



## Drug negotiations: new 'simplified' and 'fast-track' procedures launched

*The aim is to shorten the time taken for procedures relating to the inclusion of medicines on the reimbursement lists, whilst ensuring financial sustainability for the National Health Service.*

The Italian Medicines Agency adopted the new 'Document on the harmonisation of procedures to streamline the price and reimbursement negotiation process'. The initiative aims to reduce the time taken to conclude procedures for determining price and reimbursement eligibility, speeding up market access for specific categories of medicines and enabling the Scientific and Economic Commission (CSE) to focus its activities on dossiers requiring more complex evaluation.

*"This is an important step towards simplifying and reducing bureaucracy within the Agency," says **AIFA President Robert Nisticò**. "Having up-to-date and harmonised negotiation procedures in place means we can ensure faster and more transparent processes, and therefore more timely access to reimbursed treatments for patients."*

**Technical and Scientific Director Pierluigi Russo** commented: *"Following the update of the guidelines for price and reimbursement application dossiers submitted by pharmaceutical companies, the document published today aims to optimise the administrative process, as well as to streamline and coordinate the work of the offices involved in pricing and reimbursement procedures"*.

To ensure faster and more timely decisions, AIFA has identified two categories of procedures: 'simplified' and 'fast track'.

### Simplified procedures

These procedures **are not subject to assessment by the CSE**. Applications are processed by the Pricing and Reimbursement Office and submitted directly to the Board of Directors (BoD) for approval prior to publication in the Official Gazette. This group includes:

- **Equivalents and biosimilars:** fast-track procedures are provided for both the initial negotiation and subsequent ones, provided that companies propose a price in line with the reduction set out in the Ministerial Decree of 21 July 2022 (Bracket Decree), or prices aligned with or lower than the lowest reference prices already negotiated.
- **Extension of therapeutic indications:** automatic recognition of reimbursement eligibility for equivalent/biosimilar medicines requiring extensions of indications already reimbursed for the originator medicine, provided the price is aligned with the reference price or the lowest price in force.
- **Changes to primary packaging:** a simplified procedure for the admission to reimbursement of new packages with different packaging materials or types, provided that the proposed price is aligned with that of the package already reimbursed.

- **Parallel imports:** a simplified procedure for parallel-imported medicines that offer a specific price reduction compared with the corresponding product already marketed in Italy.
- **Automatic renegotiation of contractual terms:** Companies can access this procedure via a 'Smart dossier' by submitting a specific discount proposal without any reassessment of the medicine's therapeutic positioning or reimbursement status.

### Fast Track Procedures

These procedures **involve referral to the CSE**, but are characterised by an extremely swift assessment based on standardised opinions and negotiation parameters established in advance by the Commission. This group includes:

- **Changes in dosage and dosage units:** new package sizes resulting from changes to the number of dosage units or dosage (increases or reductions) will be subject to a rapid assessment, with fixed price reductions applied.
- **New fixed drug combinations:** new fixed combinations will be eligible for the fast-track procedure if they offer a price lower than the sum of the lowest current prices of the individual active ingredients already reimbursed.
- **Renegotiation for medicines in short supply:** to prevent shortages of essential medicines, a renegotiation procedure is provided for to offset the impact of statutory price reductions and ensure their continued availability on the market.
- **Renegotiations for medicines with a spending cap:** companies may access this procedure via the 'Smart Dossier', provided the medicine has stable or declining sales and has never exceeded the cap for at least three consecutive administrative checks.
- **Classification of medicines in Category C:** streamlined procedures are provided for requests for classification in Category C where analogues are already available in the same reimbursement class, such as vaccines.

For the purposes of submitting the dossier, the Applicant is required to submit the standard application form, stating in the cover letter their intention to make use of the procedures set out in the Document and specifying the relevant reference type.

Pending the update of the e-Dossier IT platform, the Applicant may refer to the table "Methods of submitting the dossier for simplified procedures" to identify the negotiation sub-type, which highlights the correspondence between the sub-types currently available on the platform and those indicated in the Document. The procedures for submitting the dossier set out for negotiation type TN 8 remain unchanged.

The new Document cancels and replaces all simplified procedures previously in force.

Further information can be found on the 'Reimbursability and price application' page:

<https://www.aifa.gov.it/domanda-rimborsabilita-e-prezzo>