

CHIESI ACCESS POLICY PRINCIPLES FOR ORPHAN MEDICINAL PRODUCTS



Chiesi Commitment to Patients

We commit to:

- proactively seek and listen to insights and needs from the patient community to get to informed decisions on our therapeutic solutions throughout development and commercialization. Patient insight should support our aim to deliver treatments that provide value to patients as well as to the healthcare system, to the Society, and to Chiesi.
- provide educational opportunities for patients to seek better care and for professionals to improve understanding of the condition, diagnosis and to make better treatment choices
- improve and maintain the highest standard of quality for our products and seek advice from patients and caregivers to make them user-friendly and improve experience of care
- provide timely and accurate medical information
- fully respect patient community's independence, operating according to the highest compliance standards
- work with the patient community and other stakeholders, such as, but not limited to, governments, payers and healthcare professionals, to facilitate patients access to the treatments they need and benefit from.

Access to Chiesi therapeutic solutions

Principles

We invest to identify and develop treatments that truly respond to unmet medical needs, demonstrate outcomes-based value for patients, and improve their daily lives.

We believe all individuals who need and would benefit from Chiesi treatments should be able to access them, overtime, everywhere.

Patient Access during new treatment development

We are committed to build our products development plan taking into consideration, from the earliest stage, Patient Access Planning.

Expanded Access programs

We recognize there may be circumstances when it is appropriate for Healthcare Professionals to give their patients, affected by rare conditions, our investigational products to treat life threatening or seriously debilitating diseases, where no satisfactory alternatives exist.

We include consideration of the opportunity and/or the need for expanded access programs into our Access Plan, and are committed to explore options for patient access over time to our investigational exclusive OMPs in those countries where we have conducted trials.

Also, where a medicine is registered and not commercially available, we are committed to engage with regulatory or pricing and reimbursement Authorities to find agreed solution, and, in the meantime, we commit to providing it, for a reasonable period of time, as permitted by local legislation, and according to the clinical evaluation of the treating physicians, to patients who participated in trials and are at the time benefitting from the treatment, to ensure it is not interrupted.

Commercialization

We are committed to a responsible approach to commercialization, which considers the value our OMPs deliver to patients, healthcare systems and society, as well as the sustainability of our business.

We strive to identify reasonable access programs for our OMPs according to the characteristics of the Countries in scope, adopting, where appropriate, patient assistance programs and equitable commercial models based on purchasing power of patients and payors

We plan to regularly review our global access strategy to ensure alignment with our access principles

We cooperate with other stakeholders and international institutions to improve HC systems, with the aim of removing barriers and hurdles, improving processes and supply conditions to access to OMP, and we support efforts in the direction of harmonizing assessment criteria.