s technical complexity, the quality of the submitted documentation, and the reviewers’ workload at the time. A common mistake among first-time developers is the underestimation of the importance of advance preparation: incomplete documentation, a poorly structured comparison with the predicate device, or an ambiguous definition of the intended use can lead to additional questions from the FDA that extend timelines by months or even years.

The agency sets time targets, but these are not guarantees, and a well-advised developer knows that investing in document quality from the first draft pays dividends in terms of approval speed.

For products that do not fit comfortably into any existing predicate device but also do not reach the level of risk that would justify a PMA, the FDA offers the *de novo* pathway, an alternative that has gained popularity with the proliferation of innovative software. This route allows the manufacturer to request a specific classification for its product, effectively establishing a new predicate for future competitors. It is a pathway that requires a more detailed evaluation than the standard 510(k), generally including a more thorough characterization of risks and benefits, but avoids the overwhelming burden of a PMA.⁽⁴⁾ Success in a *de novo* application not only authorizes your product but also creates a new regulatory category that can pave the way for an entire emerging industry, as occurred with the first AI-based diagnostic imaging algorithms.

The PMA pathway represents the other end of the spectrum: it is the most demanding, the longest, the most expensive, and, fortunately, for most software developers, the least frequently needed. Robust clinical evidence, which is typically obtained through prospective controlled trials that convincingly demonstrate the product's safety and efficacy, is needed. The process includes multiple reviews by independent advisory committees, inspections of manufacturing facilities, and a significantly higher rejection rate than in the other pathways. With respect to medical software, except in very specific cases involving devices that support vital functions or autonomous diagnoses of serious diseases, this pathway remains a theoretical possibility rather than a common practical reality.

18.1.3. SPECIAL PROGRAMS AND THE CHALLENGE OF CONTINUOUS INNOVATION

Given that traditional processes could stifle innovation in a field evolving as rapidly as medical software does, the FDA has developed special programs in recent years designed to accelerate the market entry of promising products without sacrificing safety standards. The Breakthrough Devices Program offers fast track for products that provide more effective treatment or diagnosis of life-threatening or debilitating diseases or that offer significant advantages over currently approved alternatives.⁽⁵⁾ Participation in this program does not guarantee approval, but it does provide priority access to engagement with the FDA, guidance on developing clinical evidence, and flexibility in study design—elements that can drastically reduce development timelines for truly transformative products.

Another forward-looking regulatory experiment is the Software Precertification Program, or Pre-Cert Program, a pilot initiative that represents a fundamental paradigm shift in how the FDA views its relationship with developers.⁽⁶⁾ Instead of evaluating each product individually, this program proposes evaluating the developing organizations themselves on the basis of their quality processes, compliance history, postmarket monitoring capabilities, and culture of continuous improvement. The logic is that a company with robust and transparent processes can iterate and improve its products with lighter regulatory oversight, indicating that its own quality control systems will detect and mitigate risks. Although this program is still in the development and evaluation phases and its final scope remains uncertain, it points in a clear direction: the FDA is exploring models that recognize that software is not a static product manufactured once but a living system that evolves.

This evolutionary nature of software poses one of the most complex and as yet unresolved regulatory challenges: the management of updates. An artificial intelligence algorithm, by definition, can continuously improve its performance as it is exposed to new data. A clinical decision support system can add new features on the basis of user feedback. The FDA has published specific guidelines on when an update constitutes a major change requiring new regulatory authorization and when it may be considered minor and managed internally by the manufacturer. In general, changes that directly affect clinical performance, introduce new indications for use, or modify the target population require a new review by the agency. Changes that improve usability without altering clinical logic, correct minor errors, or optimize technical performance without impacting safety may be implemented with appropriate documentation but without additional prior authorization.

Artificial intelligence and machine learning have been a particular focus of the FDA in recent years. In 2021, the agency published an action plan for the regulation of AI/ML that establishes five strategic priorities: fostering a culture of quality in developer organizations, gathering real-world evidence on the performance of these algorithms, developing evaluation methodologies adapted to the adaptive nature of AI, ensuring transparency toward users and patients, and establishing

mechanisms for continuous postmarket monitoring.(7) The FDA has already approved hundreds of algorithms based on these technologies, but its approach goes beyond initial approval: it expects manufacturers not only to demonstrate that their algorithm works at the time of launch but also to establish systems to keep it functioning correctly over time, detecting and correcting performance deviations that may arise owing to changes in input data, clinical practice, or the patient population.

18.1.4. LONG-TERM RELATIONSHIPS: BEYOND INITIAL APPROVAL

Preparing an application for the FDA is a meticulous process that begins long before the first form is drafted. It requires thoroughly documenting the entire development process, from initial requirements to final validation testing, including systematic risk analyses per ISO 14971 and usability testing per IEC 62366. It requires a crystal-clear and well-defined intended use because any ambiguity at this stage can result in a classification different from what was expected or in unexpected market restrictions.(8) It requires identifying and analyzing the relevant predicate devices and preparing detailed comparisons that anticipate reviewers' questions. It requires being prepared for a dialog that can extend for months, answering technical questions, clarifying methodologies, or providing additional data that the agency deems necessary for its evaluation.

However, the relationship with the FDA does not end with the issuance of the letter of authorization. Manufacturers must maintain robust postmarket surveillance systems, reporting to the agency on significant changes to the device, on adverse events that meet certain criteria for severity or frequency, and on updates that may affect safety or efficacy. This ongoing reporting obligation is particularly relevant for software, where the frequency of updates is inherently higher than that for physical devices. A developer who ignores this postmarket dimension exposes themselves to regulatory actions that may include product recalls, significant fines, or bans on future marketing.

For healthcare professionals who use these products, understanding the meaning of different FDA approvals is an increasingly necessary digital literacy skill. A 510(k) approval does not imply that the product has been tested in prospective clinical trials in the same population that the clinician treats; it guarantees only that it is substantially equivalent to another product already on the market, whose own evidence may date back decades. De Novo approval offers greater assurances of specific evaluation, while a PMA provides the highest level of premarket clinical evidence. Products designated as breakthrough products have been explicitly recognized by the FDA as representing significant advances. All this information is publicly available in the FDA's databases, and clinicians who know how to interpret it can make more informed decisions about which technologies to adopt in their practice.(4)

The future of medical software regulation in the United States is taking shape in two directions that appear contradictory but are actually complementary: toward greater international harmonization and toward an increasingly sophisticated adaptation to the unique characteristics of software as a distinct product. The FDA actively participates in the International Medical Device Regulators Forum (IMDRF), collaborating with its counterparts in Europe, Canada, Australia, Japan, and other countries to align criteria and facilitate global access to healthcare innovation. Moreover, it explores specific regulatory frameworks for artificial intelligence that will likely serve as a model for other regulators in the coming years, recognizing that software cannot be treated as a physical device with a defined lifespan but rather as a complex system that evolves, learns, and requires continuous monitoring.

Ultimately, it is worth remembering that the FDA, with all its complex processes and seemingly bureaucratic requirements, is not an arbitrary obstacle but an institutionalized safeguard. Its requirements exist to protect patients from unsafe, ineffective, or poorly designed products, and approval from this agency remains among the most recognized and respected seals of quality in the healthcare world. For the strategic developer, investing in doing things right from day one, rather than seeking regulatory shortcuts, is not just a matter of ethical compliance but of business acumen. At the end of the day, what truly matters is not simply obtaining authorization to place a product on the market but reaching that market with a solution that doctors and patients can fully trust, knowing it has been evaluated against one of the most demanding standards on the planet.

18.2. EUROPEAN MDR AND IVDR REGULATIONS

In recent years, the European regulatory landscape has undergone a transformation of historic magnitude, comparable in its impact only to the creation of the single European market itself. In May 2017, two legal texts published almost simultaneously radically altered the terrain on which all medical device manufacturers operate, explicitly and for the first time, systematically including medical software. Regulation (EU) 2017/745, known as the MDR (Medical Device Regulation), and its counterpart Regulation (EU) 2017/746, known as the IVDR (In Vitro Diagnostic Regulation),⁽⁹⁾ are not mere technical updates to previous regulations; they represent a complete overhaul of the European regulatory framework, replacing directives that had governed the sector for more than two decades with significantly stricter requirements, more intrusive control mechanisms, and unprecedented levels of transparency through the European database EUDAMED.

The distinction between a directive and a regulation, seemingly subtle to those unfamiliar with EU law, has enormous practical consequences for medical software developers. A European directive sets out objectives that each member state must achieve but leaves room for countries to choose how to implement them in their national legislation, which has historically led to differences in interpretation, uneven timelines, and, occasionally, gray areas that manufacturers could exploit. A regulation, on the other hand, is directly applicable and binding in all Member States from the moment it enters into force, without the need for national legislative transposition. This means that the rules are exactly the same in Stockholm, Seville, or Sofia, which facilitates market harmonization but eliminates any possibility of seeking out jurisdictions with more permissive interpretations or less stringent requirements.

The new regulations did not arise from a legislative vacuum or a mere bureaucratic desire to complicate the market; they were a response to profound crises of confidence that shook the pre system to its foundations. The PIP breast implant scandal, in which it was discovered that a French manufacturer had used unauthorized industrial silicone gel instead of approved medical-grade material, revealed catastrophic failures in the oversight of notified bodies and in postmarket surveillance. Similar cases involving defective hip implants and other problematic medical devices demonstrated that the previous CE certification system, while functional in many respects, had structural cracks that allowed unsafe products to reach patients for years before being detected. That is why the MDR and IVDR place a renewed and almost obsessive emphasis on total transparency, the absolute traceability of every device from manufacture to end use, and continuous surveillance that does not end with initial certification.

18.2.1. THE FIVE PILLARS OF CHANGE: WHAT THE NEW FRAMEWORK TRULY TRANSFORMS

For medical software development teams, the transition from the previous framework to the new MDR and IVDR regime involves the assimilation of five structural changes that profoundly alter how a digital medical device is conceived, developed, and marketed. The first pillar—and perhaps the one that has generated the most surprises among developers accustomed to the previous regulation—is the reclassification of software risk. Under the previous directives, much of the medical software was typically classified into low-risk classes, often Class I, which meant that the manufacturer could self-assess its conformity without third-party intervention. The new regulations establish specific and much more restrictive rules for software that, in practice, substantially increase the classification of most digital products with real clinical impact.

Rule 11 of the MDR is particularly decisive in this regard: it establishes that any software intended to provide information used to make decisions for diagnostic or therapeutic purposes is automatically classified as at least Class IIa. If these decisions can have serious consequences for the patient's health or even survival, the classification increases to Class IIb or, in the most extreme cases, to Class III. This means that diagnostic imaging support algorithms, clinical alert systems, medication dosing applications, or physiological signal interpretation software—which could previously be marketed on the basis of a manufacturer's self-assessment—now inevitably require the intervention of a notified body, with the associated costs, timelines, and complexities. The transition has forced many companies to reconsider their business models or even withdraw products from the European market.

The second transformative pillar is the radical strengthening of the role of notified bodies—those private entities designated by the national authorities of Member States that act as independent conformity assessors for medium- and high-risk products. Under the MDR, the requirements for being designated as a notified body have been drastically tightened, demanding

greater technical capacity, more medical specialists on staff, more rigorous audit procedures, and stricter financial independence from the manufacturers they assess. Many bodies that operated under the old directive have failed to renew their accreditation, creating a severe bottleneck in the system: fewer entities are available to assess more products that, moreover, now require mandatory certification because they have been reclassified. Waiting times for an evaluation appointment have multiplied, and manufacturers have learned the hard way that planning for certification years in advance—not months—is now a matter of survival.

The third pillar introduces a new, mandatory professional role: the person responsible for regulatory compliance (PRRC). Every manufacturer must designate at least one person with specific qualifications to assume legal responsibility for ensuring that each product complies with all applicable regulatory requirements. This person must have a university degree in law, medicine, engineering, or related sciences and demonstrate prior practical experience in medical device regulation. This is not merely an external consultant who reviews documentation occasionally; it is a key figure who must be permanently available to notified bodies and competent authorities, who must actively participate in decisions regarding significant product changes and whose absence or incompetence may result in the suspension of the marketing authorization.

The fourth pillar exponentially increases the requirements for clinical evaluation, understood as the systematic collection, evaluation, and analysis of clinical data related to a product to verify its safety and clinical performance in accordance with its intended use. Whereas previously technical validation tests in the laboratory or a claim of substantial equivalence with products already on the market might have sufficed, the MDR requires manufacturers to actively demonstrate that their product fulfills its specific clinical purpose on the basis of sufficient and appropriate evidence. For medical software, this often translates into the need to conduct prospective clinical studies specifically designed for the product, not just technical performance tests or algorithm validation against historical datasets. The possibility of claiming equivalence with existing products has been significantly restricted, and the required standards for the quality and relevance of clinical data are notably more ambitious.

The fifth pillar is transparency operationalized through EUDAMED, the European database for medical devices, which, once fully operational, will radically transform the sector's visibility. Manufacturers must register each product with its unique identifier, essential technical characteristics, intended use, and classification. Notified bodies must publish the certificates of conformity issued and their exact scopes. Serious incidents and safety field actions must be reported in real time through the system.⁽¹⁰⁾ Crucially, EUDAMED will be accessible to the general public, not just professionals, allowing any patient or clinician to check which products are legally authorized, what safety incidents have been reported, and what clinical studies support their marketing. Although the full implementation of EUDAMED has faced significant delays because of technical complexities, its eventual operation will eliminate the shadows where deficiencies could previously be hidden.

18.2.2. IVDR: THE SISTER REGULATION FOR IN VITRO DIAGNOSTICS

While the MDR has garnered the most media and academic attention, its counterpart, the IVDR, poses an equal or greater regulatory challenge for a specific but growing segment of medical software: that intended for the analysis of biological samples, the interpretation of clinical laboratory results, diagnosis on the basis of molecular or genetic biomarkers and the monitoring of biochemical parameters. The In Vitro Diagnostic Medical Devices Regulation is, in many respects, even more demanding than the MDR because it has massively reclassified products previously considered low- or moderate-risk into categories requiring mandatory evaluation by a notified body. Laboratory tests that could previously be marketed with minimal oversight, such as certain genetic tests or tumor markers, now require rigorous certification through specific clinical studies demonstrating their sensitivity, specificity, and predictive value in real-world populations.

For software that processes, interprets, or reports in vitro diagnostic results, the implications are profound. An algorithm that analyzes digital histopathology images, a system that interprets genomic sequencing results, or an application that calculates genetic risks on the basis of SNP profiles now falls under the scope of the IVDR with very strict clinical validation requirements. The risk classification for this type of software tends to be high by default, especially when the results influence clinical management, therapeutic, or public health decisions. The manufacturer must not only demonstrate that its algorithm works technically but also that its clinical interpretation is correct, reproducible, and clinically useful in the care setting where it will be used.

The transition from the old In Vitro Diagnostic Directive to the IVDR has been particularly traumatic for the sector because of the magnitude of the reclassification. Thousands of products that were legally circulating under manufacturer self-assessment have suddenly required third-party certification, further overwhelming the available notified bodies. The shortage of evaluation capacity has been especially acute in this area, forcing transitional extensions that have prolonged regulatory uncertainty. For diagnostic software developers, this has meant that planning commercial launches has become extremely difficult, with market availability dates depending more on obtaining certificates than on the completion of technical development.

The interaction between the MDR and the IVDR creates areas of additional complexity when software combines functionalities from both regulations. A system that collects data from an in vitro diagnostic device, processes it using its own algorithms, and generates therapeutic recommendations may be subject simultaneously to requirements from both legal texts. Determining which one takes precedence, or whether both apply in a complementary manner, requires sophisticated regulatory analysis and often formal consultations with the competent authorities. This duality reinforces the need for specialized advice and regulatory planning that begins in parallel with technical design, not as a final phase prior to launch.

18.2.3. ADAPTING TO THE NEW PARADIGM: OPERATIONAL IMPLICATIONS FOR DEVELOPERS

The transition to MDR and IVDR compliance demands a profound shift in mindset for medical software developers that goes beyond merely updating documentation procedures. It is no longer feasible to develop a complete product, validate it technically, and only then seek regulatory certification as a final step. The new regulations require the integration of regulatory requirements from the initial design phase, the so-called “quality by design” approach. Clinical evaluation must be planned years in advance because prospective studies demonstrating clinical performance under real-world conditions require time for design, recruitment, execution, and analysis. Documentation is not an afterthought but a living, audited record of every decision made during development.

Software change management takes on a complex regulatory dimension under the new framework. In the previous system, many manufacturers, especially in the agile world of software, were accustomed to continuous update cycles, deploying new versions weekly or even daily, often without explicitly notifying the authorities of every minor modification. The MDR clearly states that significant changes to the device's design or intended use require a new assessment by the notified body, which can drastically slow the pace of innovation. The distinction between major changes requiring recertification and minor changes that the manufacturer can manage autonomously is not always clear and requires organizations to develop formal internal procedures to make these decisions, document them thoroughly, and defend them during audits.

The practical implementation of the MDR and IVDR has, it must be acknowledged, been problematic and fraught with unforeseen difficulties. The original deadlines have been repeatedly delayed because of the lack of preparedness of many notified bodies to meet the new accreditation requirements and because of the technical complexity of implementing EUDAMED as a functional pan-European system. Many products, especially from small and medium-sized manufacturers, have had to be withdrawn from the European market because their certificates under the previous directive expired before they could obtain the new MDR certification. Small businesses, innovative startups, and individual developers have been disproportionately affected by increased certification costs, bureaucratic complexity, and the need to hire specialized staff or costly external consultants.

Despite these implementation hurdles, the strategic direction is unequivocal, and there is no turning back. Europe has decided that it wants medical devices, including medical software, that are safer, better monitored, and more transparent, and manufacturers wishing to access the market of nearly 500 million consumers will have to adapt to these requirements. Those who succeed will find, paradoxically, a more predictable and uniform market than under the old directive, where certification in one member state guarantees access to all and where EUDAMED's transparency can become a competitive advantage for truly robust products against lower-quality competitors.

18.2.4. CLINICIAN'S PERSPECTIVE AND FUTURE REGULATORY CONVERGENCE

For healthcare professionals who use medical software in their daily clinical practice, the new MDR and IVDR framework offers additional safeguards that they must know how to interpret correctly. When a clinician now sees a product with the CE mark, they must pay attention to which regulation underpins that mark: if it is under the new MDR or IVDR, they will know that the product has undergone a substantially more rigorous evaluation than under the old directive, with more demanding clinical studies, more intrusive supervision by a notified body, and stricter postmarket surveillance obligations. Once fully operational, the EUDAMED database will allow you to consult the product's complete history: when it was certified, by which notified body, which clinical studies support its marketing, what safety incidents have been recorded, and what corrective actions the manufacturer has implemented.

However, clinicians will also need to develop regulatory expertise to navigate the transitional periods during which products certified under the old directive and under the new regulation coexist. During these years of transition, the meaning of the CE marking is not uniform; a product with an old certificate may have been evaluated under less stringent standards than one recently certified under the MDR. This temporary duality requires healthcare professionals, especially those involved in hospital procurement or the selection of clinical tools, to actively inquire under which regulatory framework each product was certified and to understand the implications of that difference.

This growing complexity, although intimidating for developers and clinicians alike, serves a noble and shared ultimate purpose: to build a digital health system in which patients can fully trust, where professionals have sufficient information to decide which tools to adopt, and where responsible innovators who invest in real quality can compete on equal footing against those seeking regulatory shortcuts. The radical transparency imposed by EUDAMED, the clinical rigor demanded by the new regulations, and the mandatory role of the compliance officer are mechanisms designed to ensure that patient safety does not depend on the good faith of manufacturers but rather on robust systems of independent verification. In this context, medical software will cease to be a special, less-regulated category and will become a medical device in its own right, with the same guarantees and standards as a cardiac implant or a biologic drug.

18.3. AI ACT: WHEN THE ALGORITHM BECOMES A REGULATED PRODUCT

The European Union has taken a regulatory step unprecedented in the global history of technology: it has created the world's first comprehensive law dedicated exclusively to regulating artificial intelligence as a specific category, with its own risks, obligations, and oversight mechanisms. The Artificial Intelligence Regulation, universally known as the AI Act, does not treat AI as just another technology among many others but rather recognizes that algorithmic systems possess unique characteristics—such as autonomous learning capabilities, inherent opacity, potential for systematic bias, and critical dependence on data quality—that warrant their own regulatory framework. Approved in 2024 after years of intense debate, this regulation establishes a system of obligations proportional to the level of risk each system presents, creating a new regulatory layer that overlaps and complements existing sector-specific regulations such as the MDR and the IVDR.⁽¹¹⁾ For any team developing medical software with artificial intelligence components, understanding this regulation is no longer a strategic option but a legal necessity for survival.

It is essential to understand from the outset that the AI Act does not replace or supersede sector-specific medical device regulations; rather, it complements them and, in many respects, reinforces them. An artificial intelligence system used in medical diagnosis, clinical decision support, or patient monitoring must simultaneously comply with all MDR requirements as a medical device and with the specific obligations of the AI Act as a high-risk system. This dual regulation may seem, at first glance, like an overwhelming bureaucratic burden that unnecessarily complicates the path to the market. However, for strategically minded developers, this overlap also offers opportunities for differentiation: those who master both frameworks will be able to navigate with an advantage in an ecosystem where many competitors will be left behind by the complexity. The AI Act is genuinely new because it provides a perspective focused on the specific risks of artificial intelligence that traditional health regulations address in a generic or indirect manner.

18.3.1. THE RISK PYRAMID: CLASSIFICATION AND SCOPE IN MEDICINE

The cornerstone upon which the entire AI Act is built is a system for classifying artificial intelligence systems into four levels of increasing risk, each with specific and proportionate obligations. At the base of the pyramid are systems with minimal risk, such as video games that use AI to generate the behavior of nonplayable characters, email spam filters, or optical character recognition applications for digitizing administrative documents. These systems have no specific obligations beyond the general ones applicable to any digital product and represent the vast majority of everyday applications of artificial intelligence. At an intermediate level are limited-risk systems, such as customer service chatbots, which must primarily comply with transparency obligations, clearly informing the user that they are interacting with a machine and not a human.

The top tier—and where the true regulatory transformation lies—is occupied by high-risk systems. These are defined as those that can significantly affect people's health, safety, or fundamental rights, and the regulation includes specific lists in Annexes II and III detailing the categories automatically considered highrisk. For the healthcare sector, the classification is clear-cut and virtually all-encompassing: Annex III explicitly includes artificial intelligence systems used in medical diagnosis, clinical decision support, real-time patient monitoring, management of critical hospital resources, clinical research, and health insurance management systems that determine eligibility or premiums. This means that the vast majority of medical software incorporating any artificial intelligence component—from an algorithm for detecting diabetic retinopathy to a sepsis prediction system in intensive care units—will automatically be considered a high-risk system and must comply with the full set of the regulation's most stringent obligations.

At the apex of the pyramid, completely separate and prohibited, are systems of unacceptable risk. These include practices considered contrary to the fundamental values of the European Union, such as social scoring systems that classify citizens on the basis of their behavior, subliminal manipulation systems that operate beyond people's awareness, or emotional recognition systems in workplaces and institutional education settings for classification purposes. Although these prohibitions seem far removed from the medical field, developers must remain vigilant: a system that evaluates the "cooperation" of chronic patients to adjust their priority on waiting lists, or that scores the behavior of medical residents, could skirt these prohibited boundaries if not designed with extreme ethical care.

The practical implication of this classification for medical software is that there is virtually no room for medium- or low-risk artificial intelligence systems in the clinical setting. With the exception of purely administrative applications with no impact on healthcare decisions, every medical algorithm will be highrisk by legal definition. This eliminates the temptation to seek favorable classifications and establishes a uniformly high regulatory floor for the entire industry. Developers must assume from the product's conception that they will be subject to the strictest regime, which dictates technical architectures, development budgets, clinical trial plans, and documentation strategies.

18.3.2. SIX FUNDAMENTAL OBLIGATIONS OF A HIGH-RISK SYSTEM

Being classified as a high-risk artificial intelligence system entails assuming a set of six fundamental obligations covering the entire product lifecycle, from conception to market withdrawal. The first of these obligations concerns transparency and comprehensive technical documentation. Manufacturers must create and maintain a documentation dossier that verifies how the system was developed, which design and validation methodologies were used, how AI-specific risks were managed, and how each applicable requirement of the regulation is met. This documentation is not mere archival formality; it must be permanently available to national supervisory authorities, who may request it at any time and must be updated with every significant change to the system. The level of detail required far exceeds standard practices in agile software development, forcing organizations to adopt rigorous document management processes.

The second fundamental obligation is data governance, a critical pillar that recognizes that the quality of an artificial intelligence system cannot exceed the quality of the data with which it is trained and validated. High-risk systems must be developed using training, validation, and test datasets that are relevant to the intended use, representative of the actual target population, and free from discriminatory biases to the greatest extent possible. Manufacturers must meticulously document the origin of all the data; the demographic and clinical characteristics of the population, including exclusions and their justifications; and the technical and methodological measures

adopted to detect, quantify, and correct biases. In medicine, where algorithmic biases can result in misdiagnoses for minority groups or systematic exclusions of certain patient profiles, this obligation has far-reaching ethical and legal implications.

The third obligation focuses on transparency for end users, which is distinct from documentation for authorities. Systems must be designed so that physicians, nurses, patients, or caregivers who are interacting with them are fully aware that they are dealing with artificial intelligence, understand its actual capabilities and specific limitations, and have sufficient information to exercise critical judgment. This involves providing clear, nontechnical instructions for use that explain the system's expected performance, validation metrics in relevant populations, known circumstances in which the system may not function properly, and warning signs indicating that the algorithm's output should be questioned. This operational transparency is essential for human oversight to be effective rather than merely nominal.

The fourth obligation establishes strict requirements for effective human oversight. High-risk systems must be technically designed to allow competent humans to monitor their operation, intervene at any point in the decision-making process, have the actual ability to override automated decisions when they deem it appropriate, and completely halt the system's operation if they detect anomalous or risky behavior. Human oversight is not a cosmetic addition or a legal fig leaf; it is a functional safety requirement that must be integrated into the system's architecture from the initial design phase. In the medical context, this means that the algorithm may recommend, alert, or suggest, but the final clinical decision must always rest with a human healthcare professional who has the information, training, and technical authority to disregard or modify the algorithmic recommendation.

The fifth requirement demands adequate levels of technical robustness, accuracy, and cybersecurity. Systems must achieve clinically validated performance metrics and be resilient to input errors, adversarial attacks, variations in the quality of input data, and gradual performance degradation over time. They must incorporate automatic mechanisms for detecting deviations in their operation, alerts when performance falls below predefined thresholds, and the ability to adapt or undergo controlled retraining when necessary. This requirement for continuous performance monitoring is particularly relevant for medical artificial intelligence, where a model can degrade silently as patient populations, clinical reference practices, or the characteristics of data acquisition equipment change.

The sixth requirement mandates a formalized risk management system specific to artificial intelligence. Manufacturers must establish processes that identify, assess, mitigate, and continuously monitor the risks associated with the system's use, including not only technical risks of malfunction but also risks of misuse by inadequately trained operators, risks of discriminatory bias, risks to privacy and data protection, and risks of overreliance or deskilling among professionals using the system. This risk management system must be proactively updated throughout the product's commercial lifecycle, incorporating lessons learned from incidents, new scientific evidence, and changes in the clinical environment of use.

18.3.3. GOVERNANCE, SANDBOXES, AND THE SURVEILLANCE ECOSYSTEM

The AI Act established a multilayered governance system of considerable institutional complexity. The national market surveillance authorities of each member state—generally the same bodies that already regulate medical devices—will be primarily responsible for monitoring compliance with the regulation within their territory. At the European level, a European Artificial Intelligence Committee coordinated by the Commission is established, which will be responsible for harmonizing interpretations, resolving conflicts between national authorities, and proposing updates to the regulation as technology evolves.⁽¹²⁾ Notified bodies—those accredited private entities that already assess MDR and IVDR compliance—will also assume responsibility for evaluating compliance with the AI Act's requirements where applicable, creating institutional continuity that facilitates regulatory integration for manufacturers.

A particularly valuable development for the innovation ecosystem is the institutionalization of regulatory testing environments, known as regulatory sandboxes. These spaces allow developers to test innovative artificial intelligence systems under real-world but controlled conditions under the active supervision of competent authorities before the full burden of regulatory compliance for general marketing is assumed. With respect to medical software, where traditional clinical validation can be extremely costly and time-consuming, sandboxes offer a unique opportunity to generate real-world evidence of safety and efficacy with mitigated risks. Member states are

required to establish these sandboxes and actively encourage their use by developers, particularly small and medium-sized enterprises, startups, and public sector entities. Participation in a sandbox does not exempt participants from future compliance, but it allows them to accumulate operational experience and performance data that greatly facilitate the preparation of final documentation.

Another significant innovation is the formalized obligation to report serious incidents. When a high-risk artificial intelligence system causes or contributes to serious harm to human health, a substantial violation of fundamental rights, or significant damage to property or the environment, the manufacturer must notify the competent authorities without undue delay. This obligation complements the existing one in the MDR for incidents involving medical devices, creating a more comprehensive and multidimensional surveillance system. Reported incidents must be thoroughly investigated; findings must be shared with other operators and authorities to prevent recurrence; and, when necessary, safety field actions must be implemented, which may include corrective updates, usage restrictions, or market withdrawals.

For medical software developers, adapting to the AI Act undoubtedly represents a considerable challenge. The additional requirements translate into more technical documentation to maintain, more data governance processes to implement, higher certification costs to bear, and greater organizational complexity to manage. Small businesses and startups, particularly those with small teams and limited resources, may feel disproportionately affected by this regulatory burden, with the real risk that the barrier to entry into the European market will rise so high that it favors large corporations with specialized regulatory departments. However, the compensatory opportunity is substantial: the AI Act creates, for the first time, a common, clear, and predictable framework across the European Union, where products that demonstrate compliance will have a credible quality differentiator compared with competitors from less-regulated markets.

18.3.4. INTERACTION WITH THE HEALTHCARE FRAMEWORK AND FUTURE OUTLOOK

The relationship between the AI Act and sector-specific medical device regulations, particularly the MDR, is not without gray areas and practical complexities that the first years of implementation will clarify. In some respects, the requirements of both regulations overlap redundantly: both require risk management, both require postmarket surveillance, and both mandate comprehensive technical documentation. In other respects, they complement each other usefully: the MDR provides expertise in the clinical evaluation of medical devices, while the AI Act provides specificity regarding the unique risks of artificial intelligence, such as algorithmic transparency, bias mitigation, and human oversight. The European Commission has published guidance documents to help manufacturers navigate this interaction, but some uncertainty inevitably persists during the first few years as interpretive practices and administrative case law take shape.

What is indisputable is that no manufacturer of medical software with artificial intelligence components can afford to ignore either of these frameworks. Products must cumulatively comply with all applicable requirements of both regulations, which demands integrated regulatory planning from the earliest stages of development. Development teams must include hybrid regulatory expertise encompassing software engineering, traditional healthcare regulations, and the specific governance requirements of artificial intelligence. Here, the role of the P r MDR Compliance Officer takes on additional dimensions of technical complexity.

The future of the AI Act's application in the medical field will depend critically on how it is implemented in practice and how artificial intelligence technology itself evolves. The regulation is deliberately designed as an adaptive framework, with built-in periodic review mechanisms and the flexibility to update the annexes defining high-risk systems without needing to reopen the entire legislative text. As new algorithmic architectures, foundational multimodal language models, generative AI systems with clinical applications, and federated learning algorithms operating on distributed data emerge, the regulation will require evolving interpretations or specific amendments. International cooperation will also be crucial: the European Union has been a pioneer, but other economic blocs are developing their own regulatory frameworks, creating a global mosaic that international manufacturers will need to navigate with agility.

In conclusion, it is important to bear in mind that the AI Act is not a regulatory end in itself but rather an instrumental means to achieve higher social goals: ensuring that artificial intelligence is developed and deployed in a manner that scrupulously respects fundamental rights, human dignity, and the physical and psychological safety of individuals. In the field of medicine, where

algorithmic decisions can determine diagnoses of serious illnesses, painful treatments, or even the continuation of life, this ethical imperative takes on particular urgency. Stringent regulation is not an irrational obstacle to technological innovation; it is the necessary condition for that innovation to be socially sustainable, clinically reliable, and ethically legitimate. Developers who understand this underlying logic and work constructively with regulation, rather than seeking shortcuts or jurisdictions with lower standards, will inevitably lead the future of digital health in Europe and, likely, the world.

18.4. OVERVIEW IN LATIN AMERICA AND SPAIN

The regulatory journey for medical software does not end at the FDA offices in Maryland or with the European Union's notified bodies. For companies hoping to bring their diagnostic algorithms, chronic condition monitoring apps, or clinical decision support systems to Spanish-speaking markets, the landscape becomes considerably more complex, fragmented, and often unpredictable. Latin America, in particular, is by no means a homogeneous bloc; it is a mosaic of twenty countries with levels of regulatory development ranging from sophisticated to nascent, with technical requirements that vary dramatically and with approval processes that can range from relatively streamlined to extremely bureaucratic and opaque. Spain, for its part, although geographically European and culturally Latin, presents its own unique challenges in applying EU regulations but with local particularities in implementation, healthcare financing, and technology adoption that the foreign developer ignores at their own risk. Understanding this landscape in depth is not a strategic luxury for ambitious companies; it is an inescapable operational necessity for any organization seeking to operate with sustainable success in these markets.

Let us begin by examining Spain, which, owing to its population of forty-seven million, has a geographical position as a natural bridge between Europe and the Americas and its historical role as a hub for the dissemination of Spanish-language culture, often serves as the preferred gateway to the Spanish-speaking market for many healthcare technology companies. As a full member of the European Union, Spain fully implements the European Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR) without national transposition, exactly as Germany, France, or Italy do. This means that any medical software intended for sale in Spain must bear the CE marking in accordance with these regulations, obtained in advance through a European notified body accredited for the evaluation of products in its risk class. There is no additional national premarket health authorization process; once the manufacturer holds a valid CE mark, they may legally market their product throughout the European Economic Area, including Spain, without any additional health registration procedures.⁽¹³⁾

14.4.1. SPAIN: BEYOND THE CE MARKING, THE MAZE OF PUBLIC FUNDING

However—and this nuance is crucial for actual commercial viability—CE marking represents only half the battle in the Spanish healthcare system. For a digital health product to be funded by the public National Health System and thus accessible to the vast majority of patients at no direct cost, it must undergo additional processes of economic evaluation, budget impact analysis, and a formal decision on inclusion in the National Health System's common portfolio of services or in the service portfolios of the autonomous communities. The Spanish Agency for Medicines and Health Products (AEMPS) acts as the competent authority for the regulation, surveillance, and safety of medical devices, but the decision on public funding rests with the General Directorate of the Common Portfolio of Services of the National Health System within the Ministry of Health and ultimately with the health departments of the seventeen autonomous communities, which directly manage virtually all public healthcare spending. This process of evaluating health technologies and deciding on funding can take years, involves political competition between regions, and is not guaranteed even when the product bears the CE mark and demonstrates clinical superiority over existing alternatives.

AEMPS, aware that traditional regulatory rigidity can stifle digital innovation, has developed specific initiatives in recent years to facilitate the entry of software-based medical devices into the Spanish market. Of particular note is the regulatory sandbox program for digital health, which allows developers to test their products in controlled and real-world clinical settings under the agency's active supervision before undertaking the full burden of formal certification. This regulatory testing environment offers a valuable pathway to generate Spanish clinical evidence,

validate cultural or linguistic adaptations of the product, and establish a constructive relationship with national regulators. The AEMPS has also published specific guidelines on software as a medical device, clarifying risk classification criteria, interpretations of MDR Rule 11 for algorithms, and specific documentation requirements. For developers, especially those whose products are genuinely innovative and do not fit comfortably into existing regulatory categories, establishing an early and ongoing dialog with the AEMPS can prove strategically invaluable.⁽¹³⁾

Another aspect of growing importance in the Spanish ecosystem is the role of regional health technology assessment agencies. Regions such as Catalonia, through the *Agència de Qualitat i Avaluació Sanitàries de Catalunya* (AQuAS), the Basque Country with its agency *Osteba*, or Andalusia with the *Agencia de Evaluación de Tecnologías Sanitarias* (AETSA), maintain their own medical device evaluation processes that can decisively influence the adoption and funding of the product within their respective territories. These regional agencies evaluate not only clinical efficacy and safety but also cost-effectiveness, budgetary impact, and alignment with the local needs of the healthcare system. For a company aspiring to an effective national presence in Spain, it is highly recommended to familiarize itself with these agencies and their economic evaluation methodologies and to consider requesting specific evaluations targeted at particular regional health services where the product may have a greater impact or where there are more streamlined channels for technology adoption.

18.4.2. BRAZIL AND MEXICO: THE GIANTS OF THE LATIN AMERICAN MARKET

Turning our gaze across the Atlantic, we find a Latin American landscape of extraordinary regulatory diversity where each country demands its own approval pathway without mutual recognition mechanisms equivalent to the European single market. Brazil, owing to its immense population of 215 million, the size of its economy, and the relative sophistication of its healthcare infrastructure, is unquestionably the most attractive and complex market in Latin America. Its regulatory agency, the *Agência Nacional de Vigilância Sanitária* (ANVISA), is also among the most demanding, technically well-equipped, and has the strongest tradition of professional independence in the entire region. ANVISA maintains a medical device registration process that can be complex, document-intensive, and time-varying but has made significant progress in recent years toward harmonization with recognized international standards.⁽¹⁴⁾

For medical software specifically, ANVISA has published specific resolutions and technical guidelines clarifying its regulatory treatment and offers the possibility of using international reference certifications—particularly FDA approval or the European CE mark—as supporting evidence that can substantially streamline the Brazilian registration process.⁽¹⁴⁾ However, it is important not to fall into the misconception that foreign certification completely replaces local registration: ANVISA continues to require a specific health registration for Brazil, technical documentation translated into Portuguese by certified translators, adaptations to local labeling regulations and instructions for use, and in some cases, additional validation studies demonstrating the product's performance in the Brazilian population or under local conditions of use. The process, although improved, remains slow and costly, often taking twelve to eighteen months from initial submission to obtaining final registration.

Mexico is the second-largest Latin American market, with a population of 130 million and a complex healthcare system that combines public, private, and social security segments. The Federal Commission for Protection against Health Risks (COFEPRIS) is the competent regulatory authority, and its medical device registration process has traditionally been criticized for its complexity, its highly variable timelines—which ranged from six months to three years with no predictability—and its documentation requirements, which often changed without prior notice.⁽¹⁵⁾ However, in recent years, COFEPRIS has implemented significant reforms aimed at streamlining the process, making it more predictable and better align it with international standards. The agency has established priority review pathways for innovative products and has improved its electronic submission platforms.

COFEPRIS, like ANVISA, accepts international reference certifications as proof of compliance, although with specific requirements that must be verified on a case-by-case basis. A particularly important regulatory aspect in Mexico is the requirement to have a local legal representative established in the Mexican territory, who acts as the holder of the health registration with COFEPRIS and assumes legal responsibility before the authority for the marketed product. For foreign companies without a Mexican subsidiary, this necessarily involves finding a local distributor, a strategic partner, or a reliable legal representative to fulfill this role, which adds a dimension of

business relationship management to the purely regulatory complexity. The choice of this local partner is critical, as their actions or interactions can affect the validity of the registration and the product's reputation in the market.

18.4.3. EMERGING MARKETS: ARGENTINA, CHILE, COLOMBIA, AND THE REST OF THE REGION

Argentina, through its National Administration of Medicines, Food, and Medical Technology (ANMAT), has one of the regulatory agencies with the longest history and strongest institutional tradition in all of Latin America, building on decades of pharmaceutical regulatory development. ANMAT has shown a growing and explicit interest in digital health, publishing specific guidelines for mobile health applications, telemedicine services, and, more recently, guidance on artificial intelligence in medical devices. ANMAT's registration process is well established, with documented procedures and relatively predictable timelines, although Argentina's macroeconomic situation—with its recurring currency crises, high inflation, and trade restrictions—can severely impact the actual commercial viability of approved products. For foreign developers, it is imperative to assess not only regulatory feasibility but also the actual market: the payment capacity of healthcare systems, reimbursement mechanisms, and the stability of technology imports.⁽¹⁶⁾

Chile, through its Institute of Public Health (ISP), often offers a relatively streamlined entry route for companies wishing to test the South American region before committing to larger and more complex markets. The ISP has made consistent progress in harmonizing with international standards, actively participates in the Pan American Network for the Harmonization of Pharmaceutical Regulations, and accepts reference certifications with simplified procedures. In addition, Chile maintains trade agreements with a broad network of countries, including the United States, the European Union, and numerous Asian partners, which facilitate the importation of technological products and reduce tariff barriers. The Chilean market, although smaller than the Brazilian or Mexican markets, offers a predictable regulatory environment, a healthcare system capable of adopting technology, and a strategic geographic position as a platform for expansion into other Andean countries.⁽¹⁷⁾

Colombia, through the National Institute for Food and Drug Surveillance (INVIMA), maintains a registration process that can be slow but offers a degree of predictability once the applicant understands its specific requirements. The country has made a firm commitment to telemedicine and digital health as a health policy strategy, accelerated particularly by experiences during the COVID-19 pandemic, which has created specific opportunities for medical software focused on remote consultations, home monitoring, and chronic disease management. INVIMA accepts international reference certifications, although with additional local documentation requirements that must be carefully prepared. The Colombian market, with its mixed healthcare system and population of fifty million, represents an opportunity that falls between regional giants and smaller markets.⁽¹⁸⁾

Peru, Uruguay, Paraguay, Ecuador, and other countries with smaller populations have smaller regulatory agencies, fewer specialized technical resources, and less developed and often more informal registration processes. These markets, although individually limited in size, can offer entry opportunities with lower initial regulatory investment and can serve as learning platforms for the region. However, the decision to enter these markets must be based on a rigorous cost–benefit analysis that considers not only formal regulatory requirements but also the actual size of the addressable market, the intensity of local and international competition, nonregulatory commercial barriers to entry, and the ability to generate returns that justify investment in local adaptations, translations, and registration management.

18.4.4. NAVIGATION STRATEGIES AND THE VALUE OF DIVERSITY

A cross-cutting challenge throughout Latin America, regardless of the specific country, is the extreme variability in actual regulatory approval times. While in some countries with optimized processes, a marketing authorization can be obtained in three to six months by submitting complete documentation and reference certifications, in other less efficient or more congested systems, the process can drag on for two, three, or even five years with no predictability. This time-related uncertainty severely hinders business planning, the management of development resources, negotiations with investors, and the coordination of multinational commercial

launches. For this reason, it is highly recommended that companies without prior experience in the region work with local regulatory consultants with a proven track record, who are familiar not only with formal processes but also with actual timelines, the unwritten nuances of each agency, and the professional contacts that can facilitate the resolution of administrative hurdles.

Another common challenge is the management of technical and legal documentation. Although many Latin American countries accept reference certifications as a starting point, almost all require specific local documentation, translations certified by official translators recognized in each country, and in some cases, additional clinical validation studies demonstrating safety and efficacy in the local population or under country-specific conditions of use. This can entail significant costs, especially when translation into multiple languages is needed: Portuguese for Brazil, Spanish with local variants for the other countries, and occasionally specific document format requirements. Planning for these regulatory localization costs from the product design phase and including them in international marketing budgets is essential to avoid surprises that could compromise the economic viability of regional expansion.

Regulatory harmonization in Latin America remains, however, a distant goal rather than an imminent reality. Mercosur has established some mechanisms for technical coordination among its full members—Argentina, Brazil, Paraguay, and Uruguay—and associates, but these agreements remain limited in scope and do not result in automatic mutual recognition of health registrations. The Pan American Network for the Harmonization of Pharmaceutical Regulations (RED PARF), under the umbrella of the Pan American Health Organization, actively promotes regulatory convergence and has made progress in specific areas such as good manufacturing practice inspections, but its progress toward the harmonization of software medical device registrations is slow and piecemeal. As these regional mechanisms mature, medical software manufacturers must accept diversity as the operating norm and develop internal capabilities for multinational regulatory management.

For developers facing this patchwork landscape, the recommended strategy must be based on rigorous and realistic prioritization. It is neither operationally feasible nor strategically necessary to attempt simultaneous registration in all Latin American countries. The sensible approach involves identifying the two or three most attractive markets on the basis of criteria such as size, purchasing power, alignment with the product profile, and manageable regulatory complexity; studying them thoroughly through market research and local consulting; and establishing a realistic sequential expansion roadmap. It often makes strategic sense to start with countries that have more streamlined and predictable processes—Chile or Uruguay, for example—to gain operational experience, accumulate local clinical references, and validate product adaptations before addressing more complex and competitive markets such as Brazil or Mexico. It may also be valuable to explore strategic alliances with established local partners who understand the regulatory landscape, have health registration infrastructure in place, and can facilitate access to distribution channels and relationships with payers.

For healthcare professionals in Latin America and Spain, understanding this fragmented regulatory landscape provides valuable tools for assessing the quality and legitimacy of the products they encounter. Medical software that holds a valid ANVISA health registration in Brazil has undergone a rigorous technical evaluation process and can be considered of proven quality; conversely, a product that only bears the European CE mark but lacks specific registration in the Latin American country where it is marketed may not be legally authorized and warrants further scrutiny. This regulatory knowledge also empowers clinicians to actively participate in national health policy debates, suggesting that regulatory processes that effectively protect patients from unsafe or ineffective products without creating unnecessary bureaucratic barriers that stifle legitimate and beneficial innovation.

The future of medical software regulation in Latin America will inevitably move toward greater regional harmonization and the institutional strengthening of national agencies. The experience during the COVID-19 pandemic has forcefully demonstrated the importance of having agile yet robust regulatory systems capable of rapidly evaluating technologies critical to public health without sacrificing safety standards. It has also highlighted the potential of regional cooperation to accelerate equitable access to essential health technologies. In the coming years, we are likely to see significant progress in these areas, although the pace will necessarily be gradual given the differences in institutional development across countries. In the meantime, regulatory diversity will remain the operational reality, and those who develop the ability to navigate it with intelligence, patience, and respect for local particularities will have a substantial competitive advantage in one of the world's digital health markets with the greatest growth potential.

In closing, it is worth remembering that behind every documentation requirement, every

registration procedure, and every evaluation process, there are real patients who trust—often without knowing it—that the technological products reaching the market where they live are safe and effective and have been evaluated by competent authorities. The regulatory diversity that characterizes Spanish-speaking markets is not a bureaucratic whim but a reflection of the diversity of healthcare systems, public policy priorities, cultures of the relationship between the state and citizens, and levels of economic development. Respecting this diversity, striving to genuinely understand it and working constructively with it rather than against it is the only way to build sustainable long-term commercial relationships and, more importantly, to contribute ethically and effectively to the health and well-being of people in these countries.

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