FROM NEED TO TREATMENT: EARLY AND FAST ACCESS EXPLAINED

PROCEDURE FOR EARLY AND FAST ACCESS TO INNOVATIVE MEDICINES IN BELGIUM

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ASSOCIATION GÉNÉRALE DE L'INDUSTRIE DU MÉDICAMENT
ALGEMENE VERENIGING VAN DE GENEESMIDDELENINDUSTRIE

FOREWORD

Caroline Ven
CEO

This flexibility ensures that treatments addressing unmet medical needs can reach patients more swiftly and equitably.

For patients awaiting innovative treatments, every day matters. All too often, complex procedures and administrative delays hinder access to medicines that could transform – or even save – lives. The Early & Fast Access reform represents a vital step forward: it aims to accelerate access to promising therapies as soon as they become available and validated.

This reform has introduced a unified new procedure – Equitable Early/Fast Access – which becomes effective as of 1 March 2026. Under this framework, companies may voluntarily enter either the Early Access phase or the Fast Access phase, provided the relevant conditions are met.
This flexibility ensures that treatments addressing unmet medical needs can reach patients more swiftly and equitably.

The reform is part of the broader NIHDI Roadmap, which outlines strategic priorities for improving access to care and strengthening the healthcare system's responsiveness. By embedding Early & Fast Access into this roadmap, Belgium signals its commitment to patient-centred innovation and timely therapeutic intervention.

As healthcare stakeholders, we have a responsibility to support this momentum. Providing rapid access to treatment is not only a recognition of the value of innovation – it is, above all, a response to human urgency. Because behind every dossier and every procedure, lives are at stake.

SUMMARY

The objective of the Early and Fast Access programmes is to offer patients free-of-charge, early access to innovative medicines that meet an unmet medical need or have a significant therapeutic advantage, without compromising safety or evidence requirements.

In an Early/Fast Access procedure, the company must commit to submitting a standard reimbursement application for the indications in question within six months of obtaining marketing authorisation.

As is currently the case with cohort decisions, the framework decisions for Early and Fast Access – including the conditions for intervention in the event of a positive decision – are published on the NIHDI website:

– **Dutch**
– **French**

01 INTRODUCING EARLY AND FAST ACCESS

What is Early Access?

Early Access refers to health insurance intervention decisions made before EMA approval. These decisions apply to specific indications and defined groups of beneficiaries.

A positive decision is conditional on both of the following elements being met:

The medicine must be approved for a compassionate use programme or for a medical need programme

AND

The medicine must address a medical need listed on the Unmet Medical Need list

What is Fast Access?

Fast Access refers to health insurance intervention decisions made after EMA approval but before the standard reimbursement decision. These decisions apply to specific indications and defined groups of beneficiaries.

A positive decision is conditional on either of the following elements being met:

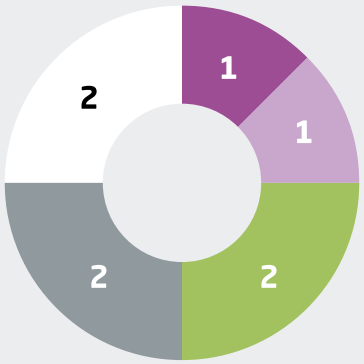
A positive Early Access decision was granted before EMA approval

OR

EMA approval was obtained via PRIME or accelerated assessment procedure

EARLY AND FAST ACCESS

Composition of the Committee for Advice on Temporary Reimbursement for the Use of a Medicinal Product (CATT)



Members with voting rights

- President of the Colleges of physicians for orphan drugs
- Chair of the Committee for Medicinal Products for Human Use
- Members of the Commission of Reimbursement of Medicines (1 sick fund and 1 academic or the Chair)
- Members from the sick funds
- Members of NIHDI staff

Members without voting rights

– 2 representatives from FAMHP

– 1 member of FAMHP staff

– 1 representative from the pharmaceutical industry

– 1 representative from the patients organisations

In addition, the CATT consults ad hoc experts selected on the basis of relevant expertise on a specific topic (medical, personal experience, social, etc.).

02 HOW DOES IT WORK IN PRACTICE?

famhp

CUP/MNP procedure

Approval within 55 days

EARLY ACCESS IN WORKING DAYS

Indication on UMN List

Acknowledgment of admissibility = Day 0

(possibly request for additional information within 15 working days (wd) after submission; company has 90 wd to respond)

EXPERT CONSULTATION

Day 5: Company provides completed Engagement Form

Day 30: Proposal

Company has 7 wd to react

Day 55: Final decision

(without clockstops)

FAST ACCESS (AFTER EARLY ACCESS) IN CALENDAR DAYS

EMA approval X+1 if informed ≤ 10th of month X

EMA approval X+2 if informed > 10th of month X

FAST ACCESS (PRIME/ACCELERATED ASSESSMENT) IN CALENDAR DAYS

EXPERT CONSULTATION

CONSULTATION DATA PROTECTION AUTHORITY: CLOCKSTOP

Acknowledgment of receipt = Day 0

(within 8 days after submission; if additional info is requested, company has 90 days to react)

Day 60: Proposal

Company has 10 days to react

Day 90: Final decision

NIHDI

Early Access Timelines

An application for early access can only be submitted before CHMP opinion. The Early Access application is submitted to the CATT in accordance with the procedure and guidelines that are published on the NIHDI website. If the dossier is incomplete, the applicant will be informed of the missing elements within 15 working days of submission and will have 90 working days to provide the necessary documents.

Once a dossier is deemed admissible the Early Access procedure starts and an acknowledgment of receipt is sent to the company. This date is considered Day 0 of the procedure.

The company is required to sign the Engagement Form within five working days.

On Day 0, the CATT determines whether to involve an external expert. If so, the dossier and a standardised form are sent to the expert. The external expert's opinion must be provided within 10 working days of receiving the dossier. The standard questions and answers from the ad hoc experts are annexed to the proposal and commented on by the Commission.

The CATT formulates a proposal within 30 working days of Day 0.

The company has the opportunity to respond to the proposal. This response is required within seven working days from the receipt of the proposal.

A definitive decision is expected on Day 55 (working days), provided there is no clock stop during the procedure.

Decisions

NO DECISION

If, on the 56th working day, the CATT has not made a decision, the NIHDI administration shall notify the company as soon as possible, and this notification shall include a positive decision under the conditions of intervention proposed by the applicant.

NEGATIVE DECISION

If there is a negative decision, there will be no Early Access programme.

POSITIVE DECISION

In case of a positive decision, the CATT publishes the decision on Early Access and the conditions of intervention on the NIHDI website.

Duration and renewals

Decisions on Early Access can be made for a maximum period of four years.

An Early Access decision may be renewed. The new application must be submitted six months prior to the expiry of the previous decision.

TIP

It is recommended that the application for the CUP/MNP to FAMHP be submitted at the same time with the aim of obtaining a more or less simultaneous decision by both authorities i.e. decision on CUP/MNP by FAMHP and decision on Early Access by CATT.

Fast Access Timelines

THE CONDITIONS FOR A FAST ACCESS ARE:

– An approved Early Access procedure - **OR**

– PRIME status granted by EMA or an accelerated assessment by EMA: timeline for submitting an application is from CHMP to 1 month after EMA approval

THE EARLY ACCESS PROGRAMME IS AUTOMATICALLY INCLUDED ON THE LIST, FOR THE REGISTERED INDICATIONS:

– On the first day of the month (X+1) following the month (X) in which the marketing authorisation is issued, provided the company communicates it no later than the tenth day of month (X) - **OR**

– On the first day of the second month (X+2) following the month (X) in which the marketing authorisation is issued, if the company communicates it after the tenth day of month (X) - **OR**

– On the first day of the month following a 10-day period after its publication in the Belgian Official Gazette, if the listing legally reduces patients' access rights to treatment within registered indications

In the case of PRIME status or accelerated assessment, a request for a Fast Access procedure may be submitted to the CATT by the Minister of Social Affairs or by the company.

This can be done from the date of the CHMP positive opinion up to ONE month after the Market Authorisation is granted, and it must be accompanied by a series of commitments signed by the company.

The Fast Access application must be submitted to the CATT in accordance with the procedure and guidelines that are published on the NIHDI website. If the dossier is incomplete, the applicant will be informed of the missing elements within eight days of submission and will have 90 days to provide the necessary documents.Once a dossier is deemed admissible the Fast Access procedure begins and an acknowledgment of receipt is sent to the company. Day 0 of the procedure is the day of reception by the secretariat of the CATT of an admissible dossier.

On Day 0 the CATT determines whether to involve an external expert. If so, the dossier and a standardised form will be sent to the expert. The expert must provide their opinion within 14 days of receiving the dossier. The standard questions and answers from the ad hoc experts are annexed to the proposal and commented on by the Commission.

The CATT must submit a proposal to the Minister within 60 days.

If the CATT's proposal differs from that of the applicant, the CATT first draws a provisional proposal, which is communicated to the applicant, who then has ten days to reply.

– If the applicant agrees, the provisional proposal becomes final

– If the applicant does not respond within 10 days, the provisional proposal becomes final

– If the applicant does not agree, the CATT will examine the comments made and draw up a final proposal based on the provisional proposal and the comments made

If the CATT requests consultation with the Data Protection Authority, the timeline is suspended (clock stop).

After reviewing the CATT's proposal, the Minister issues a decision within 90 days of the start of the procedure, taking into account any periods of suspension. The Minister may deviate from the CATT's proposal for social and/or budgetary reasons.

Decisions

NO DECISION

If no final decision is made by Day 90, the NIHDI administration shall notify the company as soon as possible, and this notification shall include a positive decision under the conditions proposed by the company.

NEGATIVE DECISION

In the event of a negative decision, the list remains unchanged.

POSITIVE DECISION

In case of a positive decision, the CATT publishes the decision on Fast Access and the conditions for intervention on the NIHDI website.

03 HEALTH INSURANCE INTERVENTION

Early Access

LUMP SUM PER COHORT: € 25,000

LUMP SUM PER PATIENT PER MONTH:

CHEMICAL COMPOUNDS:

– € 700/patient/month for orphan chemical medicines

– € 140/patient/month for non-orphan chemical medicines

BIOLOGICALS:

– € 1,500/patient/month for orphan biological medicines

– € 300/patient/month for non-orphan biological medicines

CELL AND GENE THERAPIES:

– € 120,000 one-off

Fast Access

NO LUMP SUM PER COHORT

LUMP SUM PER PATIENT PER MONTH:

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– € 700/patient/month for orphan chemical medicines

– € 140/patient/month for non-orphan chemical medicines

BIOLOGICALS:

– € 1,500/patient/month for orphan biological medicines

– € 300/patient/month for non-orphan biological medicines

CELL AND GENE THERAPIES:

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IF THE MEDICINAL PRODUCT UNDER FAST ACCESS IS BEING REIMBURSED LATER ON, A RETROSPECTIVE COMPENSATION OF 75 % OF THE NET PRICE IS APPLIED WITH DEDUCTION OF THE LUMP SUMS THAT ALREADY HAVE BEEN PAID

If the medicinal product under Fast Access is being reimbursed later on, a retrospective compensation of 75% is applied of the difference between:

The totality of the lump sums actually owed by the health insurance to the company responsible for providing the medicine concerned under the Fast Access programme, based on individual claims that have been approved by the CATT and on the actual duration of treatment of the beneficiaries concerned.

AND

The total net cost of the medicine concerned, calculated at the ex-factory price, which would have been covered by the health insurance for beneficiaries whose individual request for intervention under the Fast Access programme was approved by the CATT, if the medicine concerned had been included in the list of reimbursable pharmaceutical specialties for the patients and indications concerned on the date of its inclusion in the list of reimbursable pharmaceutical specialties for which health insurance coverage is provided under the Fast Access programme.

04 DATA COLLECTION

Protocol for Use and Therapeutic Monitoring

For both the Early and Fast Access programmes, data must be collected by the hospitals concerned (specifically, by the prescribing physicians and hospital pharmacists at the hospital where the treatment is initiated). This mandatory data collection is carried out via an electronic platform managed by the NIHDI.

A remuneration for this data collection registration by the hospitals is provided by the company responsible for the medicinal product in question. To this end, the company shall enter into a compensation agreement with the hospital concerned. An example of a template convention for remuneration of data entry is available on the NIHDI website.

THE PROTOCOL FOR USE AND THERAPEUTIC MONITORING MAY INCLUDE THE FOLLOWING ELEMENTS:

1. The name of the medicinal product, the prescribing, dispensing and usage details, as well as the method of beneficiary supervision
2. How the beneficiary is informed of the absence of a therapeutic alternative, the risks involved, the limitations and the potential benefits of a medicinal product
3. The data relating to the prescription of the medicinal product
4. The data relating to consultations and discussions with the prescriber regarding the prescription in accordance with the conditions defined in the decision
5. Identification details of the prescribing physician and the hospital pharmacist responsible for preparation and dispensing of the medicinal product
6. The personal data relating to the beneficiary
7. The clinical data of the beneficiary
8. Information about the actual use of the medicinal product such as dosage and duration of the intended treatment, concomitant treatments or supportive care
9. In the event of permanent discontinuation of treatment, the reasons for discontinuation

The collected data will be retained for five years from the expiry of the duration of the decision, unless another legal or regulatory provision requires a longer retention period.

Data Holder

The NIHDI is the data holder and takes the appropriate technical and organizational measures in accordance with Article 32 of the General Data Protection Regulation (GDPR), both with regard to (access to) the platform where the data must be registered and the further processing by the NIHDI – including the anonymization strategy.
This will be communicated in full transparency on the NIHDI website so that data subjects and healthcare providers have insight into how data is processed.

05
EXIT STRATEGY

If the Minister issues a negative decision regarding the reimbursement of a medicinal product used in the context of Early/Fast Access following the standard reimbursement procedure, the company commits to ensure the access and availability of this medicine free of charge for eligible patients who have already started treatment for the relevant indications, until the end of their treatment, as long as the medicine continues to provide a therapeutic benefit to the eligible patient. For a maximum of three years following a negative reimbursement decision by the Minister, health insurance may continue to intervene under the same financial conditions as those set out in the Early or Fast Access decision.

06 ROLES AND RESPONSIBILITIES

Role of The Hospital Pharmacist

The Early and Fast Access programmes will run in the hospital. The hospital pharmacist is responsible for the data input, in accordance with the protocol for use and therapeutic monitoring.

Role of The Physician

- Submits a substantiated request for the supply of the medicine for the patient to the company contact responsible for the programme
- Submits the individual request for the patient's inclusion in an Early or Fast Access programme to the CATT, including personal and relevant medical data
- Is responsible for data input, in accordance with the protocol for use and therapeutic monitoring

07 THE EARLY/ FAST ACCESS DOSSIER: REQUIRED STEPS AND DOCUMENTS

Criteria for unmet medical need

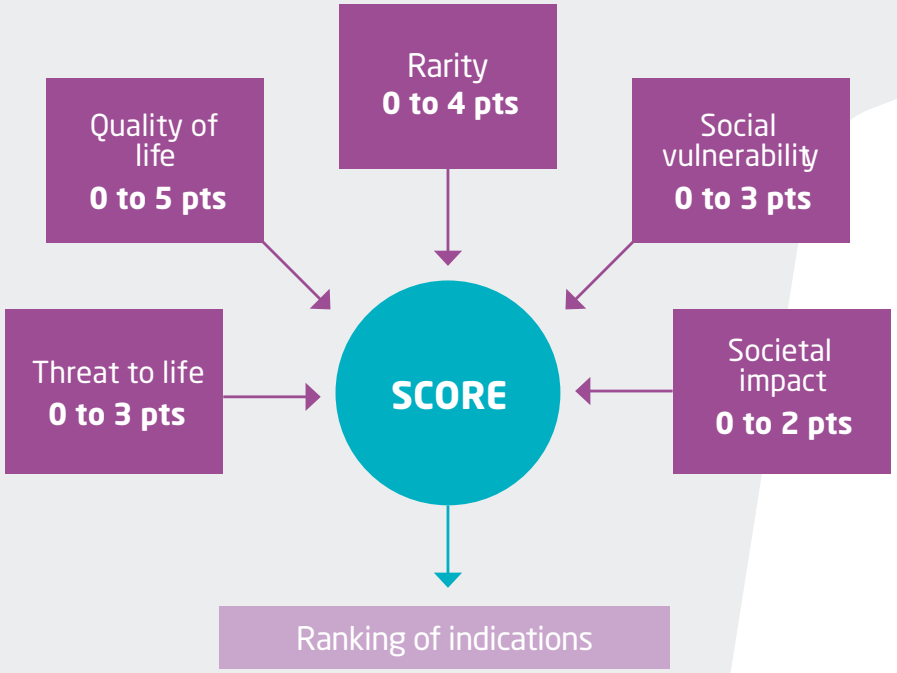
The level of medical need is assessed based on:

– The impact of the disease on the patient: quality of life; prognosis; effectiveness and side effects of current treatment; quality of care; accessibility of care; social & professional impact

– The impact of the disease on society: incidence/prevalence; cost of care; absence of preventative measures; loss of productivity

– The impact of the disease on the future: disease burden

Each indication is evaluated according to the criteria below, and a score is assigned to it.



Source: NIHDI

Template for unmet medical need request

A request may be submitted by:
– The Minister of Social Affairs
– The Minister responsible for Public Health
– The College of Medical Directors
– A company
– The National Intermutualistic College
– A medical-scientific organisation
– A patient association

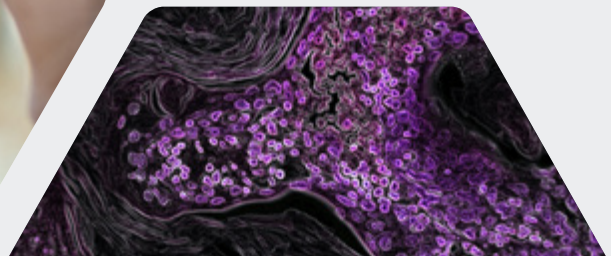
A standard template for such requests can be found on the NIHDI website. It focuses on:
– Impact of the disease on QoL, discomfort & survival
– Epidemiology
– Public and personal healthcare expenditure
– If deemed relevant and important: information on social, emotional and/or functional wellbeing

The UMN list is publicly available on the NIHDI website:
Dutch French

DOWNLOAD THE TEMPLATE:
Dutch French

Timing of submission and decision

– The request must be submitted before 15 May of Year T-1
– A confirmation of receipt is issued within 10 days
– The request is evaluated by the General Council, based on recommendations from the CATT
– During the assessment the medical and economic impacts of the pathology are assessed, using a scoring system
– A final decision is taken by the NIHDI General Council by 31 October of Year T-1
– If the advice is positive, the pathology is added to the UMN list from 1 January of Year T0



EARLY ACCESS REQUEST SUBMISSION: CONTENT OF THE DOSSIER

1. **Name of the medicinal product** and the elements that have been communicated to the FAMHP

2. **Qualitative & quantitative composition** of all substances of the medicinal product and INN or chemical name

3. **Therapeutic indication** for which the request is submitted as well as an **estimation of the likely number of beneficiaries** to be treated

4. **Dosage, pharmaceutical forms**, proposed methods and routes of **administration** for the concerned therapeutic indication

5. If the medicinal product does not benefit from a valid Marketing Authorisation (MA) in Belgium, a copy of any MA obtained for the medicinal product and/or details of any decision to refuse a MA for the medicinal product in any country

6. A proposal for the conditions of the intervention.

   Furthermore, the company:

   1. Indicates the deadline within which it will file an application for MA, it is being understood that this deadline cannot exceed six months from the date of the application
   2. Indicates the deadline within which it will submit a request for reimbursement after obtaining the MA, it is being understood that this deadline cannot exceed six months from the date on which it received the MA
   3. Defines the group of targeted beneficiaries
   4. Provides a justification for the intended beneficiary group
   5. Provides an estimation of the budgetary impact for the early access programme

Only companies that have dated and signed an identification form relating to the medicinal product concerned may submit requests for an Early Access decision.

FAST ACCESS REQUEST SUBMISSION: CONTENT OF THE DOSSIER

1. **Name of the medicinal product**

2. **Qualitative and quantitative composition** of all substances of the medicinal product and INN or chemical name

3. **Therapeutic indication** for which the request is submitted as well as an **estimation of the likely number of beneficiaries** to be treated

4. **Dosage, pharmaceutical forms**, proposed **methods and routes of administration** for the concerned therapeutic indication

5. The opinion of the CHMP, where applicable, the MA

6. A proposal for the conditions of the intervention

7. If applicable, proof of eligibility for PRIME

8. If applicable, proof that the medicine has been subject to an accelerated procedure by the EMA

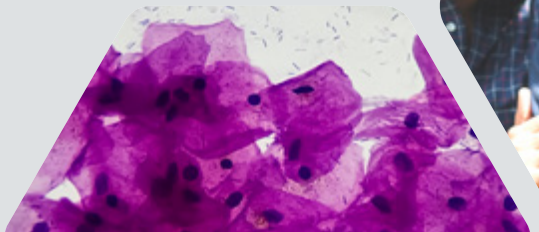
9. Furthermore, the company:

    1. Indicates the deadline within which it will file a reimbursement request after having obtained the MA
    2. Defines the group of targeted beneficiaries
    3. Provides a justification for the intended beneficiary group
    4. Provides an estimation of the budgetary impact for the Insurance

Only companies that have dated and signed an engagement may submit a request for inclusion in the list.

GLOSSARY

CATT	Committee for Advice on Temporary Reimbursement for the Use of a Medicinal Product
CHMP	The Committee for Medicinal Products for Human Use (CHMP) is the European Medicines Agency's (EMA) committee responsible for human medicines
CUP	Compassionate Use Programme
EMA	European Medicines Agency
FAMHP	Federal Agency for Medicines and Health Products
MA	Marketing Authorisation
MNP	Medical Need Programme
NIHDI	National Institute for Health and Disability Insurance
PRIME	PRIority MEdicines (a scheme run by EMA to enhance support for the development of medicines that target an unmet medical need)
QoL	Quality of Life
UMN	Unmet Medical Need



REFERENCES

FAMHP

– Guidance on compassionate use and medical need programmes

CATT

– **Dutch**: Onbeantwoorde medische noden (Unmet Medical Need)
– **Dutch**: Ondernemingen verantwoordelijk voor een geneesmiddel dat of een farmaceutische specialiteit die in aanmerking komt voor vroege of snelle toegang | RIZIV

– **French**: Besoin médical non rencontré (Unmet Medical Need)
– **French**: Entreprises responsables d'un médicament ou d'une spécialité pharmaceutique éligible à un accès précoce ou à un accès rapide | INAMI

COORDINATED LAW OF 14 JULY 1994

– **Dutch**: Wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen gecoördineerd op 14 juli 1994

– **French**: Loi relative à l'assurance obligatoire soins de santé et indemnités coordonnée le 14 juillet 1994

ROYAL DECREE

– **Dutch:** Koninklijk besluit tot vaststelling van de procedures, termijnen en voorwaarden inzake de tegemoetkoming van de verplichte verzekering voor geneeskundige verzorging en uitkeringen bij vroege toegang en bij snelle toegang tot geneesmiddelen

– **French:** Arrêté royal fixant les procédures, délais et conditions en matière d'intervention de l'assurance obligatoire soins de santé et indemnités dans l'accès précoce et l'accès rapide aux médicaments

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