

3

Commission to Investigate Parallel Importation of Drugs to Israel
Final Report

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parallel Importation of Drugs to Israel

Chapter 1: The Recommendations of the Commission

1. Parallel importation is possible only when the drug is registered in Israel.
2. The parallel preparation must be registered and approved for marketing in the country in which it was manufactured and/or marketed.
3. Any parallel importation of a new preparation must obtain approval.
4. Approval of parallel importation will require a fee (as will be laid down in Ministry of Health regulations, after the approval of the inter ministerial fee committee at the Ministry of Finance).
5. Identity of therapeutic action and of quality of the parallel preparation must be proven with a manufacturer of the preparation, by submission of appropriate approvals, laboratory tests or any other test required by the Pharmaceutics Division as per the Director's approval.
Responsibility for the quality and testing of the parallel preparation applies to the parallel importer.
6. Parallel importation (as regular importation) will be effected only by means of a drug trading house or by a medical institution.
7. Parallel importation can be effected only for drugs which were manufactured in recognised manufacturing sites, i.e. USA, Canada, west European countries, Australia and Japan, which have received GMP approvals from the Ministry of Health in Israel.
8. Parallel importation can be effected from recognised medical institutions or from recognised suppliers who hold a wholesale license issued by the relevant authority for the sale of drugs in their own country (USA, Canada, west European countries, Australia, Japan), and which was recognised by the Ministry of Health in Israel.
9. A parallel importer (who is not a non-profit medical institution) must provide all the approvals required for ensuring the chain of supply in order to guarantee the source and the quality of the preparation along the entire route of arrival to Israel. After a year's trial, the possibility of changing the requirement for ensuring the chain of supply will be re-examined vis-à-vis all parallel importers.
10. The approval will be specific per preparation, manufacturing site and importer. In any case of a change in one of the above items, a new application must be submitted for approval of the change.
11. Every imported batch will be accompanied by a batch certificate and a certificate of analysis of the manufacturer for the batch.

12. Each preparation will be marked with a label as required by law, including the name of the importer and the batch number, with a leaflet enclosed in the accepted manner.
13. Every batch from every consignment will be sampled and tested for quality at the Standards and Control Institute for Medical Substances. The preparation will be marketed only after receipt of marketing approval.
14. Parallel importation of a drug with an expiry date of one year or less will not be approved, except in cases where the Director decided otherwise.
15. The owner of an original registration will be required to register the preparation in all the commercial names and from all the sites where the preparation is manufactured, in order to broaden the possibility of ensuring regular supply.
(The opinion of the Attorney General contends that this requirement cannot be implemented. The validity of the contention has not been tested.)
16. Parallel importation to Israel for the purpose of export is forbidden, and this should be explicitly stated in the regulations.

parallel Importation of Drugs to Israel

Chapter 2: Summary

General:

Israel has only one importer with a monopoly on the importation of drugs directly from the manufacturer. Parallel importation of drugs will enable also the importation of drugs to Israel by a number of importers, not necessarily directly from the manufacturer (via intermediate suppliers). The economic viability of parallel importation derives from opening the market to extensive competition and from the fluctuations in exchange rates and the various price-setting mechanisms around the world, so that at times there is a difference of up to 60% in the price of the same drug in different countries.

the situation in israel:

On 7/7/96 the Government decided, as part of its discussions of the 1997 budget, to maintain parallel importation of drugs to Israel. The thinking behind the decision was that parallel importation can significantly lower the price of purchasing drugs in Israel, thereby decreasing the total national expenditure for health or enabling the saved resources to be routed to other needs in the health system.

Today, medical institutions - sick funds, hospitals and S.R.A.L., may and actually do effect limited parallel importation in accordance with the Pharmacists Regulations. Parallel importation contributes to the purchase of drugs at a lower price, both by its implementation and as a mean of bargaining during negotiations with the supplier in Israel.

the situation worldwide

According to the information in our possession, parallel importation is forbidden in the USA, Switzerland and New Zealand. The WHO issued directives requiring purchase directly from the manufacturer, so as to prevent problems of counterfeiting and inferior quality. In the USA there is an internal movement of goods between the various states, and parallel importation is absolutely forbidden.

Parallel importation of drugs exists only in Europe, since the European Union has turned Europe (like the USA) into one trading territory, and following the Treaties of Rome concerning free movement of goods within the European Union, parallel importing is legal. In Europe too, parallel importation is permitted only from within the countries of the Union, and not from other countries. In Europe, parallel importation is legal and is therefore carried out openly and directly.

According to statements of the Director of the Office for Supervision of Pharmaceutical Goods in the European Union, during his visit to Israel, the only reason for the existence of parallel importation in Europe is the upholding of the principle of free movement of goods in accordance with the Treaties of Rome (a statement which was not backed up by data). The market segment of parallel importation is 5 - 8% of total sales in the drugs market, and has not led to any significant decrease in the prices of original/local drugs.

the problems involved in parallel importation to Israel

The multinational drug companies oppose parallel importation but are unable to prevent it inside Europe. Their opposition to parallel importation means that some of the drug dealers in Europe who engage in parallel importation, are forced to use circuitous ways and deception in order to obtain the drugs. Therefore, parallel importation of drugs to Israel is liable to be an outcome of shadowy activities carried out, at least in part, in the grey area between legal trading and illegal trading. Thus, the parallel importation of drugs to Israel incorporates potential risks for public health, and therefore a rigid and independent system must be established which can ensure the quality of the drugs imported in parallel. The risk which exists in parallel importation is the importation of defective or counterfeit drugs, or drugs which do not meet the quality requirements of the western world.

An essential condition for the existence of parallel importation is the training of a control and quality assurance system at the Pharmaceuticals Division.

Obstacles:

The multinationals contend that parallel importation infringes international agreements - to which Israel is a signatory - the GATT/TRIPS agreements, and also violates the laws of Israel - patent protection. Furthermore, these companies explained that the infringement of their intellectual property rights (the patent) is liable to cause the companies to reduce their investments in Israel (for example, clinical trials, the establishment of research systems and ties with start-up companies, etc.).

Proposed solutions:

1. In principle and according to a legal opinion, even if the legal arguments turn out to be correct, the parallel importation of unpatented imported drugs can still be permitted.
2. To avoid problems of drug quality, parallel importation should be permitted only to medical institutions or limited by conditions and directives that only recognised and financially strong entities will be able to bear liability for their goods so as to effect parallel importation.
3. To ensure the quality of the drugs, the following practices can be adopted:
 - a. To request of the parallel importer all the approvals required for guaranteeing the chain of supply for ensuring the source and quality of the preparation along the route of its arrival to Israel.
 - b. To exempt the medical and public institutions in Israel from submitting the approvals for guaranteeing the chain of supply, while imposing the responsibility for the quality and testing of the drugs on the institutions, as was the case until today.
4. In order to make it easier for the medical institutions to purchase the drug from additional manufacturing sites abroad, each importer will be required, when submitting the registration application, to register all the sites abroad where the drug is manufactured, so as to broaden the importation possibilities. (According to the legal opinion, this possibility is estimated as being partially practicable. The validity of

this contention was not tested.)

5. The ability of the Pharmaceuticals Division to supervise and control quality should be enhanced by means of adjusting resources as required (in accordance with revenues from fees), and improving the skill of workers by specific professional training in this subject.

parallel Importation of Drugs to Israel

Chapter 3: Summary of the Work of the Commission

general:

On 7/7/96 the Government decided, as part of its discussions of the 1997 budget, to maintain parallel importation of drugs to Israel (Appendix No. 1), in order to lower the prices of purchasing drugs in Israel and thereby to reduce the total national expenditure for health or in order to route the saved resources in favour of other expenses in the health system.

Pursuant to the decision of the Minister of Health, on September 17, 1997, the Director General of the Ministry of Health appointed a committee to examine the subject of parallel importation of drugs to Israel (Appendix No. 2).

Definition: Parallel importation of drugs is defined as the importation of a medical preparation which is registered in the Government Register of Medical Preparations, by an importer who is not the owner of the original registration (who is a local importer or manufacturer).

The Commission convened for the first time on September 18, 1997, and its members held 6 one- day sessions and numerous meetings and telephone discussions with interested parties.

The Commission's aim was to examine in depth the implementation of the Government decision on the subject of parallel importation, without preconceived notions and without bias. Initially, internal discussions were held for understanding the basic principles of parallel importation, a review of the situation in Israel and worldwide, identification of advantages, disadvantages, opportunities and obstacles relating to the implementation of parallel importation of drugs to Israel. The Commission approached the health authorities in England for a better understanding of how parallel importation of drugs is carried out in Europe from the regulatory aspect.

The Commission then approached relevant entities on the subject, requesting their position in writing and orally: Clalit, Maccabi and Meuhedet Leumit Sick Funds, Sheba Hospital, the Federation of Pharmacists in Israel, the SuperPharm chain, a potential parallel importer, the Pharmaceuticals Division in the Israel Manufacturers Association, the Drug Import Division at the Union of Chambers of Commerce, and the local branches of the multinational drug companies (for the positions of the various entities, see Appendix No. 3, A - L).

Having heard all the various positions, the Commission received operative proposals from the various entities, including the nature of the changes required in the Pharmacists Regulations for the method of implementing parallel importation to Israel (Appendix No. 4, A - C), and convened to discuss and clarify the subject and formulate its recommendations.

In the course of the discussions, subjects arose which were outside the mandate of the

Commission but required its comment as part of the general review of the subject of the drugs market in Israel, and are therefore reflected in the Report.

The situation in Israel:

In Israel, only one importer (a monopoly) imports a drug directly from the manufacturer. Parallel importation of drugs will allow, in addition, the importation of drugs to Israel by a number of importers, and not necessarily directly from the manufacturer (through intermediate suppliers), thus increasing competition. The economic viability of parallel importation derives from competition between a large number of suppliers who enable purchase at lower prices than today's purchase prices, and in addition the ability to exploit opportunities afforded by fluctuations in exchange rates in various countries. Today, medical institutions - sick funds, hospitals and S.R.A.L., may and do actually implement limited parallel importation in accordance with the Pharmacists Regulations. Parallel importation by medical institutions is effected and contributes to reducing purchase costs (subject to a guarantee of the quality of the drugs). In addition, parallel importation is a means of bargaining when negotiating with the importer in Israel for obtaining lower prices.

The situation worldwide:

According to the information we have, parallel importation is forbidden in the USA, Switzerland and New Zealand. The WHO issued directives for the purchase of drugs directly from the manufacturer, so as to avoid problems of counterfeiting and inferior quality.

Parallel importation of drugs exists only in Europe, since the European Union has turned Europe (like the USA) into one trading territory, and following the Treaties of Rome concerning free movement of goods inside the European Union, parallel importation is legal. In Europe too, parallel importation is permitted only within the countries of the European Union and not from other countries. In Europe, parallel importation is legal and therefore is carried out openly and directly, despite the fierce opposition of the multinational drug companies (the manufacturers).

Parallel importation of drugs in Europe exists following a ruling of the Supreme Court of the European Union (de Peijer), who held that the principle of free movement of goods in Europe overrides monopolistic agreements of a sole and exclusive marketing channel:

1. "If local laws permit a manufacturer or his official representative to refuse to supply information on the preparation, thereby constituting a monopoly which does not allow the existence of importing, then those laws are restrictive. Only if the manufacturer or his official representative can supply data or documents which prove a difference between the original preparation and the parallel preparation, can they be related to as two different preparations."
2. The European Union notifies the authorities of the Member States that they may not oppose parallel importation by contending that the parallel importer cannot supply documents concerning the quality of the preparation which are in the possession of the manufacturer or his official representative only. The national authorities must permit the

flow of information among them so as to ensure the identity of the preparations."

Parallel importation is a politically charged subject in Europe, and therefore no official directive has yet been issued by the Union on the subject (due to the inability to reach a consensus in the European Parliament). The only official European document is a communication which constitutes a recommendation only, and which aims to give a practical interpretation to the court ruling and to propose guidelines for a procedure for the parallel importation of drugs in Europe (Appendix No. 5).

Below are the guiding principles of the European Union:

1. Parallel importation is possible only when the original drug is registered in the country to which the importation is effected.
2. Parallel importation is possible only from another country in the European Union.
3. The parallel preparation must be registered and approved for marketing in the country from which it is imported.
4. The licensee of the parallel preparation in the country from which it is imported, must be part of the multinational company which holds the registration of the original preparation in the country to which the import is effected.
5. It is forbidden for there to be any significant therapeutic difference between the parallel preparation and the original preparation.

Economic viability:

The economic viability of parallel importation derives from competition among suppliers and from the exploitation of opportunities from fluctuations in exchange rates and price-setting mechanisms around the world (Appendix No. 6), which sometimes create a difference of up to 60% in the price of the same drug in different countries.

Nevertheless, according to the statement of the Director of the Office for Supervising Pharmaceutical products in the European Union (DG III), Mr. Patrick Deboyser, at the time of his visit to Israel, he estimated (without back-up data) that the economic consideration in parallel importation had not proved itself, and the sole reason for the existence of parallel importation is the upholding of the principle of free movement of goods, in accordance with the Treaties of Rome. According to Mr. Deboyser, the market segment of parallel importation is 5 - 8% of drug market sales, and does not lead to any significant reduction in the prices of the original/local drugs. In addition, it is difficult for a government to define how the actual saving is expressed for the country, and the gap in the purchasing price of the parallel drug usually remains as a larger profit for the parallel importer. In addition, a single article which was published in 1997 in the newspaper *Health Policy* (Appendix No. 7), which describes the drugs market in Britain, explains that parallel importation constitutes only about 8% of the prescription drugs market since it is difficult for the parallel importer to guarantee the regular and orderly supply of cheap goods, and the British pharmacists are sceptical of the quality of the products and are therefore not keen to purchase them despite their low price. (Note: This fact applies partially to Israel, due to the unique structure of the health system in Israel.)

The problems involved in parallel importation to Israel:

Following a detailed review of the subject of parallel importation, reading the extensive

material on the subject and hearing the various bodies and entities involved in the subject, and in view of the understanding of the complexity of the question of parallel importation, below is a list of all the potential obstacles identified by the Commission:

1. Guarantee of identity of the parallel preparation to the original preparation:

a. A drug manufacturer sometimes manufactures a medical preparation under the same commercial name but with different compositions, depending on the site of manufacture and the country for which the medical preparation is designated.

b. It is possible that in different countries, the terms of registration of an identical preparation will be different (e.g. instructions for use, labelling, shelf-life, etc.).

c. The packing and composition of the preparation can differ between Europe and Israel, so as to cope with different climatic conditions.

d. Every multinational maintains a large number of manufacturing sites around the world. When a preparation is registered in Israel, it receives marketing approval only after assurance of the proper conditions of its manufacture, a large part of which is assessment of the manufacturing plant. It is not clear of the manufacturing conditions at all sites are identical, and accordingly, whether the quality of the preparation of the same commercial name and similar composition, is manufactured in the same conditions of quality at different manufacturing sites.

e. At times, plants in Europe which comply with all the quality standards at the time of marketing in Europe, manufacture the same product at a lower quality or inferior quality by order, for third world countries. This fact was confirmed in a conversation with the Director of the Office for Supervising Pharmaceutical Products in the European Union (DG III), and therefore, emphasis must be given to identification of the batch designation.

2. Marketing channel / chain of supply of the medical preparation:

Importation which is not direct involves a number of intermediaries, creating a situation where from the moment the preparation left the manufacturer's premises until its arrival at the parallel importer's premises, it is in the ownership of other merchants. In that time, there is a possibility of counterfeiting the preparation or of it being held in defective storage conditions.

3. Direct contact between the importer and the manufacturer:

There has always been direct contact between the manufacturer and the importer (who is not a medical institution), an essential requirement in the opinion of the Ministry of Health for ensuring the quality of the imported preparation.

In this context, two Supreme Court rulings are quoted here:

A. Bagatz 2201/90 Alpha Pharma - Test Committee

"There is no dispute that parallel importation of drugs is possible provided that

direct contact is maintained between the manufacturer and the importer."
 "The solution whereby the Ministry of Health will carry out the quality test cannot be entertained, due to the imposition of legal liability on the Ministry, since the manufacturer will deny his responsibility for a product of which he lost control, unless it is proven that the defect is in the manufacture and is not one which derived from later in the chain of supply."

B. **Bagatz Ruling 2313/95 Contact Linsen versus The Ministry of Health (majority opinion of Justice Zamir):**

"There is no room to disqualify the requirement of the Ministry of Health that the importer of contact lens solutions should prove contact with the manufacturer of the solutions or with a certified agent of the manufacturer or with his recognised supplier."

4. **Difficulties in transferring information:**

In importation which is not direct, there is no direct contact between the manufacturer and the parallel importer, and therefore, in a case where side-effects come to light, defective batches or any other health-related problem connected with the use of the drug, the parallel importer will have difficulty in providing that information in real time, since the information will reach him considerably later, due to the chain of supply of the preparation, or it will not reach him at all.

5. **Regular supply:**

According to the Pharmacists Regulations - Medical preparations (5746-1986), one of the conditions for registration is an undertaking of the owner of the registration for the regular supply of the drug in Israel. It is estimated that the more intermediaries there are in the chain of supply, the greater the possibility that the parallel import is the result of opportunities and not of orderly contact with a supplier, and therefore it will not be possible to demand an undertaking of the parallel importer for regular and orderly supply.

On the other hand, parallel importation is liable to disrupt the possibility of the main importer to anticipate consumption in Israel, and therefore the owner of the registration is liable to seek to revoke his undertaking for orderly and regular supply of the preparation. Another reason is that by law, it is not possible to differentiate in the requirements between the parallel importer and the main importer.

6. **Cooperation between health authorities:**

In importation which is not direct, there is no direct contact between the manufacturer and the importer, and therefore, when submitting the application, the importer will be missing data. According to the directives of the European Union, the authority (ministry of health) must obtain these data from the manufacturer or from the competent authority in the country of manufacture. In Europe, the cooperation among the health authorities is automatic, due to the ruling of the High Court of Justice of the European Union.

In order to achieve cooperation of this type between the health authorities in Israel and the appropriate authorities abroad, there must be official cooperation

agreements, which several ministries, among them the Ministry of Health, are currently working to achieve, but the process will take years.

7. Product liability:

In case of defective products, the following questions arise: who guarantees the quality of the preparation in Israel, who is liable and who is sued? The manufacturer is liable to shrug off any liability in any case of a parallel preparation since it did not arrive in Israel on his responsibility, and will always contend that the defect derived from the method of conveying to Israel and not as a result of a malfunction in manufacture.

8. Labels and leaflets:

To prevent confusion among the public and to comply with registration requirements, the parallel preparation must be marked with labels and leaflets identical to the terms of registration which were approved for the original preparation.

The importers of the drugs argued that the consumer leaflet and the leaflet to the physician are tantamount to intellectual property of the owner of the original registration, and therefore an identical leaflet cannot be approved for the parallel preparation.

9. The financial saving deriving from parallel importation:

a. In Europe, it is difficult for a government to define how the actual saving is expressed for the country, and usually the difference in the purchasing price of the parallel drug remains as larger profit for the parallel importer. The only article found in the literature is from 1993 (Appendix No. 8), and shows that about 80% of the parallel drugs were sold at a price of more than 90% of the price of the original preparation. Thus, if parallel importation is approved for private entities in Israel, a method must be determined by which the State can participate in the profits of the private importer so as to realise a contribution to reducing the national expenditure on drugs.

b. The proposed reform in setting the prices of imported drugs is supposed to reduce the prices of the drugs by more than about 20%. Since the rationale behind parallel importation relates to the considerable differences in prices, it is estimated that lowering the prices of the drugs in Israel is liable to be partially offset by the contribution of parallel importation to saving in the national expenditure for drugs.

c. Multiplicity of preparations with different names, packaging, shape and colour reduces patient compliance, which is liable to lead to a rise in visits to specialist physicians, emergency departments, hospitalization days, etc., which are reflected in a rise in the national expenditure for drugs.

10. Parallel export:

Inexpensive purchasing of preparations will give rise to the thought of selling those preparations abroad at a high profit. The multinational companies will respond with severity, as did Serono - cessation of the supply of Pregonal to Israel due to the

suspicion that Pregonal from Israel had reached the market in the USA.

11. Blood products, biotechnological preparations and radioactive preparations:

The above group of products is unique among the range of medical preparations, and therefore, with preparations of this type, particularly strict control is needed. Laboratory tests cannot always ensure the safety and quality of the parallel preparation, and therefore it is possible that the parallel importer will be requested to submit additional data with his application, to ensure the identity and the quality of the parallel product, for each manufactured batch separately.

12. Parallel importation as infringing the intellectual property right of the manufacturer:

A legal opinion which was given by Adv. Luthi, as the representative of the multinational drug manufacturers -

a. "A permit for parallel importation of drugs, and in particular drugs which are protected by a patent registered in Israel, contravenes Israeli law and violates the international commitments which Israel took upon itself in the GATT-TRIPS Agreement."

b. "Any permit for parallel importation of drugs which are not patent-protected cannot include a permit for the parallel importer to exploit the Israeli registered trademark, where the drug was marketed abroad under another trademark."

c. The health authorities in Israel are not permitted to rely on the technical and professional information which was supplied to them by the patentee, in a manner which will enable the parallel importer to benefit from that information."

The legal opinion of the Ministry of Health (Appendix No. 9) contends that:

a. The Ministry of Health is not qualified to examine the subject of the harm to the property right and is not offending against the patents laws in Israeli law or the GATT-TRIPS Agreement. If there is concern of infringement of the intellectual property right, a patentee may initiate a legal proceeding for clarification of his case opposite the parallel importer.

b. Amendment of the Regulations will on o way harm protected rights. Clearly, the license for parallel importation cannot permit the importer to use a registered trademark. The owner of the property right can enforce his right, if infringed, or can reach any agreement with the parallel importer.

c. It is doubtful whether the use of the information by the Ministry of Health for the registration constitutes unfair commercial use, as long as it is not exploited by the parallel importer. However, an opinion should be given on the problems which are liable to be generated on this subject, and to lay down in the procedures an arrangement which will protect the rights of the main importer.

13. Resources for handling parallel importation:

a. The control and quality assurance array at the Israeli Ministry of Health takes for granted that the drugs market in Israel consists of honest players, and has no experience in dealing with those who counterfeit drugs. The risk in parallel importation is the penetration of poor-quality, defective or counterfeit drugs. For example, in 1989 a batch of parallel-imported Zantac from Greece was tested and found to be counterfeit.

To cope with this risk, the number of tests of the preparations must be many times those of the original preparations, which will considerably increase the volume of activity of the Ministry's control and quality assurance array.

b. For the maintenance of effective supervision of parallel importation which will ensure the quality of the parallel preparations and preserve public health in Israel, additional special resources are needed (which will be determined according to the pricing of the costs and an appropriate fee). The maintenance of a registration mechanism which includes a registration fee will enable the addition of special professional positions for this subject in the Pharmaceuticals Division and at the Institute for Control and Standards of Medical Substances, or as part of outsourcing.

14. The original registration owner (the position of the monopoly drug companies):

a. The multinational companies are currently opening local branches in Israel. They contend that parallel importation will cause them to reconsider their desire to invest in Israel, and accordingly they will considerably reduce or completely stop their investments in Israel. These investments contribute workplaces and a great deal of money to the State, due to the investment in clinical trials, scientific research and the participation in start-ups.

b. Even though, by law, competition and freedom of occupation should not be prevented, it is clear that the original owner of the registration invested his own money in the process of registering the preparation, and therefore the question is whether he should be compensated in any way.

c. The penetration of a new drug in the market involves many expenses for publicity and for training the medical team in the correct use of the drug. Taking away the profitability from the original registration owner is liable to lead him to reduce his investments in marketing and to harm the training of the medical team.

d. As part of the service of a large importer in Israel, he is willing to register new preparations for which the market is small and the profit is low. Parallel importation is liable to cause the importer to cease registering such preparations and to cancel the registration of the existing preparations.

e. The harm to the original registration owner is liable to cause him to prefer to become a parallel importer, whereupon most of the importation to Israel will be parallel and a material change will take place in the structure of the drugs market in Israel.

the conclusions of the commission:

On 7/7/96 the Government decided, as part of its discussions of the 1997 budget, to maintain parallel importation of drugs to Israel with the aim of saving on the costs of purchasing drugs.

The Commission was required, in its letter of appointment, to examine the subject of parallel importation and to propose solutions.

The problems involved in parallel importation derive from opposing considerations of upholding the principle of freedom of occupation and economic viability, versus conservation of public health.

The Commission recognises the necessity of greater efficiency and savings in the health system, due to the desire to maintain medical care of quality and equality, despite the limited resources allocated to that system.

Today, the medical institutions in Israel are permitted to effect parallel importation of drugs, and the experience gathered proves the financial viability of parallel importation along with problems concerning the quality of the preparations. The multinational drug companies oppose parallel importation but cannot prevent it within Europe. Their opposition to parallel importation means that some of the merchants who deal in parallel importation are liable to need circuitous routes and fraudulent means to obtain the drugs. It is highly probable that some of the parallel importation of drugs to Israel will be the result of shady activities which are undertaken, at least in part, in the grey area between legal trading and illegal trading.

Thus, parallel importation of drugs to Israel incorporates potential risks to public health, and therefore an appropriate system must be established, which can ensure the quality of the drugs imported in parallel. The risk existing in parallel importation is the importation of defective or counterfeit drugs or drugs which do not meet the quality requirements of the western world, and therefore an essential condition for the existence of parallel importation is the training of a control and quality assurance array of the Pharmaceuticals Division.

Additional points raised for discussion:

1. The regulations must forbid a situation of parallel importation to Israel for export purposes.
2. Manufacturing sites - a multinational company manufactures at a large number of sites around the world. Today, parallel importation is limited to the manufacturing site which is registered in Israel. To broaden potential parallel importation, importing must be permitted from every approved manufacturing site of the multinational company. It is desirable to require the registration owners to register all the manufacturing sites of the preparation.
3. Packaging and commercial names - Importation should be permitted of a parallel preparation which does not have the same commercial name and packaging as that

approved in Israel, but as registered in the country of manufacture/marketing.

4. Parallel importation of preparations manufactured locally -
 - a. Packing in Israel of a preparation manufactured abroad: Currently, parallel importation of the institutions is effected only for imported preparations, and therefore any preparation manufactured abroad and packed in Israel is deemed, at this stage, to be local manufacture, and there is no possibility of importing a parallel preparation from the manufacturing plant abroad.
 - b. Preparations of Teva Co: Teva is a multinational company, and therefore there is a need to consider whether products of local manufacture can be imported from abroad, or identical products which were manufactured at the overseas manufacturing site of the company.
 - c. A preparation manufactured under a know-how agreement: A preparation which is manufactured in Israel on the basis of a know-how agreement with a foreign company. According to the local manufacturers, after signing the agreement the connection ends between the foreign manufacturer and the local manufacturer, and therefore, as the years elapse, the composition of the locally-manufactured preparation differs from the composition of the original preparation which is manufactured abroad. Parallel importation of the original preparation can be allowed by proving identity of action between the two preparations by means of bioavailability tests.
5. In order to achieve saving in the national expenditure on drugs, there must be a guarantee that the parallel importer which is not a medical institution will sell the parallel preparation at a price which is considerably lower than the price of the main importer.

The legal opinions of the Ministry of Health (Appendices Nos. 9 and 10) contend that -

1. The Ministry of Health is not qualified to examine the subject of the harm to the property right and is not offending against the patents laws in Israeli law or the GATT-TRIPS Agreement. If there is concern of infringement of the intellectual property right, a patentee may initiate a legal proceeding for clarification of his case opposite the parallel importer
2. In order to permit parallel importation by private entities, separate regulations must be promulgated for them, so that it will be possible to impose different requirements for medical institutions, which are already permitted today to effect parallel importation.
3.
 - a. The consumer leaflet is written on the basis of a Ministry of Health questionnaire which is filled in by the registration applicant. Collation of the answers to the questionnaire is done by the Ministry of Health, and therefore it appears that the Ministry creates the document and owns the rights therein.
 - b. Obligating the parallel importer to use the physician's leaflet of the registration

owner could cause infringement of copyright and the filing of suit against the Ministry as the direct cause of the infringement. This difficulty can be solved by waiving the requirement for a physician's leaflet from the parallel importer.

4. The owner of the registration cannot be obligated to register all the manufacturing sites unless the requirement is based on public health considerations. It seems that the way to deal with importers who unfairly exploit their control of the market and import their products from particularly expensive manufacturing sites, is by means of a rewording of the Pharmacists Regulations and/or by means of the Anti-Trust Commissioner on a point-by-point basis.

manner.

13. Each batch from every consignment will be sampled for quality testing at the Standards and Control Institute for Medical Substances. The preparation will be marketed only after receipt of a marketing permit.
14. The parallel importation of drugs with an expiry date of one year or less will not be approved, except in cases where the Director decides otherwise.
15. An original registration owner will be required to register the preparation in all the commercial names and from all the sites where the preparation is manufactured, in order to broaden the importation possibilities so as to ensure regular supply. (The legal opinion of the Attorney General contends that this requirement is impracticable. The validity of that contention was not tested.)
16. Parallel importation to Israel for export purposes is absolutely forbidden, and this should be stated explicitly in the regulations.