

# Advancing the Pre-Approval Access Landscape

## KEEPING PATIENTS AT THE CORE OF DECISION MAKING

Johnson & Johnson remains dedicated to advancing patient care and public health by finding patient-centric solutions to some of the most complex medical challenges, including the evaluation of compassionate use requests for investigational medicines. It is part of the company's mission to review these requests, received from around the globe, in an equitable and timely manner.

The landscape of pre-approval access continues to evolve with two key advancements in transparency and education. The passing of the 21st Century Cures Act as well as the creation of the Reagan-Udall Foundation Expanded Access Navigator tool have created mechanisms for patients and providers to access important policy and procedures information to support their search for investigational medicines.



## PRE-APPROVAL ACCESS PRINCIPLES

Because weighing the needs of individuals versus the needs of society will always remain a bioethical challenge, we must assess requests for investigational medicines while simultaneously furthering research to obtain regulatory approval so that patients may seek access by prescription where medically appropriate. We recognize, however, that some people with a life-threatening illness may not be able to wait for health authority approval.

When evaluating compassionate use requests for investigational medicines, Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) follows three important ethical principles:

1. That we are not putting patients at risk of unnecessary harm.
2. That we continue to conduct thorough scientific studies to understand the potential benefits of new medicines to provide the fundamental information needed to acquire approval from government health authorities and bring new medicines to all patients who need them.
3. That we treat all patients fairly and equally.

Additional considerations include patient eligibility for participation in a clinical trial, availability of alternative therapies, and availability of investigational drug supply, among others.

## BUILDING ON A HERITAGE AS A CARING COMPANY

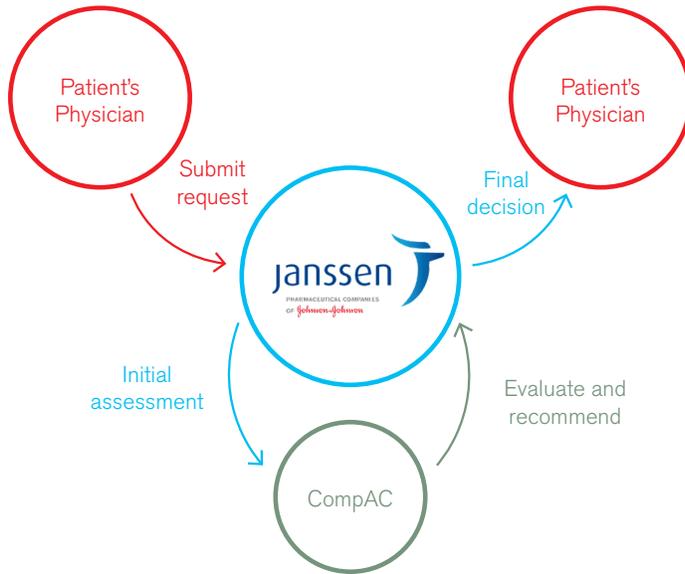
J&J has a long-standing history of working to understand and meet the needs of patients. Through open collaboration with patients, physicians and advocacy groups, the company extends its commitment by finding patient-centric solutions to complex medical challenges.

Putting patients first includes a fair, ethical evaluation of compassionate use requests while developing new treatments and conducting robust clinical trials of investigational products that show great promise to human health.

## EVALUATING COMPASSIONATE USE REQUESTS

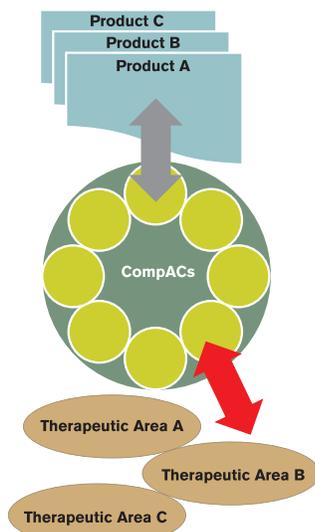
The Compassionate Use Advisory Committee, or CompAC, is an innovative model that J&J employs globally to provide a fair, ethical evaluation of compassionate use requests for specific investigational medicines. CompAC is comprised of internationally recognized medical experts, bioethicists and patient representatives and is formed and led by the NYU Division of Medical Ethics.

### Model for the Compassionate Use Advisory Committee (CompAC)



## EVOLVING THE COMPAC MODEL

Based on the success of our collaboration with NYU and CompAC, the Office of the Chief Medical Officer (OCMO) made the pivotal decision in 2016 to expand this model to additional assets in the Janssen pipeline. Going forward, CompAC will serve as an umbrella term for therapeutically based CompAC groups to provide recommendations on various requests for investigational medicines. While the model has evolved from a single product focus to multi-therapeutic, multi-product, the core principles and practices remain to support transparent and fair decision making for compassionate use requests at Janssen.



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## 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 around access to investigational medicines. Information about pre-approval access, a link to ongoing clinical trials, and the J&J global policy for pre-approval access can be found on the Janssen website:

**[www.janssen.com/compassionate-use-pre-approval-access](http://www.janssen.com/compassionate-use-pre-approval-access)**

## REQUESTING ACCESS TO INVESTIGATIONAL MEDICINES

If patients are interested in requesting access to an investigational medicine, they should discuss their treatment options with their physician.

If the physician assesses that compassionate use is appropriate, a request may be made by doing the following:

### **In the United States (U.S.)**

The treating physician may make a request on a patient's behalf by contacting Janssen Medical Information either by calling **1-800-JANSSEN** or emailing **[janssenmedinfo@its.jnj.com](mailto:janssenmedinfo@its.jnj.com)**.

### **Physicians outside the U.S.**

Contact the Janssen office in their specific country by visiting **[www.janssen.com](http://www.janssen.com)**.