

"We have a responsibility to patients and their families to ensure their well-being in everything we do. By ensuring compassionate use requests for our investigational medicines are evaluated by a well-informed, external committee, we can

better weigh what we know about these therapies against the patient's condition and risk factors to make the most responsible decision for each patient," said Dr Amrit Ray, chief medical officer for Janssen Pharmaceutical Companies of Johnson & Johnson.

For compassionate use requests, Janssen has a long-established single point of contact: all interested treating physicians can contact Janssen Medical Information (1-800-JANSSEN in the United States or janssenmedinfo@its.jnj.com). Physicians outside the US may contact the Janssen office in their country. Physicians are asked to provide information about the patient, that is then used to evaluate the request.

If permitted by local authorities, Janssen typically establishes an expanded access program (EAP) for investigational medicines when a favorable benefit-risk profile has been reported in a pivotal trial and there is a viable regulatory path to approval confirmed with a health authority. The EAP can potentially allow the treatment to be made available to patients living with the same serious or life-threatening condition for which the medicine was originally studied and who have exhausted other treatment options. If patients do not qualify for an EAP or an existing clinical trial, their requests will be forwarded to CompAC.

"Our goal is to ensure that compassionate use of specific investigational medicines still in development is guided by ethical principles, and that the selection process continues to be thorough, transparent and fair. Compassionate use decisions are incredibly challenging, and we readily acknowledge that the current allocation system remains a work in progress. This new initiative hopes to create a more robust model to help guide these decisions," said CompAC chairman Dr Art Caplan, director, Division of Medical Ethics at the NYU School of Medicine, and Dr William F and Dr Virginia Connolly Mitty, professor of Bioethics.

Dr Caplan likens the CompAC to what the United Network for Organ Sharing (UNOS) has achieved with its allocation process. He said, "We want to establish a model that will create a structured policy of allocation based on equality, need and efficacy to ensure that the utility of our scarce resources are maximized. If successful, CompAC will serve as a model for others in industry and in government to follow."