



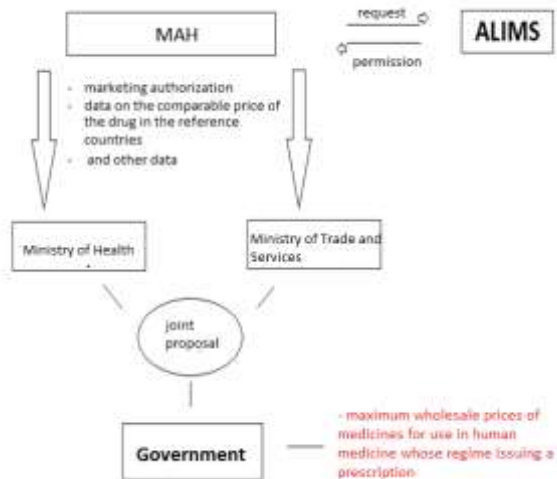
F6: THE ESTABLISHMENT OF NEGOTIATION COMMITTEE, THERAPEUTIC GUIDELINES AND HEALTH TECHNOLOGY ASSESSMENT EFFORTS IN CEE COUNTRIES

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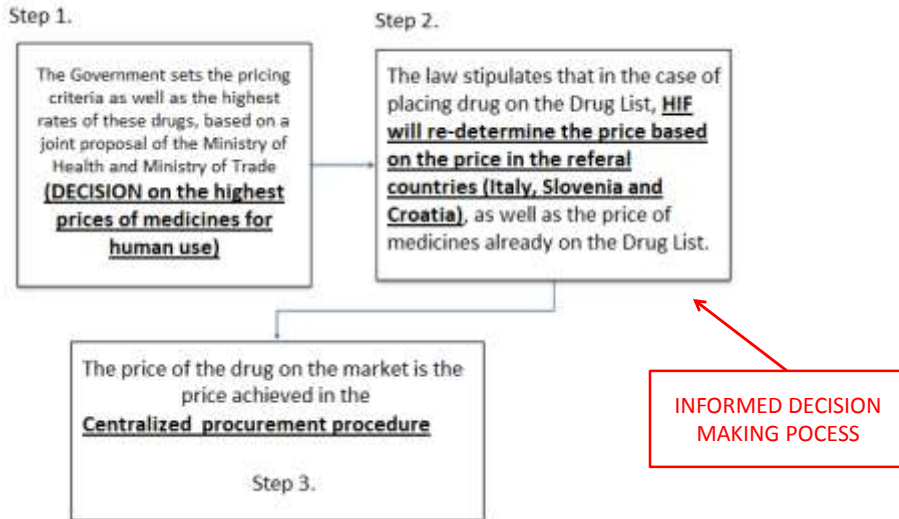
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According to the current legislation, the first requirement for placing a drug on the market is the issuance of a marketing authorization by ALIMS. The law stipulates that this procedure must be completed within 30 + 30 + 210 days, with the possibility of an expedited procedure and a deadline of 30 + 150 days in case of a medicinal product registered in the EU under the so-called centralized procedure.

The process of marketing authorization is followed by the process of pricing which is under strict administrative control



TRIPLE DRUG PRICES



INFORMED DECISION MAKING PROCESS

Central Drug Committee (CDC) housed within NHIF assesses all applications for inclusion of new pharmaceuticals on the reimbursement list, in accordance with the current Rulebook on Criteria for Listing of Reimbursement Medicines.

The entire process corresponds to the procedure of HTA.

The key information required by the Rulebook are evidence of safety and efficacy, together with a pharmacoeconomic assessment, cost/defined daily dose, and budget impact analysis.

Cost-effectiveness analysis is required, even though it is still not a routine part of assessment done by NHIF.



THE CRITERIA FOR PLACING THE DRUG ON THE DRUG LIST

- General criteria:
 - pharmacotherapeutic justification
 - pharmacoeconomic justification
 - funding provided by the Financial Plan of the Republic Fund
- Specific criteria:
 - managed entry agreements
 - priority order

Source: Rulebook on Criteria for Listing of Reimbursement Medicines

TYPES OF MANAGED ENTRY AGREEMENTS:

- "risk-sharing" agreement
- "volume cap" - limitation of the number of insured persons
- "value-cap" - limitation of the amount of money
- "cost-sharing "
- and other types that are considered permissible under the law governing the protection of competition.

Source: Rulebook on Criteria for Listing of Reimbursement Medicines

PRIORITY ORDER

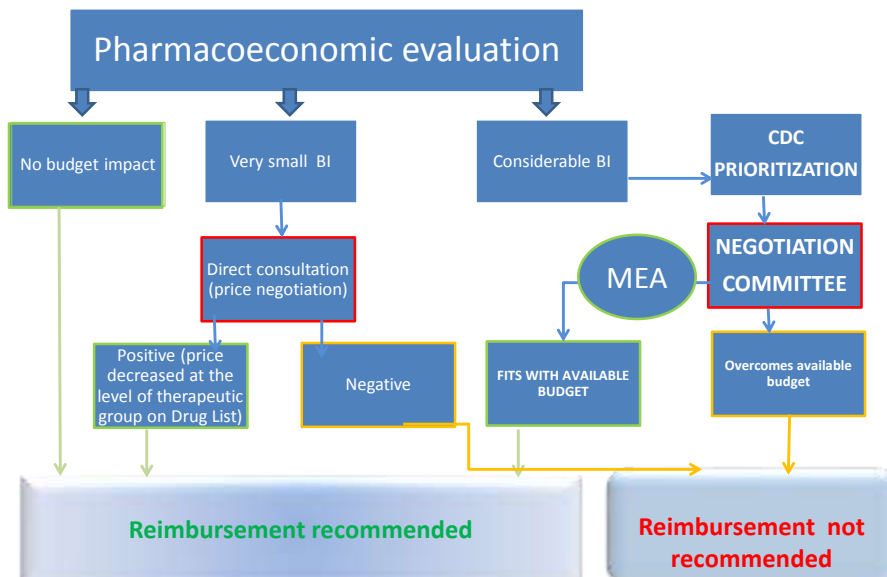
Applies in the case when the funds intended for drugs are not enough for all the drugs that have met the general criteria.

DETERMINING THE PRIORITY ORDER

CDC performs based on the following criteria:

- There is no drug on the Drug List, within the same pharmaco-therapeutic group, for the certain medical indication
- Public health significance
- Ethical aspects

PRICE NEGOTIATION RELATED TO THE REIMBURSEMENT PROCESS



RESULTS & CONCLUSIONS

Since the invisible pricing does not exist as an option, the two types of agreements were implemented:

- Cross Product (giving some % of discount on the drug already listed if the new drug enters the List) and
- Natural Rebate.

- The first experience with MEA and Negotiations (October 2016) - (19 MEA signed in the area of children, transplantation, hematology, and oncology drugs
- To consider the possibility of listing new innovative drugs for Hepatitis C within available resources - Central Drug Committee, October 2017
- No negotiation process for orphan drugs (belongs to MOH funds and distributed by HIF)

Capacity building on pharmacoeconomics, managed entry agreements and negotiations, including prioritization
Setting the criteria for rare diseases fund and clear distinction between Drug list and Rare diseases fund