**Cytiva**
Björkgatan 30
751 84 Uppsala
Sweden

# Statement

## Regarding:
## Cytiva's Humanitarian and Compassionate Use Medical Product Policy

Cytiva is committed to supporting access for organizations treating patients across the globe with our technologies and products.

**What is Humanitarian and Compassionate Use ("Exceptional Use") Regulation for Medical Products?**
Although rare, in some cases there may be no other product available for treatment for certain patients, in which case Cytiva may collaborate with the clinical organization and local governmental and/or regulatory authorities to seek approval for humanitarian or compassionate use programs to use a Cytiva product for a different purpose, modify a product for a new purpose or use a marketed non-medical product for a medical purpose.
Each country has its own specific regulatory requirements for humanitarian and compassionate use. These programs typically balance the risks and benefits to the patient taking into account recommendations which include:

- carrying out a risk assessment and providing this to ethics, regulatory, and/or governmental bodies
- considering the ethical, regulatory, and legal implications
- implementing suitable precautions to minimize risk to patients and operators
- reviewing the risk assessment at suitable periods and providing follow-up information to the manufacturer and to ethics, regulatory, and/or governmental bodies relevant to the safe use of the product in other patients
- getting approval from regulatory bodies for humanitarian or compassionate use of non-complying products (if necessary)

Generally, you are also required to inform patients and/or their legally authorized representative during the consent procedure and make a note on their records that you will be using a product that is not approved/cleared for use in this way. It is the clinical organization's responsibility to ensure patient consent in compliance with local laws, regulations, and ethics requirements.

**How do I determine if my organization is eligible for this Cytiva Humanitarian and Compassionate Use Medical Product Policy?**

The determination of if a product may be supported for humanitarian or compassionate use is made on a case-by-case basis based on the patient medical need, availability of the product, regulatory requirements in the region the product will be used, and other factors determined by Cytiva for specific products and programs. The country specific regulatory framework is the overarching determinant of an organizations eligibility for this Policy.

**If eligible, when will the product be available and what is the cost?**
Where eligible, Cytiva will work with appropriate organizations to support local and national requirements to assist humanitarian and compassionate use on a case-by-case basis. The availability, timing, and cost of products for humanitarian use will be determined in collaboration between Cytiva and the sponsoring clinical organization.

**What information is made public?**
Cytiva maintained patient privacy, and personal health information submitted as part of a Humanitarian or Compassionate use request or application will be used only for these purposes, and as required by local law and regulation, and will not be publicly released. To support transparency and comply with local laws and regulations, the following information may be made publicly available on Cytiva or governmental websites and other materials, such as scientific publications and papers, made by Cytiva:

- Names, addresses, and regional information about eligible organizations that receive Humanitarian and Compassionate Use support from Cytiva
- Identity, quantity, and details of the Humanitarian and Compassionate Use product used in Humanitarian or Compassionate use capacities
- Non-identifiable information about the therapeutic areas of Humanitarian and Compassionate Use (no patient-specific information will be included)

**Who should I contact for more information or to make a request related to Humanitarian or Compassionate Use?**
For more Cytiva's Humanitarian and Compassionate Use Product Programs, please contact:
Cytiva Customer Regulatory Support at RegulatorySupport@cytiva.com

| | |
|---|---|
| Signature: | Date:<br>21 November 2023 |
| Name: | Title |