# What is Global Innovative products on Fast Track(GIFT)?

혁신제품 신속심사
GLOBAL INNOVATIVE PRODUCTS ON FAST TRACK

The GIFT means a supporting program for accelerating regulatory review of “global innovative products", which can facilitate market launch of innovative medicinal products intended for treatment of life-threatening or serious diseases and faster supply of them to patients.

## Scope of products for GIFT designation

1. A medicinal product intended for treatment of life-threatening or serious diseases such as cancer or rare diseases, without existing treatment or with a significant improvement in efficacy compared to the existing treatment.
2. A medicinal product intended for prevention or treatment of infectious diseases with a serious threat to public health, such as an infectious disease outbreak caused by bioterrorism or pandemic (including outbreak of infectious disease with a significant concern of pandemic), without existing treatment or with a significant improvement in efficacy compared to the existing treatment, or a novel product with completely different mode of action/mechanism from existing treatments.
3. A new medicinal product developed by an innovative pharmaceutical company designated and notified by the Ministry of Health and Welfare.
4. A combination of a medical device and a medicinal product designated for expedited review.

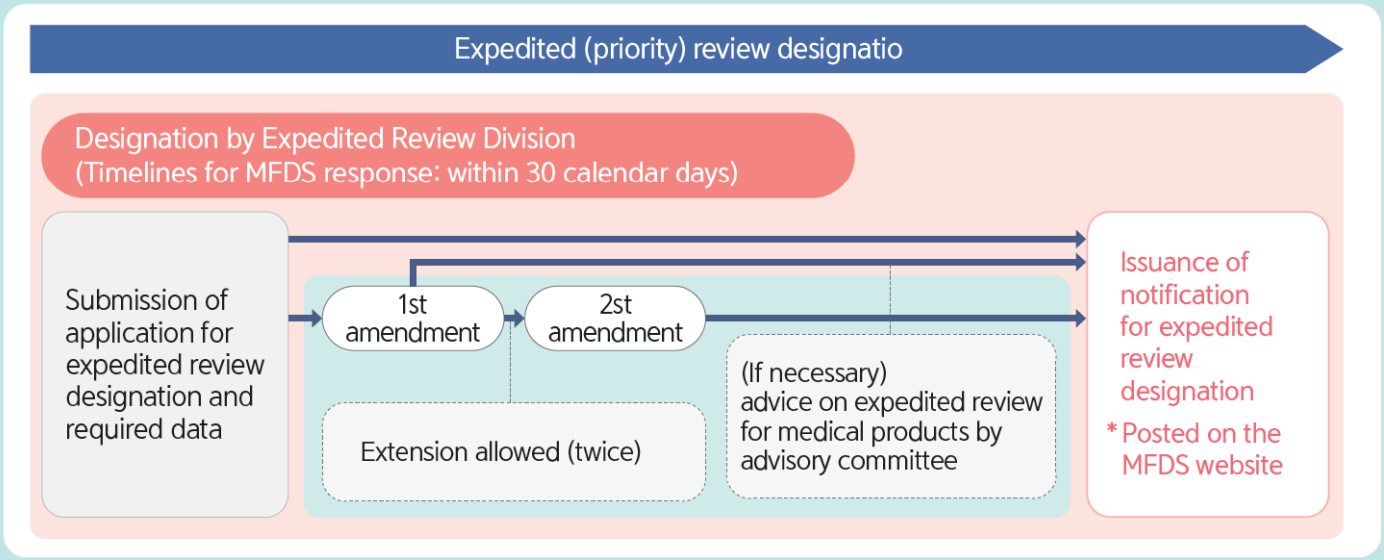
## Key benefits of GIFT

For GIFT-designated products, the period of regulatory review process can be **shortened to 75%** of usual review time. Additionally, the following regulatory supports are provided:

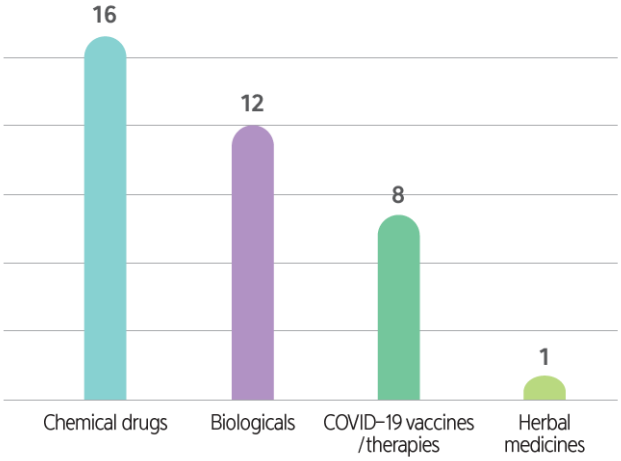
1. A product for expedited review is designated in the early stage of clinical development stage.
2. It is allowed to submit some data not directly related with the product’s safety after product approval.
3. Rolling review process is applied which enables regulatory review on prepared and available information and data first.


4. Regulatory supports, including RA (regulatory affairs) consulting and review schedule, are provided through close communication between the regulatory reviewer and the developing company, such as product briefing and explanation of supplementation.

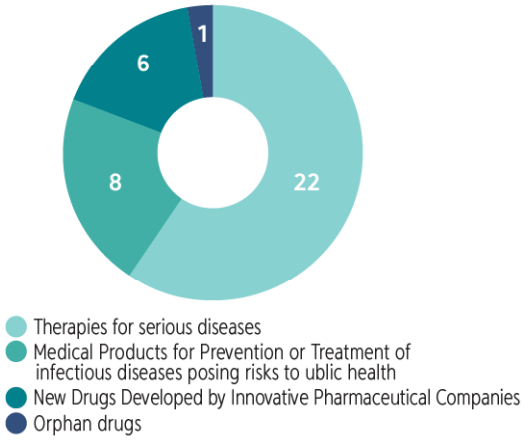
## GIFT designation application process and submissions




## 3 years experience of GIFT




Classification of drug products designated for expedited review*




Expedited review designations

*GIFT designation incl.

## Products indications designated for expedited review