

Innovating Solutions for Pre-approval Access

Placing patients at the core of the decision-making



If you or someone you love faced a life-threatening or serious illness, had exhausted standard treatment options, and did not qualify to participate in a clinical trial, it is important to have clear information on where to seek help. Increasingly, patients and their physicians may opt to seek access to investigational medicines not yet approved by health authorities such as the U.S. Food and Drug Administration.

Janssen Research & Development, LLC (Janssen) understands the need for physicians of patients with limited options to request medicines prior to approval, and is committed to working diligently using a fair and timely decision-making framework. Creating a transparent, ethical and consistent process for pre-approval access requests is a top priority for the company.

In April 2014, Johnson & Johnson launched a Pre-approval Access Task Force to enhance the process for managing pre-access requests. A goal for the Task Force included championing external dialogue on this important issue and collaborating with others who could help bring solutions for patients. Several important priorities and commitments have been established:

ACCESSIBLE INFORMATION AND EDUCATION FOR PATIENTS

Janssen recognizes the importance of ensuring that patients, their families and their physicians have easily accessible, clear information to support decision-making. Information about pre-approval access and a link to ongoing clinical trials can be found on the Janssen website: <http://www.janssen.com/research-and-development/access-investigational-medicines>.

PRE-APPROVAL ACCESS PRINCIPLES

Subject to applicable laws and regulations, pre-approval access programs may be implemented once Janssen has enough information to believe the risks associated with a particular medicine are reasonable in light of the potential benefit for a particular patient group. Other considerations include patient eligibility for participation in a clinical trial, availability of alternative therapies, availability of investigational drug supply, and potential impact on the research and development program intended to make the medicine available to patients in need.



When considering pre-approval access of investigational medicines, Janssen follows three important principles:

- That all patients are treated fairly and equally
- That we conduct thorough scientific studies to understand the potential risks and benefits of any investigational medication; these studies provide the information needed to seek approval from government health authorities and bring new medicines to all patients who need them
- That we are not putting patients at risk of unnecessary harm

One of the chief considerations throughout the request process is respectful communication. The approach to each request must be transparent, concise and responsive for both the patient and the physician who is acting on the patient's behalf.

A PROGRAM FOR INNOVATION: INDUSTRY AND ACADEMIA PARTNER FOR PATIENTS

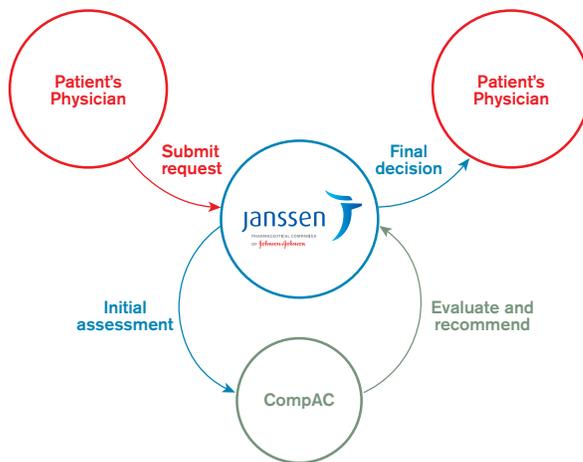
In May 2015, Johnson & Johnson announced a first-of-its-kind pilot partnership between Janssen and the Division of Medical Ethics at the New York University (NYU) School of Medicine to form the Compassionate Use Advisory Committee (CompAC). Comprised of external bioethical experts, physicians and patient representatives convened by NYU, the purpose of CompAC, a pilot program, is to ensure a fair, objective and ethical evaluation of single patient requests for investigational medicines.

REQUESTING ACCESS TO INVESTIGATIONAL MEDICINES

If patients are interested in requesting access to an investigational medicine, they should discuss with their physician what clinical trial and early access options might be available for them.

“Single patient” or “compassionate use” requests are considered on a case-by-case basis. In the United States (U.S.), the treating physician may make a request on the patient's behalf by contacting Janssen Medical Information either by calling 1-800-JANSSEN or emailing janssenmedinfo@its.jnj.com. Physicians outside the U.S. may contact the Janssen office in their specific country by visiting www.janssen.com

Model for the Compassionate Use Advisory Committee (CompAC)



BUILDING ON A HERITAGE AS A CARING COMPANY

Janssen has a long-standing history of working to understand and meet the needs of patients. Through open collaboration with patients, physicians and advocacy groups, the company can continue its commitment to patients by continuously assessing access to investigational medicines.

Putting patients first includes listening and responding to physicians requesting assistance on their patient's behalf. As the Janssen Pharmaceutical Companies continue to develop new therapies, it is imperative that all voices, including those of patients, continue to be valued and incorporated into how Janssen brings new therapies to patients.