

# You can get various supports from Japanese government if you have the willingness to **develop drugs in Japan.**



**We, Ministry of Health, Labour and Welfare of Japan (MHLW), are looking for the companies to develop unapproved drugs in Japan!**

Unapproved drugs are the ones which are approved in some European countries or US, etc. but not in Japan. In February 2010, we began accepting requests from patients including patient groups and academic societies etc. and since then has held the committee to evaluate the medical needs of such drugs.

We are looking for the companies which can develop these unapproved drugs that were evaluated as “High medical needs” in this committee but no companies in Japan which can develop them have been found. We would appreciate your cooperation so that these unapproved drugs can be developed in Japan as soon as possible and used in the medical field as well.

## What kinds of support can we provide?

We will provide various supports such as subsidy, management supports, etc. when certain requirements are met for each support.

### R & D

- **Subsidy**  
Maximum up to 50% of R&D cost within budget
- **Tax-deduction**  
20% x [R&D cost – subsidy amount]
- **R&D support**  
Support matching and communication between companies in joint development and coordination with regulatory authorities
- **Priority consultations and Priority review**

### Application for approval

- **Subsidy**  
Maximum 30 million JPY grant amount for each application
- **Management support**  
Provide comprehensive support for each stage from R&D to practical use, and the other supports in the whole process for Startup companies

### Drug price

- **Incentives for drug prices**

For more detailed information on the unapproved drugs we are recruiting to develop, please see [this link](#).

Pharmaceutical Development Support Center (PDSC)  
<http://www.pdsc.or.jp/about/information/medicine/index.html>



**MHLW**

**For inquiries, please contact Ministry of Health, Labour and Welfare of Japan (MHLW).**  
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# What are unapproved drugs?

## Unapproved drugs in Japan

Drugs which **have been approved** in either of 6 countries (US, UK, Germany, France, Canada, and Australia).

### Criteria of evaluation on medical needs

Drugs have to fulfill both (1) and (2) of the followings in order to be evaluated as “High medical needs”.

#### (1) In case that the severity of the target disease meets either of the followings:

- (A) Life threatening (lethal).
- (B) Irreversible progression and significantly affecting daily life.
- (C) Other severity which will significantly affect daily life.

#### (2) In case that the medical usefulness meets either of the followings:

- (A) No therapy exists in Japan.
- (B) In the clinical trials conducted in some countries such as Europe and US, the efficacy/safety of the drug is clearly superior to that of existing therapies.
- (C) The drug is regarded as a standard therapy in some countries such as Europe and US, and furthermore the efficacy can be highly expected in Japan despite the differences of medical environment among countries.

## Drugs subject to the “Scheme for accelerating practical use of unapproved drugs”

Drugs which **have NOT been approved** in ALL 6 countries (US, UK, Germany, France, Canada, and Australia), but have fulfilled specific requirements.

### Criteria of evaluation on medical needs

Drugs have to fulfill both (1) and (2) of the followings in order to be evaluated as “High medical needs”.

#### (1) In case that the severity of the target disease meets either of the followings:

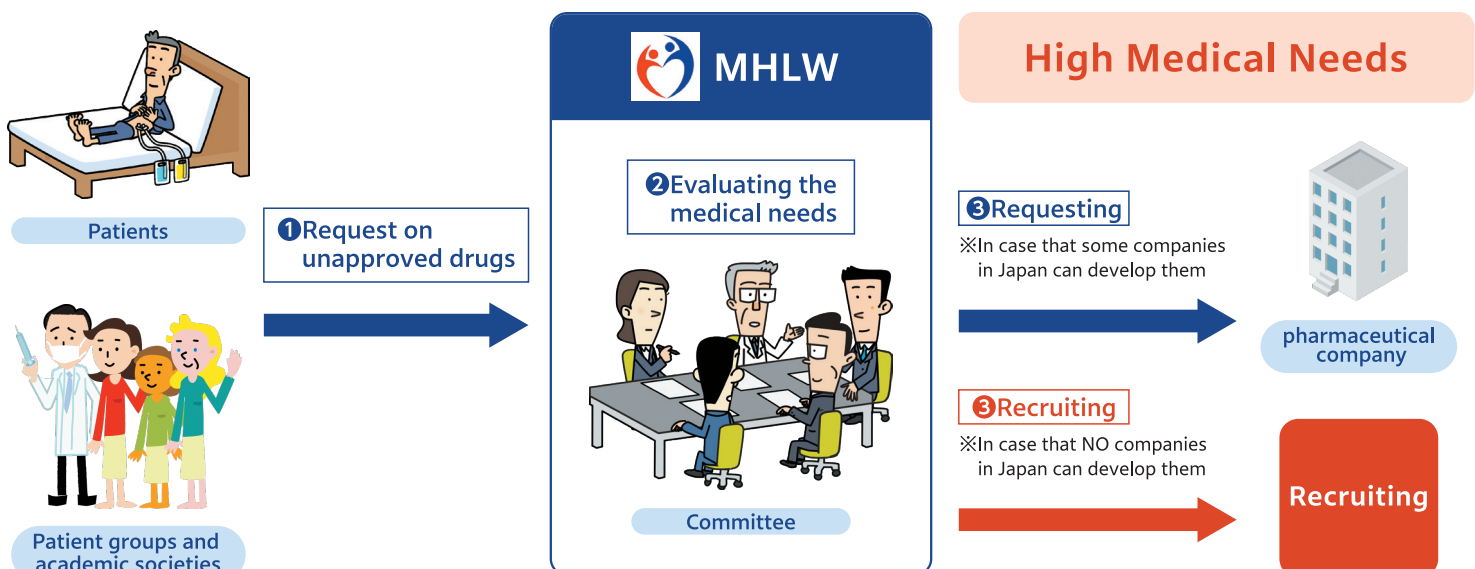
- (A) Life threatening (lethal).
- (B) Irreversible progression and significantly affecting daily life.
- (C) Other severity which will significantly affect daily life.

#### (2) In case that the medical usefulness meets either of the followings:

- (A) No therapy exists in Japan.
- (B) In the clinical trials, the efficacy/safety of the drug is clearly superior to that of existing therapies.

## Flowchart up to recruitment

We are accepting requests for developing unapproved drugs from patients and academic societies. We will consider the requests on the committee held by MHLW and evaluate its medical needs of the drugs based on the criteria. In case that the drugs were evaluated as “High medical needs” and no companies in Japan can develop them, we will recruit the companies to develop them.



# Supports you can take for the development of unapproved drugs

## Support for R&D

### Subsidy · Tax credits ※Only when the drug is designated as an Orphan Drug

#### National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN)

<https://www.nibiohn.go.jp/en/activities/research-support.html>

<https://www.nibiohn.go.jp/en/activities/orphan-support.html>

**Subsidy period** In principle, maximum of 3 years from after orphan designation to application for marketing authorization.

**Expenses eligible for subsidy** Honoraria, travels, equipment, consumables, printing and binding, communication and transportation, rents and leases, meeting, labor services and subcontracting fee.

**Subsidy ceiling** Maximum up to 50% of R&D cost within budget.

**Tax-deductible expenses** 20% x [R&D cost – subsidy amount], etc.

List of Designated Orphan Drugs (As of 31st July, 2018) ▶ <https://www.nibiohn.go.jp/nibio/part/promote/files/orphan%20drug%20E.pdf>

## Support of R&D

### Pharmaceutical Development Support Center (PDSC)

<http://www.pdsc.or.jp/> (Japanese only)

- Expert support for research, development and production of unapproved drugs for development companies.
- Support various procedures related to the application for approval by development companies (such as supporting matching and communication between companies in joint development and coordination with regulatory authorities etc.).

### Priority consultations and Priority review ※If certain requirements are met

#### Pharmaceuticals and Medical Devices Agency (PMDA)

<https://www.pmda.go.jp/english/index.html>

## Support for application for approval

### Subsidy

#### Pharmaceutical Development Support Center (PDSC)

<http://www.pdsc.or.jp/> (Japanese only)

- Maximum 30 million JPY grant amount for each application.

### Management support

#### Medical Innovation Support Office (MEDISO)

<https://mediso.mhlw.go.jp/en/>

- MEDISO provides comprehensive support for each stage from R&D to practical use, such as compliance with regulations, intellectual property strategy, business planning, marketing for Startup companies seeking pharmaceutical approvals in Japan.

#### Pharmaceuticals and Medical Devices Agency (PMDA)

Regulatory Information ▶ <https://www.pmda.go.jp/english/review-services/regulatory-info/0002.html>

## Support for drug price

### Incentives for drug prices

The products recruited are subject to incentives for NHI drug prices.

For details, please contact us.

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