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# Winrevair access in Pakistan via the DRAP named-patient pathway

How patients in Pakistan obtain Winrevair (sotatercept-csrk) for pulmonary arterial hypertension, through the Drug Regulatory Authority of Pakistan Special Permission / Personal Use Import pathway.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.*

## 1. Quick orientation

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Winrevair is the brand name for sotatercept-csrk, a first-in-class activin signaling inhibitor for pulmonary arterial hypertension (PAH, WHO Group 1). The US Food and Drug Administration approved Winrevair on March 26, 2024 as add-on therapy to background PAH regimens, and updated the label in October 2025 to include reduction in the risk of clinical worsening events. In Pakistan, families with a PAH patient at one of the tertiary cardiology centers in Karachi, Lahore, or Islamabad often need to look across borders because Winrevair is not yet routinely stocked through local distributors. The Drug Regulatory Authority of Pakistan (DRAP) Special Permission / Personal Use Import pathway, filed through the Online Import and Export System (OIES) portal, is the lawful route once a Pakistan Medical and Dental Council (PMDC) licensed PAH specialist has decided this is the right next step. Reserve Meds is the US-side coordinator that aligns the sourcing, the cold-chain logistics, and the regulatory documentation kit your treating physician and hospital pharmacy need. Reserved for you.

## 2. Why patients in Pakistan need Winrevair via NPP

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PAH is a rare, progressive, life-limiting disease. Winrevair is the first mechanistically novel addition to PAH therapy in many years, and even where it is registered internationally, routine stocking through hospital formularies, national reimbursement, and commercial distribution chains lags the regulatory timeline. Across Middle East and South Asia, registration is at an earlier stage than in the United States or the European Union, and there is no public record of DRAP registration of Winrevair at the time of this review. Pakistan's specialty drug market has matured around a small number of large private-sector tertiary hospitals, but the gap between FDA availability and on-shelf availability in Pakistan remains real for advanced cardiology and pulmonary biologics.

Three patterns drive Winrevair NPP demand in Pakistan. First, patients identified at expert PAH centers whose treating cardiologists want Winrevair as add-on therapy to a background regimen of endothelin receptor antagonists, PDE-5 inhibitors or guanylate cyclase stimulators, and prostacyclin pathway agents but where the product is simply not on the local shelf. Second, families with the cash means to procure US-origin product directly, often funded through the well-established remittance corridors from Saudi Arabia, the UAE, the UK, the United States, and Canada. Third, expatriate Pakistani families who initiate therapy at a Gulf or UK center and bring the patient back to Pakistan for ongoing care once the regimen is stable. The named-patient pathway is the recognized regulatory route for all three.

## 3. The DRAP Special Permission pathway for Winrevair

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DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing (QA&LT) Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES), an electronic application portal. Patient-level personal-use applications are submitted by the patient or applicant directly on the portal; institutional applications are filed by the hospital pharmacy.

For Winrevair specifically, the application package contains:

- **Clinical justification letter** from the treating PAH specialist, addressing WHO Group 1 PAH diagnosis, current WHO functional class, right heart catheterization confirmation of pulmonary hemodynamics, background PAH therapy in place (with documented dosing and tolerability), the rationale for add-on activin signaling inhibition, and the planned weight-based dosing schedule.
- **PMDC licensure verification** for the treating physician in cardiology, pulmonology, or a PAH-experienced subspecialty.
- **Baseline laboratory documentation** including hemoglobin and platelet counts (the FDA label requires assessment before each dose because increases in hemoglobin and reductions in platelets are recognized class effects), and the monitoring plan with label-defined thresholds for dose interruption or modification.
- **Patient identifier:** CNIC for adult patients, with B-Form used in place of CNIC for minors and passport for foreign nationals.
- **Product details** including brand name (Winrevair), international nonproprietary name (sotatercept-csrk), manufacturer (Merck & Co., Inc., known as MSD outside the United States and Canada), country of origin (USA), strength (45 mg or 60 mg single-dose vial as a lyophilized kit with diluent), pack size, requested quantity for the initial sourcing window, lot, and expiry.
- **Destination dispensing facility license** showing the receiving pharmacy is licensed to handle imported biologics with cold-chain storage and reconstitution capacity.
- **Manufacturer or authorized distributor letter** confirming the product is genuine and was sourced through the legitimate US specialty supply chain. US distribution moves through Accredo Specialty Pharmacy and CVS Specialty Pharmacy as Merck-named channels.
- **Chain-of-custody plan** from the US specialty pharmacy through international air freight (with validated 2 to 8 degree Celsius packaging and continuous temperature monitoring) to the receiving Pakist