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Navigating global regulatory pathways for orphan medical devices

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Orphan medical devices are devices that are used for a small patient population due to the rarity of the indications. Due to the smaller patient population, manufacturers face unique challenges in generating sufficient clinical data for regulatory submission. This article discusses the Humanitarian Use Device (HUD) program of the US Food and Drug Administration (FDA) and the orphan device program introduced in the EU in 2024.

Keywords – orphan medical devices, EU MDR, notified bodies, FDA

Introduction

Orphan medical devices are intended for the diagnosis, prevention, or treatment of rare diseases, which are conditions affecting small patient populations and often lacking adequate therapeutic options. In the US, the FDA's Humanitarian Device Exemption (HDE) Program,[1] created in 1990, is intended for devices that diagnose or treat diseases or conditions that affect or are manifested in no more than 8,000 individuals per year.

In contrast, the EU has only recently introduced a regulatory pathway designed specifically for orphan devices. In 2024, the Medical Device Coordination Group (MDCG) published MDCG 2024-10,[2] which provides guidance for manufacturers and notified bodies on the clinical evaluation process for orphan medical devices under the EU Medical Devices Regulation (EU MDR), also known as Regulation (EU) 2017/745,[3] in Europe. MDCG 2024-10 defines an orphan medical device as a device intended for the treatment, diagnosis, or prevention of a condition affecting no more than 12,000 individuals annually in the EU. Additional criteria include either the lack of adequate alternatives or an expected clinical benefit over existing diagnostic or therapeutic options. The EU threshold of 12,000 individuals annually is extrapolated from the US definition of 8,000 individuals, based on the relative population sizes.

Regulatory approval of orphan devices presents several challenges, especially in generating robust clinical evidence due to small patient populations. This limitation reduces the feasibility of traditional premarket clinical investigations and may require reliance on alternative data sources, such as real-world evidence.

This article brings together advice from regulatory experts – including contributors from the Irish authority and a notified body – to provide insights on how the US and the EU handle orphan medical devices, highlighting similarities and differences in their regulatory pathways.

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Orphan devices in the US

The FDA has a well-developed program for orphan devices: the HDE program for devices designated as HUDs. The program applies to "medical devices intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year," per 21 CFR 814.3(n).[1] Devices designated as HUDs must also meet the following criteria:[4]

- The probable benefits of using the device should outweigh the risks for the patients, considering the probable benefits and risks of currently available devices or alternative treatments;
- The device is not available without the HDE; and
- No similar device other than another device approved under an HDE or investigational device exemption is available to treat or diagnose the disease or condition.

Manufacturers can apply for HUD designation by submitting a formal application to the Office of Orphan Products Development. This application must be supported by evidence that the device is used to treat or diagnose a rare disease or condition that affects or is manifested in not more than 8,000 people in the US per year.[5]

Once HUD designation is granted, a manufacturer can apply for an HDE. An HDE application has some key differences compared with a premarket authorization (PMA):[4]

- A HUD under an HDE is exempt from the requirement of establishing a reasonable assurance of effectiveness;
- The review timeline for an HDE (without major amendments) is 75 days, in contrast to 180 days for a PMA;
- No user fees apply;
- The use of an HUD in a local hospital is subject to prior approval of an Investigational Review Board or local committee, except in emergencies;
- Medical device reports must be submitted to both the FDA and to the Investigational Review Board or local committee;
- A profit prohibition applies, with some exemptions (e.g., for pediatric devices); and
- No comparable device is available to treat or diagnose the disease or condition.

Furthermore, the manufacturer of an approved HDE is required to submit periodic reports to the FDA under 21 CFR 814.126(b).[1] These reports must include clinical experience, an assessment of the probable benefit-risk ratio, and confirmation that the requirements for an HDE are still met.

Currently, 79 original products are registered in the FDA's HDE database.[6] This limited number may be due to multiple factors, including the fact that the HDE pathway is only allowed if no comparable device is available to treat or diagnose the disease or condition. Furthermore, the FDA encourages manufacturers to use the PMA route whenever possible.

In summary, the FDA has a proven process for market access of orphan devices. The program not only allows devices on the market with limited clinical data (as long as there is a probable favorable benefit-to-risk ratio) but also is attractive from a manufacturer's financial perspective as no user fees

apply. This financial incentive is important, as without it, there would be no business case for bringing an orphan device to the market. However, it should be noted that the HDE route is only possible if there is no comparable device on the market to treat or diagnose the condition or disease.

Orphan devices in Europe

As noted in the introduction, specific considerations for the conformity assessment and certification of orphan medical devices were recently introduced in Europe. It was recognized that orphan devices face multifactorial challenges – economic, regulatory, and clinical (generating sufficient premarket clinical evidence to support performance and safety). Clinical stakeholders, including the European Society of Cardiology, had also called for increased regulatory agility to ensure the availability of devices for orphan conditions or unmet medical needs.[7] In 2022, the MDCG published a position paper on the transition to the EU MDR/In Vitro Diagnostic Devices Regulation, notified body capacity, and device availability.[8] This paper acknowledged the situation of orphan devices and committed to providing a definition, specific guidance, and other means of assistance (e.g., scientific advice) to help these products meet regulatory requirements.

MDCG orphan task force and MDCG-2024-10[2]

The MDCG task force on orphan devices included regulators and representatives from the medical device industry, notified bodies, and academic clinical experts. A definition for an orphan device was developed to support the application of special considerations during clinical evaluation and conformity assessment, with the goal of enabling a more feasible regulatory approval process without compromising safety.

Orphan device criteria and justification of status

Notably, the EU definition of an orphan device includes both quantitative and qualitative components. Quantitatively, an orphan device is defined as one intended for the treatment, diagnosis, or prevention of a condition affecting no more than 12,000 individuals annually in the EU. This is an incidence-based epidemiology and is intentionally extrapolated from the FDA HUD program to reflect the EU population size. Qualitatively, manufacturers must demonstrate that adequate alternatives are unavailable or that the device will provide a clinical benefit compared with available alternatives.

Manufacturers intending to seek orphan status for their device should provide justification that their device meets these criteria. This includes information on the epidemiology of the disease or condition and a scientific rationale explaining the device's importance in managing the orphan population, considering patient- and device-specific factors. The EU criteria also recognize the concept of an orphan *subpopulation* (i.e., a clinically valid patient subgroup of patients within a disease or condition with an annual incidence of more than 12,000 in the EU). Finally, the criteria also allow a manufacturer to claim an orphan indication status for a device that may also have indications in larger or non-orphan patient populations.

> *The EU definition of an orphan device includes both quantitative and qualitative components.*

Clinical evaluation considerations

MDCG-2024-10 highlights key considerations to assist manufacturers and notified bodies in the EU in generating and assessing the required clinical data for regulatory approval. This guidance acknowledges that orphan devices with acceptable limitations in the amount and quality of premarket clinical data may be granted market access, provided that appropriate measures are implemented. For example, there should be sufficient clinical evidence to demonstrate an expected clinical benefit, an acceptable level of safety, and an adequate postmarket clinical follow-up (PMCF) plan to ensure appropriate generation of postmarket clinical data.

Clinical investigations for orphan devices can be challenging due to the limited number of affected subjects. Considerations for suitable study designs and choice of

comparator or controls are outlined in the guidance. The guidance also emphasizes the use of PMCF, including the use of registries. Orphan devices for which the premarket clinical evidence is deemed sufficient but need to be confirmed through appropriately designed PMCF activities are also highlighted as an example where notified bodies may issue certificates with specific conditions or provisions.

To further support the regulatory pathway for orphan devices in the EU, regulators recommend manufacturers seek advice from the EMA expert panels and engage in dialogue with their notified bodies. This recommendation is detailed in further sections of this article.

The role of expert panels in advancing orphan medical devices

Expert panels are instrumental in the development and assessment of high-risk medical devices, including those intended for rare or life-threatening conditions. Following the publication of the MDCG 2024-10 guidance issued by the MDCG,[2] the European Medicines Agency (EMA), in collaboration with the European Commission, launched a pilot program in August 2024 to support orphan medical devices.[7] This initiative offers manufacturers and notified bodies free advice from expert panels regarding orphan device status and the clinical data required for the conformity assessment.

Scope and eligibility

The pilot program, grounded in Article 61(2) of the EU MDR, targets Class III devices and IIb active devices destined to administer or remove a medicinal product designed for life-threatening conditions or those that cause permanent impairment of a bodily function, pediatric use, or for devices offering major clinical benefits compared with available alternatives. Running from August 2024 to December 2025, the program is open to all applicants established within the European Economic Area.

Early advice and innovation support

Expert panels also provide early guidance to manufacturers – especially small and medium-sized enterprises – on their clinical development strategies and the design of clinical investigation studies. This service, piloted until the end of 2024, has prioritized advice for devices addressing unmet medical needs, fostering innovation and improving access to safer, more effective devices.

Obtaining orphan device status influences the expected level of premarket clinical evidence, particularly regarding justifications for limitations and acceptable levels of clinical uncertainty. Manufacturers of devices that potentially qualify as orphan devices are, therefore, strongly encouraged to consult an expert panel on orphan status before or concurrently with seeking advice on clinical development.

Streamlined evaluation process

The evaluation of orphan status by expert panels is completed within 60 days. The process includes:

- Exploratory meeting (optional): Applicants can discuss the procedure's scope and submission requirements with the expert panel's secretariat;
- Presubmission meeting (optional): Thirty days before submitting their package, applicants may request a meeting with the expert panel's secretary and the panel chair to review the draft application;
- Discussion meeting (optional): Around Day 50 of the review of the submission, applicants might be asked to meet with the experts to clarify aspects of the submission request; and
- Final advice: Delivered 60 days after the start of the procedure, in the form of an advice letter.

The advice on the clinical data requirements given by the expert panels is also completed within 60 days. The process starts after a positive opinion on the orphan device status has been communicated to the applicant and includes:

- Presubmission meeting (recommended): Thirty days before submitting their package, applicants may request a meeting with the expert panel's EMA secretariat and the panel chair to review the draft application;

- Discussion meeting (recommended): Around Day 50 of the review of the submission, applicants might be asked to meet with all the experts to clarify aspects of the submission request; and
- Final advice: Delivered 60 days after the start of the procedure, in the form of a letter of advice.

All expert panel advice is provided free of charge. Detailed guidance, Q&A, and application forms are available on the EMA website.[9-11]

Progress and future directions

As of November 2025, expert panels have received 16 requests for an opinion regarding a possible orphan device status. Of these, five procedures were completed, three are currently under evaluation, and six are waiting for the final submission by the applicant. The expert panels agreed with the proposed orphan status in all five of the completed requests. This group includes devices for ventricular assistive support, pediatric scoliosis, glioblastoma, pulmonary arterial hypertension, and patent ductus arteriosus. Two of these applicants also asked for additional advice on the clinical development strategy.

> *Manufacturers that have completed or are advanced in their clinical evaluation may request expert panel advice during the transition period.*

The pilot aims to conclude in December 2025, with a comprehensive report to be published. However, support for the orphan device's development and assessment by the expert panels will be kept in a similar mode, namely, keeping the requests for advice free of charge, at least until the end of 2026. Looking ahead, plans include establishing new panels for pediatric and rare diseases[12] and developing a framework for breakthrough devices.

Transition period

During the transition period, which ends on 31 December 2027 (for Class III medical devices and Class IIb implantable devices) or 31 December 2028 (for devices from other risk classes), manufacturers that have completed or are advanced in their clinical evaluation may request expert panel advice, provided this does not interfere with the notified body's ongoing assessments.

This option may be particularly useful for orphan devices for which the manufacturer has not yet submitted its clinical evaluation report to the notified body. A manufacturer should request advice from an expert panel only if it will be able to update its clinical evaluation report, taking into consideration the expert panel's views, before the notified body assesses the manufacturer's clinical evaluation. If this cannot be ensured, a consultation of the expert panels should be left to the notified body during conformity assessment pursuant to EU MDR Article 106(11).

Notified body perspective on orphan devices in the EU

Proportionate conformity assessment

A notified body must tailor the depth and nature of its assessment to the clinical and epidemiological realities of orphan device development. Proportionate assessment does not result in relaxed standards. Rather, it aligns evidence requirements and scrutiny with the inherent limitations of small populations without lowering safety and performance expectations.

A proportionate approach emphasizes early, well-documented scientific dialogue with the manufacturer to identify critical data gaps and acceptable evidence types. It also features flexible acceptance of nontraditional evidence streams, when justified, including robust preclinical evaluation, computational modelling, and well-explained extrapolations from similar populations or indications. A proportionate approach permits the use of conditional certification when premarket clinical evidence cannot fully demonstrate expected clinical benefit, provided appropriate postmarket obligations are in place.

Documentation and traceability

Every regulatory judgment made in an orphan device

assessment must be documented thoroughly by the notified body. Clear records of the scientific rationale, risk assessment, and decision justification reduce friction during any subsequent review by a designated competent authority. Documentation, at a minimum, should include:

- The manufacturer's epidemiological case and sources used to support orphan status;
- The scientific rationale for the chosen evidence package and any extrapolations;
- The description and justification of any conditional certification and the corresponding postmarket requirements; and
- The risk-based rationale for accepting nonclinical or surrogate endpoints.

Thorough documentation ensures that any conformity assessment review can be held up when challenged by a designated authority.

The evidence challenge: Epidemiology, nonclinical data, and extrapolation

To allow for a notified body to document its assessment and grant orphan device status, manufacturers must present a coherent, data-driven case for the orphan device status. Notified bodies will expect a clear epidemiological justification demonstrating the rarity threshold has been met, along with an explanation of case ascertainment methods. Manufacturers must also provide a scientific rationale for the mechanism of action and the plausibility of the expected clinical benefit, grounded in pathophysiology. A robust assessment of nonclinical (preclinical) data is required, which includes the quality, relevance, and translatability to humans. When extrapolating clinical data from similar indications or populations, the manufacturer must provide an explicit, well-argued justification, supported by bridging science and, where possible, quantitative modeling. Notified bodies will critically appraise the relevance and robustness of nonclinical data and accept extrapolation only when supported by strong mechanistic or comparative evidence and thorough scientific justification.

Expected clinical benefit and regulatory consequences

In many orphan-device cases, premarket clinical data are insufficient to conclusively demonstrate clinical benefit. Notified bodies should therefore explicitly evaluate whether an expected clinical benefit is plausible and proportionate to residual uncertainty. Certification decisions should reflect this uncertainty, for example, by using conditional certification mechanisms that mandate targeted PMCF to drive further evidence collection. PMCF should be emphasized as a central element of the total evidence plan, recognizing that generating clinical data is often as challenging postmarket as it is premarket.

Conditional certification as a practical tool

Conditional certification allows devices to enter the market under defined constraints that enable closer surveillance and data collection. Notified bodies should consider conditional certification for orphan devices when premarket data indicate plausible expected benefit but lack confirmatory clinical outcomes. The approach requires a feasible, time-bound PMCF plan with clear milestones, data requirements, and governance. Additional measures must be in place to protect patients and to enable timely regulatory action if postmarket data do not confirm the expected benefit. Conditional certification must be accompanied by postmarket obligations, transparent timelines, and predefined criteria to allow for ongoing certification.

BSI experience and outcomes

The British Standards Institution (BSI) has handled a number of orphan device applications from which operational lessons can be derived. Since MDCG 2024-10[2] was issued, BSI recorded 12 orphan-device status claims. Two applications were progressed via the EU expert panel route and advanced based on that decision. Ten applications were submitted directly to BSI as the notified body; of these, two were deemed not appropriate for orphan designation, while eight were accepted and progressed through the orphan device assessment pathway.

This experience highlights three practical realities. First, many manufacturers attempt direct notified-body

submissions, making the notified body's initial screening and scientific engagement crucial.

Second, notified bodies must be prepared to reject inappropriate claims early and to document those decisions comprehensively. Third, accepted applications often require iterative scientific dialogue and carefully designed postmarket strategies. For example, a device that has a potential EU market of 10-20 patients will not yield significant statistical data from a typical PMCF study design; therefore, a more suitable approach may be needed, such as the development of a registry or a survey designed to reflect real-life patient-reported outcome measures.

Summary of recommendations

The following summarizes practical recommendations for manufacturers and notified bodies based on the guidance and experience discussed in this article.

Practical recommendations for manufacturers:

- Prepare a rigorous epidemiological justification, including data sources, case ascertainment, prevalence/incidence calculations, and uncertainty bounds;
- Provide a clear mechanistic narrative linking the device to expected clinical benefit, supported by nonclinical evidence;
- If extrapolating clinical data, deliver a structured bridging justification and, where possible, include supportive modeling or historical-control analyses;
- Design a realistic PMCF plan with measurable endpoints, timelines, and interim analyses aligned with notified body expectations for conditional certification;
- Anticipate and document patient-safety monitoring and procedures for acting on adverse signals through an appropriate PMS plan.

Practical recommendations for notified bodies:

- Implement structured dialogue and early engagement to set evidence expectations and document agreed assessment strategies;
- Maintain a transparent, repeatable framework for evaluating epidemiology, nonclinical data, and extrapolations;
- Use conditional certification deliberately as a pathway to manage uncertainty, not as a default workaround;
- Ensure that postmarket obligations are specific, measurable, and enforceable, with clear criteria for reassessment; and
- Keep comprehensive records to support downstream review by designated authorities and to promote public confidence.

These recommendations highlight the coordinated role of manufacturers and notified bodies in advancing orphan device development.

Conclusion

Orphan medical devices face unique regulatory and clinical challenges due to small target patient populations and limited clinical data. While the US has an established process, the EU, with the establishment of MDCG 2024-10 in 2024, recently provided a pathway that balances the need for robust clinical evidence with practical flexibility, enabling market access while maintaining safety and performance standards for these devices. Manufacturers must justify an orphan device's status through epidemiological data and demonstrate either the absence of adequate alternatives or an expected clinical benefit over the state of the art. The expert panels can provide early guidance to manufacturers, and an early discussion between the manufacturer and the notified body during a structured dialogue meeting is vital to ensure a streamlined regulatory approval process for orphan devices.

Abbreviations

BSI, British Standards Institution; **EMA,** European Medicines Agency; **EU MDR,** EU Medical Devices Regulation; **FDA,** Food and Drug Administration [US]; **HDE,** humanitarian device exemption; **HUD,** humanitarian use device; **MDCG,** Medical Device Coordination Group; **PMA,** premarket authorization; **PMCF,** postmarket clinical follow-up.

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