

Overview of National Drug Policy of Iran

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National Drug Policy (NDP) constitutes the specification of mid-term and long-term pharmaceutical objectives by the government and the determination of major strategies warranted to achieve such objectives. Stated in other words, NDP determines the frameworks for the pharmaceutical activities of private and state sectors. The specification of these policies and strategies will be an effective means in encouraging investors (state and private) to invest in the pharmaceutical industry. In a country where the drug policies and strategies are unspecified and are not stated unequivocally, the development of the pharmaceutical industry and convenient accessibility to drugs in the health and remedy system are unjustified expectations. Since drug is one of the fundamental bases of the health and remedy system and it is widely applied in the processes of diagnosis, prevention, and cure of diseases, a National Health Policy (NHP) is required to be established before the specification of national drug policies. Therefore, an effective and adequate NHP as a principal infrastructure is prerequisite to an effective and adequate NDP.

The most important base of the national drug policies in any country is the National Drug List (NDL) of that country which is established on the basis of NHP principles and the therapeutic protocols of the National Therapeutic Guidelines (NTG). A drug registered in the national drug list of a country must meet the qualitative and accessibility standards and requirements. Furthermore, the rules governing the prescription and consumption of drugs must be established on a logical basis. Since the development of the charter for drug admission to the drug list of Iran and its official approval in 2000, the three aforementioned principles have been considered as the most fundamental criteria for a certain drug to be admitted to the National Drug List. Therefore, and for the purpose of meeting the aforementioned requirements, all authorities who may affect the accessibility, quality, and rational prescribing of drugs are consulted when an admission request (for the registration of the drug in the National Drug List) is processed in order to place the drug in the National Drug List.

The major process authorities which may affect the meeting of the above requirements include: insurance companies' representative, the industry's representative, the physicians community representatives, and the representatives from the Health Deputy Office as the manager and the supervisor of Iranian NHP. These authorities are consulted en route the entry of a drug to the National Drug List. Meanwhile the National Drug Committee secretary will negotiate and debate the entry of the drug with members of the Committee, which is a national committee with about 20 specialized committees, after the preliminary evaluation of the submitted documents and ensuring the safety, efficacy, and cost-efficiency of the nominated drug and the cost-efficiency assessment in comparison to the same rank drugs. If the specialized committee approves the safety, efficacy, and cost-efficiency of the drug and if the drug has been prescribed for a minimum of 3 years in North American or West European countries, it will be referred back to the National Drug Committee for final approval. The members of the Committee include the insurance, industry, and Deputy of Health representatives and a number of pharmacological and clinical specialists designated by the Ministry of Health. If the Committee approves the entry of the drug to the National Drug List, the due process will be executed and the due procedures will be announced to the Medical Association, insurance companies, pharmaceutical manufacturers, and drug importers. The manufacturer or the importer of the drug is then allowed to submit the required documents for registration for the marketing of drugs in the country to the General Department of Medicines Affairs in compliance to additional regulations. The following criteria are emphasized when registering the drug for marketing:

- (1) The drug is accessible throughout the nation and in all times. The National Drug Distribution Charter has been established and announced on the basis of this principle.
- (2) The drug should be reasonably-priced so that the majority of people can afford it and if the drug has high demand in the national health and remedy network and its prescription

requires special regulations, the due regulations and usage of the drug must be developed and announced.

- (3) Attempts are undertaken to rationalize the consumption of drugs through informing the physicians community and the people (through the Drug Information Centers located in 22 centers throughout the nation), re-training programs, journals and the mass media.
- (4) Quality assessment of the manufactured or imported drug. For this purpose, careful supervision at the time of registration and the assessment of the drug master file (DMF) and site master file (SMF) are carried out and quality control test on the drug samples at the National Control Labs (NCL) and supervising the drug production line are implemented to ensure the safety and quality of the first batch of drugs into the market. Furthermore, periodic samples are also collected from the consumer market and tested at the NCL or other accredited laboratories to ensure the primary quality of further batches of the drug. Furthermore, physicians, pharmacologists, and nurses through Adverse Drug Reaction Center may immediately report any adverse effects of the drugs through the provided Yellow Forms to the Ministry of Health so that proper measures are taken. In addition, all manufacturers, importers, and distributors of drugs and pharmacies are required to hire a trained pharmacologist qualified by the Ministry of Health as the technical manager. The technical manager is required to form a quality assurance team in the company and must assure the quality of materials supply, their deployment, the quality of final products and shelf-life quality of the drug. Therefore the Ministry of Health requires all pharmaceutical companies to form a quality assurance team under the supervision of the technical manager so that through procedures such as documentation, validation, Good Manufacturing Practice (GMP), Good Laboratories Practice (GLP), the quality of the products in the processes of production, marketing and during consumption cycle is preserved and ensured.
- (5) The unequivocal announcement of regulations and pharmaceutical practices is another principle of the Iranian National Drug Policy which will be carried out through their regular publication in periodicals, year books, electronic networks, and the Internet. Currently all regulations concerning investment, manufacturing, importing, distribution and supplying of pharmaceutical raw materials and off-the-shelf products are available on the Deputy of Food and Drug website at www.fdo.ir. In addition to the current regulations, users may also find the latest statistics about drug consumption in the country. Pharmaceutical industries' managers may access the latest information about their institutions and compare their products sales to their competitors by visiting this site (through their access codes).