22. Educated use of generic drugs

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Background

The traditional Hippocratic medical culture, on which generations of physicians have been educated, was one of absolute commitment to the individual patient. This culture was free from considerations of "allocation of resources" or of "just distribution". These currently form the foundation stone for the post-Hippocratic economic and ethical reality of modern medicine. We no longer possess absolute economic freedom in the wasteful management of treatment of an individual patient, since by doing so we harm a broader interest of preservation of the health of the entire public.

To his detriment, the physician in the present age encounters a dual identity, one that is liable to harm his social status. On the one hand, he is the clear agent of the patient, and is supposed to act for his good in every possible way. On the other hand, the physician must also act as the agent of society as a whole, which restricts the freedom of the individual to receive every treatment and at any price.

The moment when a physician prescribes a drug for a patient clearly emphasizes this conflict. The pharmaceuticals companies are constantly developing new drugs, "ethical drugs" as they call them, whose protracted development demands tremendous investments, and the period of the patent protecting them is limited to a few years. For this reason, it is not surprising that the prices of these drugs are astronomical.

Other pharmaceutical companies specialize in the preparation of copies of the original drugs, which they rapidly introduce into the market on the date of expiry of the protection for the original drugs. Since these companies are exempt from the development of these drugs from the beginning, they can position in the market "generic drugs" that are far cheaper than the "ethical" ones. Consequently, the use of generic drugs is a broad social interest that serves the public good in that it reduces the cost of management of the national medical economy.

Health care organizations have a built-in interest to use drugs that are as cheap as possible. We must respect this economic interest as long as the substitute drug is identical in its action to the original drug, and as long as this policy is conducted properly.

The State Health Insurance Law, 5754-1994, states that "the health services included in the basket… shall be given in Israel in accordance with medical discretion, of reasonable quality… and all as part of the sources of financing available to the health care organizations". "Reasonable quality", in the opinion of the health care organizations, means that they can replace one drug by another as long as the substitute does not cause harm to the patient, and the continuity of the treatment is preserved. If it is proven that a specific drug is preferable for the patient, the health care organization is obligated to give

the patient the drug that suits him best.
The health care organizations have not always been wise enough to observe this commitment. We all recall some foolish attempts by the health care organizations to make sweeping, ill-considered changes to the original drugs, for whole populations of patients whose medical condition was stable. The patients were required to start using the "target drugs" of the health care organization, which were always cheaper than the current drugs, whether the current drug is ethical or another, more expensive, generic drug.
There is no medical, moral, or ethical problem in starting to give generic drugs to a new patient, knowing that the substitute drug is identical in its action to the original drug, but it is not correct for the health care organization to force a physician to alter the existing treatment of a stable patient for economic considerations.
Special care is required in cases in which the patient receives a drug having a "narrow treatment range", in which the minimum toxic level is a multiple of the minimum treatment level, and any deviation from this narrow range is liable to cause harm. Examples of this are drugs that counter epilepsy or anti-arrhythmic drugs.
The members of the Ethics Board call on the Ministry of Health to prepare, in cooperation with the scientific associations of the Israeli Medical Association, a list of drugs in this group, any change to the use of which may be done only with the express approval of the physician.
Finally, it should be recalled that pursuant to the Pharmacists Order [new version], 5741-1981, the pharmacist is entitled to sell to the consumer a commercial form of a generic drug that differs from that indicated by the physician in the prescription, unless the physician expressly specified in the prescription that the drug must be issued in the commercial name only.
The health care organizations do not always strictly observe this procedure, and no mechanism exists to notify the physician that his patient has received a drug different from that which he chose for the treatment.
Warnings should be re-issued of these systemic defects and action taken to correct them, while understanding that the physician cannot bear responsibility for the results of use of a drug not chosen by him.

Position paper

- The physician is obligated to give every one of his patients the best possible medical treatment.
- There is a concurrent obligation on the physician to preserve the good of the public.
- The use of generic drugs reduces costs for the Israeli medical economy and is therefore ethically proper.

- Generic drugs may be used provided that the health of the patient is not harmed.
- There is no impediment to commencing treatment with a generic drug, provided that it has been tested and found to be identical in its action to the original drug.
- In general, an existing drug, either ethical or generic, which has achieved treatment stability, should not be replaced for economic considerations of a third party.
- Notwithstanding the above, the physician is entitled to suggest to a stable patient that he replace an original drug with a generic drug, if he is convinced that it will not harm the patient, and provided that the patient consents, without pressure.
- An original drug that has a "narrow treatment range" should not be replaced for economic reasons of a third party, for a patient for whom treatment stability has been achieved. The State health authorities should prepare a list of drugs belonging to this group.
- Whenever the instructions of the health care organization for selection of drugs conflict with the physician's professional judgment regarding a specific patient, an appeal mechanism, in which the physician's opinion will be heard and respected, should be employed.
- If a patient is given a drug different from that prescribed by the physician, and the replacement was made without his knowledge, it is not proper that the physician should bear medical responsibility for this.