Parallel Import and Price Regulation in the Pharmaceutical Market: The Israeli Experience*

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Abstract

The soaring cost of pharmaceuticals in the United States has become a source of concern for patients, health care providers, and policymakers. Consequently, several attempts have been made in recent years to reduce drug prices by opening up the pharmaceutical market to parallel imports of drugs from Canada and other countries. Similar concerns in Israel led the Israeli legislature to enact reforms in the early 2000s authorizing the parallel importation of medications. The prevailing assumption at the time was that allowing parallel imports would lead to a significant drop in drug prices and a decrease in healthcare costs in Israel.

This Article presents an empirical study of Israel's experience, examining the effects of these regulatory reforms and the practical impediments to invoking the parallel importation mechanisms they established. Combining quantitative methods, interviews, and a comparative law study, this Article makes several important contributions concerning the interaction of parallel imports and price regulation of drugs.

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Our first key finding is that there has been almost no parallel importation of pharmaceuticals into the State of Israel in the twenty-plus years since such imports were authorized. In other words, despite reforms intended to incentivize competition in the Israeli pharmaceutical market through parallel importation, competition in this sector remains close to nil. We attribute this to a number of barriers to parallel importation in the Israeli market, including regulatory barriers, contractual barriers, and barriers resulting from asymmetry of information. Nevertheless, our study reveals that even without the expected influx of parallel imports into the market, the maximum price of most prescription drugs in Israel decreased from 2007 to 2020, and that Israeli HMOs typically buy medications for less than their maximum prices. Accordingly, we conclude that opening the Israeli pharmaceutical market to parallel imports may have had an indirect effect on drug prices by improving the bargaining power of these key market players and increasing competitive pressure on manufacturers.

Our study concludes that while regulatory reforms intended to cultivate a vital industry of parallel drug importation did not achieve that result, they may nevertheless have helped to control drug prices. It also highlights the viability of parallel importation in a price-regulated market, and the conditions under which such importation can take place deserves further scholarly investigation.

Table of Contents

INTRODUCTION

For many years, the Pharmacists Ordinance of 1981 imposed severe restrictions on the parallel importation of pharmaceutical products into Israel.[1] In the beginning of the twenty-first century, however, the Ministry of Health amended this legislation, effectively authorizing such parallel imports.[2] This was done to facilitate the entry of additional players into the market.[3] The prevailing assumption was that opening the Israeli pharmaceutical market to parallel imports would lead to a significant drop in drug prices and a decrease in healthcare costs in Israel.

As a result of this legislative change, many international pharmaceutical companies, including Bristol-Meyers, Eli Lilly, Howard Evans, Johnson & Johnson, and Merck, filed a joint petition with the Supreme Court of Israel claiming that the amendments allowing for parallel imports infringed their patent rights.[4] According to these companies, the Israeli legislature could have acted to reduce drug prices in alternative ways that did not burden their rights so substantially.[5] Additionally, the companies argued that allowing parallel importation would result in the theft of trade secrets and violate Israel's international obligations.[6] Finally, the companies argued that opening the Israeli pharmaceutical market to parallel imports would sever the link between manufacturers and importers, and would therefore increase the risk of defective or counterfeit

1. *See* § 47(A), Pharmacists Ordinance [New Version], 5741-1981, 5761 DMI 693, 701 (1981) (Isr.), https://www.nevo.co.il/Law_word/law18/35.pdf.

2. The legislature amended the Pharmacists Ordinance and removed the registration obligation it had in relation to drug importers. § 47(C), Pharmacists Ordinance [New Version] 5741-1981 (Isr.); *see also* § 26, Arrangements in the State Economy Law (Amendments to Legislation to Achieve Budget Objectives and Economic Policy for the Fiscal Year 1999), 5769-1999, SH 5769, 89 (Isr.) (amending the registration obligation), https://www.nevo.co.il/Law_word/law14/law-1704.pdf. In addition, the Ministry of Health amended the Pharmacists Regulations which permitted the parallel import of medical products by the HMOs. § 5A–C, Pharmacist Regulations (Preparations), 5746-1986, KT 6040, 645 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-6040.pdf.

3. Doron Barash, *Coercive Licenses in the Pharmaceutical Industry and the Statement on the TRIPS Agreement and Public Health*, 27 REFUAH VEMISHPAT 200, 200–01 (2002) (Isr.).

4. HCJ 5379/00 Bristol-Myers Squibb Co. v. Minister of Health, 55(4) PD 447, 461 (2001) (Isr.).

5. *Id.*

6. *Id.*

drugs entering into Israel.[7] The Supreme Court rejected the pharmaceutical companies' petition and affirmed the legitimacy of the legislative amendments.[8] However, the effects of this policy change on the pharmaceutical market in Israel have yet to be examined in depth. This article seeks to fill that gap.

The pharmaceutical market generally comprises brand name drugs and generic drugs. Brand name drugs are original drugs developed by pharmaceutical companies and typically benefit from strong protections under patent law.[9] The ability of a parallel importer to import brand name drugs—or other patent-protected goods—can vary from country to country and depends largely on the import country's approach to the exercise of intellectual property rights under domestic patent law.[10] While some jurisdictions have adopted a domestic theory of exhaustion of patent rights, meaning that the sale of goods protected by a registered patent exhausts the rights of the patent holder only in the territory in which the goods were sold, other jurisdictions take an international approach to exhaustion, meaning that the sale of patented goods by the patent rights holder (or someone acting on their behalf) exhausts the patent holder's rights in all jurisdictions.[11]

Under the domestic approach, parallel importation of a protected product from another country is prohibited, as it would violate the patent holder's rights.[12] Under the international approach, however, a patent holder cannot prevent the sale and distribution of protected goods through parallel importation from another country.[13] In the *Bristol-Meyers* case, the Court noted that Israeli patent law tends to favor the international approach.[14] Accordingly, parallel importation into Israel of patent-protected pharmaceutical products first sold in another country while preserving the rights of the patent holder does not violate Israeli patent law.

One might expect that the Supreme Court's decision upholding the legislative amendments removing restrictions on

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7. *Id.* at 463.
8. *Id.* at 463–75.
9. *See, e.g.*, JOHN R. THOMAS, CONG. RSCH. SERV., R44640, PATENTS AND PRESCRIPTION DRUG IMPORTATION 1–3 (Oct. 4, 2016).
10. HCJ 5379/00, Bristol Myers Squibb Co., 55(4) PD at 464–65.
11. *Id.*
12. THOMAS, *supra* note 9, at 6.
13. *Id.*
14. HCJ 5379/00, Bristol Myers Squibb Co., 55(4) PD at 470.

parallel imports of pharmaceuticals would trigger significant parallel importation of these products into Israel. But the findings of this study reveal that although the opening of the Israeli market to parallel imports of drugs has indirectly contributed to a decrease in drug prices for retailers and consumers, the parallel import mechanism has not been used—except in a handful of isolated cases—for the purpose of importing drugs into Israel. In fact, there has been almost no parallel importation of medications in the State of Israel in the nearly twenty years since such imports became legal. This finding is particularly interesting from a comparative legal perspective in view of the high volume of parallel imports of drugs into other countries, such as in those in the EU.

This article examines the impact of Israel's approach to parallel importation as follows: Part II reviews the structure of the health system in Israel. Part III discusses the price control mechanisms used in the Israeli pharmaceutical industry. Part IV examines the effects of the legislative change on drug prices and the volume of parallel imports to Israel, inter alia, through a quantitative analysis of drug prices in Israel from 2007 to 2020. Among other things, this Part discusses the regulations that allow for parallel imports of drugs and the Israeli courts' approach to the doctrine of patent exhaustion. Part V presents a comparative study of the practices in Europe, the United States, and developing countries, with reference to regulations that allow for parallel imports and patent policies regarding the exercise of patent rights. Part VI discusses possible barriers to parallel imports, including regulatory barriers, contractual barriers, and lack of information. Part VII of the article presents the research conclusions and policy recommendations regarding parallel imports in the pharmaceutical market.

I. THE ISRAELI HEALTH CARE SYSTEM

The National Health Insurance Law, 5754-1994,[15] which

15. National Health Insurance Law, 5754-1994, SH 1469, 156 (Isr.), https://www.nevo.co.il/Law_word/law14/LAW-1469.pdf. The law was enacted on the basis of the recommendations of the report of the State Commission of Inquiry into the Functioning and Efficiency of the Health System in Israel. THE STATE COMM'N INQUIRY INTO THE FUNCTIONING & EFFICIENCY OF THE HEALTH SYS. IN ISRAEL REP. NO. 285/6 (Oct. 15, 1990) (Isr.) (on file with the author); *see also* Certification Dep't, Ministry of Health, *Set for Completing Knowledge for the Functioning of a Registered Nurse in Israel* 6–7 (Nov. 2007), https://health.gov.il/PublicationsFiles/ND-knowledge-Eng.pdf (describing the

entered into force in January of 1995, led to significant changes in the health system in the State of Israel.[16] In the past, the health care system was based on voluntary insurance provided by health insurance companies, which competed with each other with respect to services covered and premium prices charged.[17] Following the enactment of the National Health Insurance Law, the health system in Israel evolved in accordance with principles of managed competition into a system in which competition among health insurance companies is subject to considerable regulation.[18] The main objectives of the National Health Insurance Law were to provide health insurance to all residents of the country, to sever the connection between an insured's income and his right to health services, and to ensure a uniform supply of services at a uniform price.[19] In addition, the law defined the health services that every insured person is entitled to receive.[20]

There are currently four public health insurers operating in the State of Israel: Clalit, Maccabi, Meuhedet, and Leumit, and these companies are responsible for providing health services to the public.[21] Clalit Health Services is the largest health

role of the Committee in drafting the National Health Insurance Law).

16. *See* Yoel Angel et al., *Adapting the Israeli National Health Insurance Law to the 21st Century - A Report from the 19th Dead Sea Conference*, 10 ISR. J. HEALTH POL'Y RSCH. 1, 1 (2021).

17. A. Mark Clarfield et al., *Health and Health Care in Israel: An Introduction*, 389 LANCET 2503, 2505 (2017).

18. Managed competition is also practiced in countries such as the Netherlands and Germany, see Baruch Levi, *"Public" and "Private" Mix in Health Systems – Comparing the Arrangement of Insurance Coverage Background to the Work of Physicians in Different International Countries*, ISR. MED. ASS'N 4–6, 11–13 (2014) (Isr.), https://www.health.gov.il/services/committee/german/doclib/09_10_012014_4.pdf.

19. THE ADVISORY BD. FOR STRENGTHENING THE PUB. HEALTH SYS., ADVISORY BOARD FOR STRENGTHENING THE PUBLIC HEALTH SYSTEM REPORT 158–59 (2014) (Isr.), www.health.gov.il/PublicationsFiles/publichealth2014.pdf; *see also* Revital Gross et al., *The Health System in Israel Following the Application of the National Health Insurance Law*, 93 SOC. SEC. (HEBREW ED.) 77, 79 (2014) (Isr.), http://www.jstor.org/stable/23785903; Yuval Karniel, *The Drug Basket - Doctors, Judges, the Media and Everything in Between*, 6 MISHPAT VEASAKIM 225, 228 (2007) (Isr.), https://www.idc.ac.il/he/schools/law/documents/lawreview/vol06/karniel.pdf.

20. §7, National Health Insurance Law, 5754-1994. For further discussion, see Gross et al., *supra* note 19, at 79.

21. Clarfield et al., *supra* note 17, at 2505. The provision of services included in the health services basket was entrusted to the HMOs, with limited exceptions. *See* Dana Schwartz-Ilan et al., *Health Insurance in Israel - from Pluralistic Model to Tier Model*, 86 SOC. SEC. (HEBREW ED.) 9, 24–25 (2011), https://www.jstor.org/stable/23279513. HMOs thus function both as insurers

insurance provider (HMO) with about 4.6 million insureds, which was 52% of the insured population in Israel in 2018.[22] The smallest HMO is Leumit Health Services with about 0.7 million insureds, or 8% of the insured population in 2019.[23]Although the National Health Insurance Law allows insureds to select the HMO of their choosing,[24] the data shows that over the years, Clalit has remained the largest HMO, followed by Maccabi, Meuhedet, and Leumit.[25] Israel's four HMOs purchase the majority of the prescription drugs sold in Israel. According to data published in 2016, the four HMOs are responsible for purchasing more than 85% of all prescription drugs sold in the country.[26] Each HMO owns a large number of pharmacies and can also make arrangements with private pharmacies to provide services to their insureds.[27] For example, Clalit uses a consignment method to sell drugs through partnered pharmacies.[28] Thus, the pharmaceutical market in Israel effectively functions as a centralized market characterized by a monopsonistic structure.[29] As a result, the HMOs are able to

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and as health service providers. *See* Shaul Ben Shimol et al., *The Health System in Israel - the Transition from Public Medicine to Private Medicine?*, STANDARD & POOR'S MAALOT 6 (2008) (Isr.), www.maalot.co.il/publications/SR20120322152430.pdf.

22. RAFAELA COHEN & NOAM DAMARI, NAT'L INS. INST., RSCH. & PLAN. ADMIN., PERIODIC SURVEYS 303, HMO MEMBERSHIP 2017 5, 29 (2018) (Isr.), www.btl.gov.il/Publications/survey/Documents/seker_303.pdf.

23. RACHEL BRENNER SHALEM, MINISTRY OF HEALTH, DEPARTURE OF INSURED PERSONS FROM HMOS 2019, MINISTRY OF HEALTH, ADMIN. FOR STRATEGIC & ECON. PLAN. 4 (Nov. 3, 2019) (Isr.), www.health.gov.il/PublicationsFiles/leaving_between_HMO2019.pdf.

24. §5 A, National Health Insurance Law, 5754-1994, SH 156, 157; *see also* BRENNER SHALEM, *supra* note 23, at 2.

25. COHEN & DAMARI, *supra* note 22, at 25. It is interesting to note that in addition to the HMOs themselves, hospitals belonging to HMOs, state run hospitals, and private hospitals also provide health services in Israel. *See generally* CENT. BUREAU OF STAT., COMMC'N. NOTICE 035/2019, SELECTED DATA ON HEALTH INSURANCES AND HEALTH INFORMATION FROM THE 2017 SOCIAL SURVEY (Feb. 3, 2019) (Isr.) (describing types of supplemental insurance purchased by Israeli residents).

26. MINISTRY OF HEALTH, DIV. FOR BUDGETING & PRICING PLAN., PRESCRIPTION DRUG PRICING MODEL 10 (2016) [hereinafter PRESCRIPTION DRUG PRICING MODEL] (Isr.), www.health.gov.il/PublicationsFiles/Price_Control%20_Model_prescription_medicine.pdf.

27. *Id.* at 20.

28. Philip Sax, *Drug Pricing and its Regulation in Israel: Issues, Problems and Suggestions for Reform*, HEALTH REP., THE FREE LIBR. (Jan. 1, 2008), https://www.thefreelibrary.com/Drug+pricing+and+its+regulation+in+Israel%3a+issues%2c+problems+and . . . -a0198851052.

29. *See* Philip Sax, *The Shaping of Pharmaceutical Governance: The Israeli*

purchase prescription drugs at a lower price than the maximum price published by the Ministry of Health.[30]

It is important to note that the public insurance market is not governed by free market principles, since the HMOs receive public funding.[31] Additionally, the State ensures the economic stability of the HMOs. For example, from time to time, the Ministry of Health transfers funds to the HMOs for the designated purposes of: 1) bringing the HMO into budgetary balance; 2) encouraging new activities that are not required by the basket of health services; and/or 3) contributing funds in additional areas (such as to provide discounts or additional services).[32]

As noted above, the National Health Insurance Law defined the set of health services to which every insured person is entitled. This was done to prevent a scenario in which one HMO specifically focuses on services that will be attractive only to a select group of people.[33] This effort was unsuccessful, however, and in 1998, the National Health Insurance Law was updated. Among other things, the updated law allowed HMOs to add services to the "basic basket of services" defined in the law.[34] On the one hand, this change went against the idea of a uniform set of services for everyone. On the other, it increased free competition among the HMOs while maintaining regulatory authority.[35]

Additionally, to preserve the quality of care and increase the

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Case, 3 ISR. J. HEALTH POL'Y RSCH. NO. 16, MAY 27, 2014, at 1, 9–10.

30. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 10. Yoel Lipschitz, *Tools for Curbing Drug Costs*, 10 MEDIC 1 (2017).

31. Clarfield et al., *supra* note 17, at 2507.

32. THE ADVISORY BD. FOR STRENGTHENING THE PUB. HEALTH SYS., *supra* note 19, at 158–59.

33. That is, the HMO will insure selectively and cherry pick insureds. Market failure of selective membership deals with situations where the insurer prefers to provide health services to populations with a low pattern of use of services in relation to the compensation they receive. THE ADVISORY BD. FOR STRENGTHENING THE PUB. HEALTH SYS., *supra* note 19, at 158–59.

34. § 8(A1) National Health Insurance Law, 5754-1994. The "basic health basket" "encompasses the entire range of services, drugs, medical equipment and devices that the insured public has a right to receive." *See The Medical Services Basket*, STATE OF ISR., MINISTRY OF HEALTH, https://www.health.gov.il/English/Topics/RightsInsured/RightsUnderLaw/Pages/SalServices.aspx (last visited Mar. 29, 2022).

35. The basket detailed in the second addition to the National Health Insurance Law has since been used as the "basic services basket" to which each of the funds is committed. *See* § 7(A), National Health Insurance Law, 5754-1994.

scope of health services provided to the Israeli public, a mechanism was established that allows for periodic updates to add new drugs and new technologies to the basket of health services provided.[36] For example, the list of medicines available under the basic basket of services[37] is updated annually based on the non-binding but influential recommendations of the Public Committee for the Expansion of the Basket of Health Services.[38] Over the years, there has been an increase in the number of drugs and technologies recommended for inclusion in the basket of health services.[39] While these drugs and technologies help treat diseases, they also present funding challenges to the health care system,[40] as health services are generally provided to consumers free of charge through the public health system.[41]

The sources of funding for the basket of health services are defined by law.[42] These sources include the health insurance fees collected by the National Insurance Institute, the deductibles that HMOs charge their members, and additional amounts set forth in the annual national budget.[43] The figure below shows the changing cost of the basic health services basket from 1995 to the present, with reference to the different sources of

36. THE ADVISORY BD. FOR STRENGTHENING THE PUB. HEALTH SYS., *supra* note 19, at 159; *see* Nava Herzberg, MINISTRY OF INDUS., TRADE & EMP., OVER-THE-COUNTER MEDICATIONS 18–19 (Mar. 5, 2009), economy.gov.il/Research/Documents/X9120.pdf; Karniel, *supra* note 19, at 228.

37. State Health Insurance Order (Medicines in the Health Services Basket), 5755-1995, KT 5562, 749 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-5662.pdf.

38. HCJ 9370/07 Dolev Medical Justice Foundation v. Minister of Health, para. 4 (2009) (Isr.).

39. *See id.* para. 10 (describing the yearly process for adding services to the basket).

40. In fact, due to budgetary reasons, most of the drugs that are nominated to end up in the basket are not included in it. *See* Karniel, *supra* note 19 at 234.

41. Receiving medical treatment is a basic right of every resident of the State of Israel. §§ 1, 3(A) National Health Insurance Law, 5754-1994; *see also* Karniel, *supra* note 19, at 228. Every citizen who is interested in additional services must purchase them separately with supplementary insurance from an HMO or insurance company. *See* § 10, National Health Insurance Law, 5754-1994.

42. *See* Angel et al., *supra* note 16, at 1, 5.

43. § 13(A), National Health Insurance Law, 5754-1994.

funding.[44]

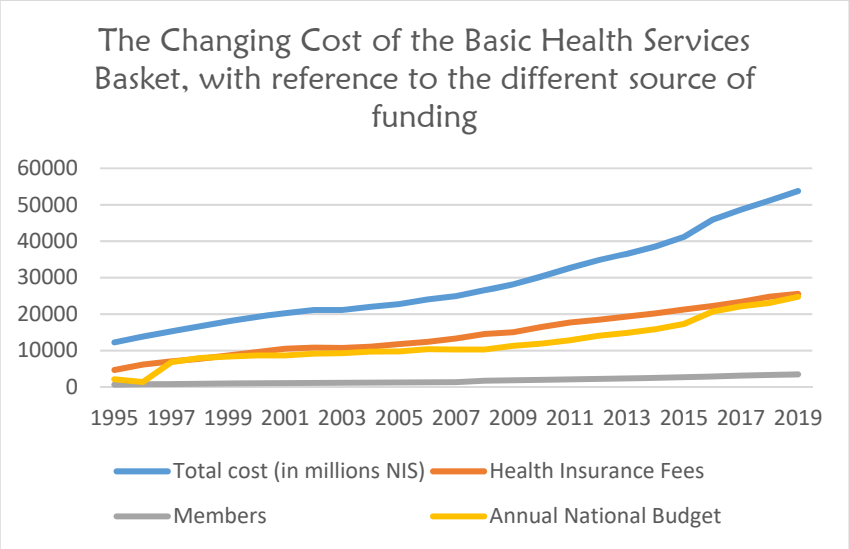

Fig. 1 The changing cost of the basic health services basket, with reference to the different sources of funding [45]

The number of prescription drugs included in the basket of health services is limited and is determined and updated by the Public Committee for the Expansion of the Basket of Health Services (PCEBHS), which balances the needs of the population with budgetary considerations.[46] Two primary factors influence the cost of the basket of services provided: 1) the size and health of the population; and 2) changes in the cost for the HMOs to provide the required services.[47] In addition, the public interest

44. RANI PLOTNIK & NIR KEDAR, MINISTRY OF HEALTH, STRATEGIC AND ECON. PLAN. ADMIN., STAT. DATA FILE 1995-2016, 34, tbl. 19 (Jan. 2017), https://www.health.gov.il/PublicationsFiles/stat1995_2016.pdf.

45. *Id.*

46. *See generally* Ruth Landau, *Orphan Diseases and the Israeli Health Basket*, 2020 MEDICINE 11 (Isr.) (discussing the dilemma of funding the treatment of numerically rare diseases through Israel's publicly funded health care system).

47. National Health Insurance Regulations (Allocation to the HMOs) (Amendment), 5777-2017, KT 7771, 640, https://www.nevo.co.il/Law_word/law06/tak-7771.pdf. It is important to note that the funds are reimbursed for most of the services they provide through the capitation mechanism. *See generally* Angel et al., *supra* note 16, at 5. That is, the formula by which the state divides the basket budget among the HMOs recognizes not

in providing residents of the State of Israel with a broad spectrum of quality health services requires the addition of new drugs and innovative services over time.[48] These changes improve the overall health of the populations but also increase the cost of the services provided by the HMOs.[49] For example, in 2019, the PCEBHS recommended the inclusion of 100 out of 700 drugs and technologies the committee considered, for a total cost of 500 million NIS.[50] The cost to include all of the drugs and technologies under consideration would have been approximately three billion NIS.[51]

A detailed discussion of the process for updating the drugs in the basket of health services is outside the scope of this article.[52] For context, however, we note that before including a new drug in the basket, the HMOs usually negotiate with importers in an effort to reduce the cost of purchasing the drug, which benefits both the public and the importer, since a price reduction can increase the drug's chances of inclusion in the health services basket. Accordingly, whether a new drug is included in the health services basket can have a profound effect on the distribution of the drug and the volume of revenue of the manufacturer or importer.[53]

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only the number of insureds but also the needs of these insureds and the differences in care costs between different groups of insureds. National Health Insurance Regulations, 5777-2017, KT 7771 at 640. In fact, the capitation formula allows the state to compensate a fund whose insureds consume "more" health services, in order to avoid a situation where the funds will have an incentive not to provide health services to the insured based on their health status, age, gender, socioeconomic status or any other relevant factor. Angel et al., *supra* note 16, at 5.

48. THE ADVISORY BD. FOR STRENGTHENING THE PUB. HEALTH SYS., *supra* note 19, at 104; *see also* Itamar Raz, *Twenty Years to the Medicine Basket - On the Bitter and Sweet*, 2020 MEDICINE 18 (Isr.).

49. The law establishes a mechanism for updating the "cost of the basket" and defines the "cost of health index." § 9, National Health Insurance Law, 5754-1994. However, some argue that the health cost index does not adequately represent the cost increases in the health care system. Angel et al., *supra* note 16, at 5.

50. *The 2019 Public Committee to Expand the Basket of Health Services for 2019*, STATE OF ISR., MINISTRY OF HEALTH (Jan. 3, 2019, 3:45 P.M.), https://www.health.gov.il/English/News_and_Events/Spokespersons_Messages/Pages/03012019_1.aspx.

51. Yuval Karniel, *The Basket of Drugs and the Public - Between the Health System, the Judiciary, the Media and Ethical Considerations*, 2020 MEDICINE 14, 16.

52. See generally *id.* at 14–16; Karniel, *supra* note 19 for discussion on the yearly updates to the health services basket.

53. Ariel Mitlis, *Court Rulings on the Health Basket: Dilemmas, Difficulties*

Along with the increase in government spending to finance the health services basket, the above figure (Fig. 1) also shows an increase in households' private expenditure on health services. One of the main problems arising from the increase in the private expenditure of Israeli residents on health services is an increased tendency of citizens to refrain from purchasing medical products or services due to their cost.[54] To investigate this issue, the Social Survey of the Central Bureau of Statistics for 2017 included a variety of questions related to the health and lifestyle of the population in Israel.[55] Among other things, interviewees were asked whether, in the preceding twelve months, they had stopped using prescription drugs due to financial difficulties.[56] The results of the survey revealed that around 8% of individuals aged 20 and over who reported needing prescription drugs also reported that they had to forgo purchasing the drug due to financial constraints.[57] In light of the above, and given a limited budgetary framework,[58] it is not surprising that the issue of rising drug prices is one of the main problems that repeatedly arises in discussions about updating the list of covered drugs, the scope of the health services basket,

and Failures, 2020 MEDICINE 6–7. Additionally, while the expansion of the health services basket is an overarching way of expanding the drugs and treatments to which Israelis are entitled, patients who need a drug not included in the health services basket may apply to their HMO's Exceptions Committee to request funding to purchase the drug. *See id.* at 6 (describing how courts expand the drugs included in the health basket). If the request is denied, the patient may appeal to the Labor Court. *Id.* Research by Adv. Ariel Maitlis found that in 100 percent of the cases heard in the past decade, the court found flaws in the committee's decision and required the HMO to fund the drug. *Id.* These decisions affect the expenses of the HMOs, as the HMOs are unable to negotiate with the importer, which has no incentive to reduce the price of the drug. *Id.* at 7; *see also* Michal Raveh, *Put the Medicine in the Basket*, GLOBES (Jan. 3, 1999), https://www.globes.co.il/news/article.aspx?did=86891.

54. FLORA KOCH DEVIDOVICH & RONI BLANK, HEALTH TERMS KNESSET RSCH. & INFO. CTR. 18–19 (2019) (Isr.), fs.knesset.gov.il/globaldocs/MMM/70b135e7-bc1f-e911-80e1-00155d0a98a9/2_70b135e7-bc1f-e911-80e1-00155d0a98a9_11_12429.pdf.

55. *Social Survey 2017: "Health and Way of Life"*, CENT. BUREAU OF STAT. 13–27, 53–55, https://surveys.cbs.gov.il/Survey/QuestionnaireE/2017/Questionnaire.pdf (last accessed Mar. 29, 2022).

56. *Id.* at 53.

57. CTRL. BUREAU OF STAT., PUB. NO. 1761, SOC. SURVEY 2017 ANN. TOPIC: HEALTH & LIFESTYLE, 21 (2019) (Isr.), www.cbs.gov.il/he/publications/DocLib/2019/seker_hevrati17_1761/h_print.pdf. The Central Bureau of Statistics' social survey is an ongoing annual survey conducted every year since 2002. *Id.* at 9.

58. Karniel, *supra* note 19, at 234.

and national health expenditure.[59]

Supervision of drug prices in Israel is generally governed by the Supervision of Prices of Goods and Services Act.[60] Over the years, however, provisions affecting the National Health Insurance Law were added to the Omnibus Law of Arrangements in the State's Economy, and these increased the government's involvement in the internal management of the HMOs, while adding control and supervision mechanisms within the Ministry of Health.[61] The policy of increased supervision was intended to control spending by the health system in the face of a continuing deficit caused by, among other things, high drug prices.[62]

The Law of Arrangements in the State's Economy recognized that public spending for drugs "constitutes a significant component of national health expenditure."[63] Accordingly, and because the pharmaceutical market in Israel has a minimal amount of competition, the Israeli legislature enacted measures to lower drug prices in Israel.[64] The legislature acted on two levels to achieve this goal: the first was to establish a mechanism for controlling the prices of medicines

59. Draft Bill for Law of Arrangements in the State's Economy (Legislative Amendments to Achieve the Budgetary Goals for the Fiscal Year 1999) (No. 2), 5769-1998, HH (Knesset) 2785 230, 247, (Isr.), https://fs.knesset.gov.il/14/law/14_ls1_292064.PDF; *Arrangements in the State Economy Law (Amendments to Legislation to Achieve Budget Objectives and Economic Policy for the Fiscal Year 1999), 1999*, NAT'L LEG. DATABASE, Knesset.gov.il, https://main.knesset.gov.il/Activity/Legislation/Laws/Pages/LawBill.aspx?t=lawsuggestionssearch&lawitemid=167167 (last visited Mar. 29, 2022) (includes links to download Knesset speeches on draft bill).

60. *See* § 7 Supervision of Prices of Goods and Services Act 5756-1996, SH 1578 191, 195 (Isr.), https://www.nevo.co.il/Law_word/law14/LAW-1578.pdf.

61. *See* Nir Kosti, *Centralization via Delegation: The Long-Term Implications of the Israeli Arrangements Laws*, *in* COMPARATIVE MULTIDISCIPLINARY PERSPECTIVES ON OMNIBUS LEGISLATION 73, 85–87 (Ittai Bar-Siman-Tov ed. 2021).

62. *See* Karniel, *supra* note 19, at 231–33 (An examination of the issue of public funding for medical care in different countries such as the United States and England shows different models regarding the scope and nature of public funding for medical care. Thus, for example, in the United States, public funding is provided as a kind of safety net only to the most necessary health services and only to the needy population or to defined groups that are entitled to public assistance. In England, on the other hand, the public funding rate for health services is one of the highest in the OECD countries.).

63. See the explanatory notes to § 32, Draft Bill for Law of Arrangements in the State's Economy (Legislative Amendments to Achieve the Budgetary Goals for the Fiscal Year 1999) (No. 2), 5769-1998, HH (Knesset) 2785 230, 264 (Isr.), https://fs.knesset.gov.il/14/law/14_ls1_292064.PDF.

64. *Id.*

based on reference prices in other countries;[65] the second was to increase competitiveness in the pharmaceutical economy by opening up the pharmaceutical market to parallel imports.[66] We discuss each of these mechanisms below.

II. MECHANISMS FOR CONTROLLING DRUG PRICES

The State of Israel, like many countries, faces the difficult challenge of ensuring adequate medical care for its population on a limited budget.[67] A report published by the Central Bureau of Statistics showed that in 2018, national health expenditures amounted to NIS 106.2 billion, or 7.6% of Israel's GDP.[68]

There is no exact data regarding the financial volume of the pharmaceutical market in Israel or the rate of national expenditure on pharmaceuticals, but 2014 estimates by the Ministry of Health's Budgetary Division, which were based on analysis of the financial reports of health funds, hospitals, and other entities in the health system, showed that total expenditures (private and public) on the purchase of drugs has been on an upward trend since 2009.[69] As illustrated by the figure below, total expenditures on the purchase of medicines was about NIS 7,317 million in 2009, and by 2013,[70] total

65. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, KT 6085 405 (outlining the method for determining the prices of medicines) (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf. *See also* PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 20–22 (discussing how the Supervisor of Drug Prices at the Ministry of Health determines the maximum prices per retailer (pharmacy) by quoting prices of similar products in the reference countries).

66. *See* Gross et al., *supra* note 19, at 85. Parallel imports are intended to reduce the cost of medicines for the HMOs and also to encourage manufacturers and importers to produce and import cheaper generic medicines. In addition, pharmacists were given the authority to provide a generic drug, even if it was prescribed under its trade name, unless the doctor explicitly states otherwise. For further discussion *see id.*

67. Karniel, *supra* note 19, at 231–33; PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 17.

68. *In 2018, the National Expenditure on Health – 7.6% of GDP*, CENT. BUREAU OF STAT. (Aug. 18, 2020), https://www.cbs.gov.il/he/mediarelease/DocLib/2020/255/08_20_255e.pdf.

69. *See* Fig. 2, *infra*.

70. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 18 (demonstrating that of the total amount, NIS 4,087 million is public expenditure on medicines and an amount of NIS 3,230 million is private expenditure on medicines).

expenditures had already risen to about NIS 9,000 million.[71]

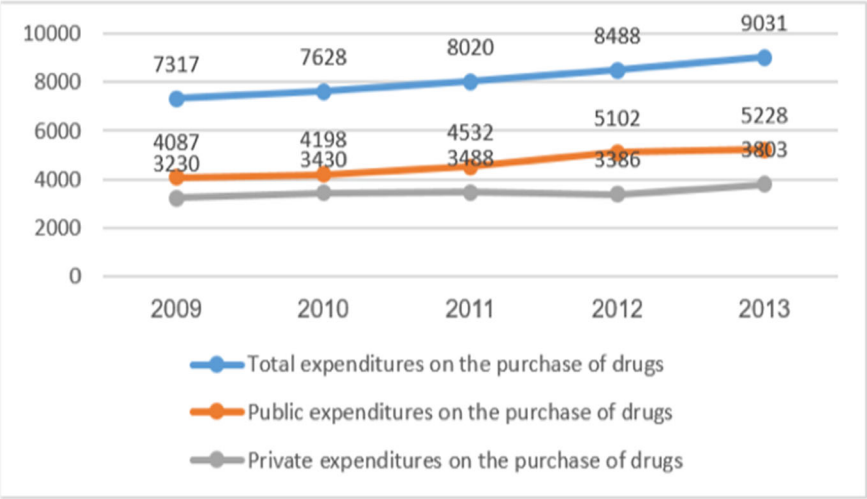

Fig. 2 Total, private, and public expenditures on the purchase of drugs[72]

As we discuss below, most of the activity to reduce expenditures on medication purchases takes place not by way of parallel imports, but by way of price regulation. Accordingly, we begin by examining these regulations.

The Ministry of Health plays a key role in regulating medication prices in Israel.[73] Prescription drug prices are determined pursuant to the Supervision of Prices of Goods and Services Act[74] and the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations).[75] Supervision of Prices of Goods and Services Act outlines the general principles for controlling medication prices and establishes three categories of supervision: 1) setting maximum prices that are updated from time to time according to objective criteria (Chapter 5 of the Law);[76] 2) determining fixed maximum prices that can be raised at the request of the

71. *Id*.
72. PRESCRIPTION DRUG PRICING MODEL, supra note 26, at 18.
73. *See* Karniel, *supra* note 19, at 234.
74. 5756-1996, SH 1578 191 (Isr.).
75. 5761-2001, KT 6085 405 (Isr.).
76. §§ 12–14, Supervision of Prices of Goods and Services Act 5756-1996.

marketer and subject to approval (Chapter 6 of the Law);[77] and 3) supervision that does not include setting a maximum price (Chapter 7 of the Law).[78]

For many years, the method used to determine drug prices was the "cost plus" method,[79] i.e., the price of the drug depended on the production, distribution, and marketing costs of the product plus a percentage of profit.[80] But in April of 1998, the Committee for the Control of Drug Prices abandoned this model in favor of the Dutch model,[81] which sets a price for a drug based on average customary prices in a number of Western countries.[82] Underlying this change was a desire to free the price control system from reliance on importers' data and to adopt an objective mechanism that would foster competitive pricing in Israel.[83] Order for the Supervision of Prices of Goods and Services in Israel has since been amended several times, but the basic Dutch model has been maintained.[84]

In 2001, the Ministry of Health determined that drug prices in Israel would be based on the average drug prices per retailer in France, Belgium, Germany, and the United Kingdom, or the lowest price in the Netherlands, whichever was lower.[85] These countries were selected as comparators, or "reference countries" based on the availability and reliability of data and similarities with Israel in terms of their advanced health care systems and standards of living, among other factors.[86] In addition, a 1.2%

77. *Id.* §§ 15–17.

78. *Id.* §§ 18–20.

79. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 9. *See also* THE PRO. COMM. FOR THE HEARING OF CLAIMS REGARDING THE ORD. FOR THE SUPERVISION OF PRICES OF GOODS & SERVS. (MAXIMUM PRICES FOR IMPORTED MEDICAL PRODUCTS), 5758-1998, JOINT PRICE COMM. TO THE MINISTRIES OF FIN. & HEALTH 9–10 (1998) [hereinafter THE PRO. COMM. FOR HEARING COMPLAINTS] (Isr.).

80. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 9. *See also* Dr. Segev Shani, *Considerations in Determining the Prices of Patent Drugs*, PHARMALINE (Oct. 6, 2020), https://www.pharmaline.co.il/article/150411/.

81. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 9.

82. *Id*.

83. THE PRO. COMM. FOR HEARING CLAIMS, *supra* note 79, at 12. Herzberg, *supra* note 36, at 48.

84. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001, as amended, KT 6085 405, https://www.nevo.co.il/law_html/Law01/999_729.htm.

85. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 12. In order to reach the price in shekels, the average prices are multiplied by the exchange rate of the relevant currency (Euro, Pound). *Id.*

86. THE PRO. COMM. FOR HEARING CLAIMS, *supra* note 79, at 12.

price increase was also factored into imported drug prices to cover import costs.[87]

In December of 2005, the Director General of the Ministry of Health appointed a committee to examine the impact on drug prices of Israel's conversion to the Dutch model.[88] The committee found that the change had succeeded in bringing maximum drug prices in Israel down to levels equivalent to those in Europe, helped curb national spending on drugs, and allowed the HMOs to purchase drugs at discounted prices.[89] The committee also concluded that lowering drug prices in Israel, and comparing prices to prices customary in EU countries, would not dissuade drug companies from registering drugs in Israel, nor would it harm public access to innovative drugs.[90]

The order for the Supervision of Prices of Goods and Services was amended several times between 2007 and 2018. The amendments generally involved changes to the list of reference countries based on their perceived relevance as comparators,[91] as well as modifications to specific features of the price-setting mechanism.[92] Additionally, provisions were made for setting prices in the event that no compatible products were found in

87. PRESCRIPTION DRUG PRICING MODEL, *supra* note 19, at 9; *see* § 1(C), Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001 KT 6085 405 (granting authority to raise prices to preserve competition).

88. STATE COMPTROLLER, ANN. REP. 58B FOR 2007 & FIN. STATEMENTS ACCTS. FOR 2006, ISSUES RELATED TO DEDUCTIBLES OF INSURED PERSONS IN PAYMENTS FOR HEALTH SERVICES 409, 414 (2008) (Isr.), https://www.mevaker.gov.il/he/Reports/Report_326/2d249ae7-c38f-4fb9-a071-04dfea65b6c3/part-118-ver-3.pdf.

89. *Id.*

90. *Id.* at 434.

91. §1(A), Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001, as amended, KT 6085 405 (Isr.) (outlining the method for determining the prices of medicines), https://www.nevo.co.il/law_html/Law01/999_729.htm. *See* MINISTRY OF HEALTH, DIVISION OF PLANNING, BUDGETING AND PRICING, REPORT OF THE COMMITTEE FOR THE EXAMINATION OF THE ORDER FOR THE CONTROL OF THE PRICES OF MEDICINES 14 (Sep. 2010) (Isr.) (recommending amending the Supervision Order to change the comparison countries to those whose GDP resembles Israel's).

92. *See* § 1A(a), First Addendum to the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, KT 6085 405, 413 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf; §1(A)(b), Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, KT 6085 405, https://www.nevo.co.il/Law_word/law06/tak-6085.pdf.

the reference countries;[93] for updating prices annually;[94] periodically;[95] and in the event of material changes in the Euro-Shekel exchange rate,[96] for eliminating import charges;[97] and for capping increases on inexpensive medications.[98]

The most recent amendments to the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) and the order for the Supervision of Prices of Goods and Services (Application of the Act to Preparations), adopted in 2018, address problems in the price-setting mechanism that resulted in an inability to determine prices for 8% of all medications.[99] Notable changes include provisions distinguishing between patented drugs and generics and establishing specific price setting mechanisms for each,[100] and freezing the prices of most prescription drugs regardless of price changes in reference countries absent an approved request submitted by the drug's supplier.[101]

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93. *See* Press Release, Ministry of Finance, The Finance Minister Signs Order to Significantly Reduce the Price of Medicines (May 23, 2018), https://www.gov.il/he/departments/news/press_230518_b; § 1A(b) Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, KT 6085 412 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf.

94. *Id.* § 3B.

95. *Id.* § 3D.

96. *Id.* § 3C. This is because in order to reach a price in shekels, the average price in the reference countries is multiplied by the exchange rate of the relevant currency. *See* PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 9, 22.

97. *Supra* note 87 and accompanying text.

98. § 2A, Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, (Isr.); *see also* PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 36.

99. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001, as amended, KT 6085 405, https://www.nevo.co.il/law_html/Law01/999_729.htm.; 4/2020 Budgets and Rates Procedures, Handling an Application for a Change in the Price of a Prescription Preparation That has not Been Determined According to the Citation Method (May 10, 2020) 1 [hereinafter Procedure: Handing an Application] (Isr.), https://www.gov.il/BlobFolder/policy/fd4-2020/he/files_circulars_fd_FD4_2020.pdf. This fact has been found to be particularly true for drugs manufactured in the United States, Japan, or Switzerland. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 31.

100. Definitions, § 1, Supervision Order for the Prices of Commodities and Services (Application of the Law on Preparations), 5761-2001, KT 6085 414, as amended (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf.

101. Procedure: Handing an Application, *supra* note 99, at 2. It is important to note that the registration holder of the product is the only entity that can submit a request for a price increase in relation to the price set for that product

The 2018 amendments also authorize the Ministry of Health's Supervisor of Prices to increase the prices above those determined by the citation method to correct any distortions in the market and ensure the continued sale of the drug in Israel[102] and set forth parameters for exercising this authority.[103] The amendments also established fixed maximum prices for prescription drugs for which no reference price was found within the framework of the Supervision Order.[104]

Until 2002, there was no separate reference in the Pharmacists' Ordinance to over-the-counter medications, which, like prescription drugs, were sold exclusively in pharmacies.[105] But the Pharmacists Ordinance was amended in 2002 to provide that over-the-counter drugs could generally be sold outside of pharmacies, except drugs whose sale by non-pharmacists was determined to be dangerous.[106] The legislature thus distinguished between two categories of over-the-counter drugs: (a) pharmacist drugs, which do not require a prescription but may be sold only in pharmacies under a pharmacist's supervision; and (b) general drugs, which do not require a prescription and may be sold outside of pharmacies in licensed stores.[107] Price control of over-the-counter medications is

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in the price list. *Id.*

102. §1 A(c), Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, (Isr.).

103. *Id.*

104. § 4(B), Order for the Supervision of Prices of Goods and Services (Application of the Law on Preparations), 5761-2001, § 4(B), KT 5741 414, (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf; Procedure: Handling an Application, *supra* note 99 (noting that the registration holder of the product is the only entity that can submit a request for a price increase in relation to the price set for that product in the price list). *See also* Uri Tal-Spiro, *Method of Compensation for Pharmacies and Pharmacists in the Sale of Prescription Drugs*, Knesset Research and Information Center, 5 (2013).

105. *See* Zohar Yahalom & Segev Sheni, *Regulating the Use of Over-the-Counter Medications Following Amendment No. 10 to the Pharmacists Ordinance [New Version], 5741-1981*, 26 MISHPAT VEREFUAH 141, 141–42 (2002) (Isr.) (describing how all drugs could only be sold with a prescription from a pharmacy).

106. Law for the Amendment of the Pharmacists Ordinance, 5772-2002, SH 1830 138 (2002) (Isr.), https://www.nevo.co.il/Law_word/law14/law-1830.pdf. See also, § 42, Pharmacists Ordinance [New Version] 5741-1981, as amended (Isr.); Pharmacist Regulations (Marketing of Over-the-Counter Drugs Outside of Pharmacies, As Well As Not by a Pharmacist), 5745-2004, KT 6346 118 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-6346.pdf.

107. *See* 55 Medicines and Cosmetics Guidelines, Guidance and Guidelines for Applying for a Permit to Sell Over-the Counter Preparations for General Marketing in a Business Other than a Pharmacy (Feb. 1, 2005) (Isr.),

governed by the control mechanisms set forth in Chapters 6 and 7 of the Supervision of Prices of Goods and Services Act.[108] Specifically, pharmacist drug prices are regulated under Chapter 6, and any price increase for these products requires approval.[109] General drug prices are subject to the provisions of Chapter 7, which supervises prices based on profitability and does not set maximum prices.[110]

The price control mechanisms described above are intended to reduce medication prices in Israel, and, in turn, to alleviate the budgetary burden on the public health system and reduce individuals' private expenditure on healthcare costs.[111] However, the state must carefully choose the mix of reference countries, since setting a price that drug companies perceive as too low can lead to the unavailability of drugs or delay the entry of certain products into the market.[112] Moreover, drug companies can impair the effectiveness of the Dutch model's comparative mechanism through strategic behavior. For example, a pharmaceutical company might decide to launch new drugs and products in "expensive" countries (e.g., Germany) first, leading to higher prices in all other countries whose price control models cite those countries.[113]

In the next part, we describe the empirical-quantitative study we conducted to examine the impact of frequent changes in the "citation" model on the maximum price of drugs as set by the Ministry of Health in 2007–2020.

III. QUANTITATIVE ANALYSIS OF ISRAEL'S PHARMACEUTICAL PRICE CONTROL

As explained above, drug prices in Israel are subject to control. To understand in depth the effects of the "citation" model and its control over the drug prices in Israel, we examined

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https://www.health.gov.il/hozer/DR_55.pdf; 56 Medicines and Cosmetics Guidelines, Procedure for Marketing Over-the-Counter Preparations for General Marketing Not in the Hands of a Pharmacist in a Pharmacy (May 1, 2005) (Isr.), https://www.health.gov.il/hozer/DR_56.pdf.

108. §§ 15–20, Supervision of Prices of Goods and Services Act, 5756-1996, SH 1578 196 (1996) (Isr.), https://www.nevo.co.il/Law_word/law14/LAW-1578.pdf.

109. *Id.* §§ 15–16.

110. *Id.* §§ 17–20.

111. *See* Lipschitz, *supra* note 30, at 14.

112. *Id.*

113. *Id.*

the changes in the maximum prices set for prescription drugs from 2007–2020 and the maximum prices set for non-prescription drugs from 2011–2019. All of the data we relied upon was derived from publicly available information published on the Ministry of Health's website.[114]

A. CHANGES IN PRESCRIPTION DRUG PRICES

Data from the Ministry of Health shows that in recent years, prescription drugs that are considerably more expensive than the drugs previously available in Israel have begun to reach the Israeli market.[115] For example, in 2007, only seventeen pharmaceutical products costing more than NIS 10,000 per package were available in Israel, while in 2015, 116 products exceeding that price were identified.[116] Therefore, we first examined the changes in the maximum consumer prices of all prescription drugs in 2007–2020.

Pursuant to Section 3 of the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), every calendar year a price list of all drugs requiring a doctor's prescription must be published on the Ministry of Health website.[117] The price list is valid for one year and includes the following information with respect to each drug on the list: code, package size, maximum price per retailer, percentage of profit per retailer, maximum price per consumer, and maximum price per consumer including VAT. In addition, the Ministry of Health publishes special updates on the maximum prices of prescription drugs when changes are made due to fluctuations in the average exchange rates of more than 3%.[118] Thus, for example, in June 2015, a special update of the

114. *Topics and Tariffs*, MINISTRY OF HEALTH, https://www.health.gov.il/Subjects/Finance/Pages/default2.aspx (last visited Mar. 5, 2020) (Isr.).

115. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 15.

116. *Id*.

117. § 3(b), Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations), 5761-2001, KT 6085 405 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf.

118. *See, e.g.*, Notice of a Special Update of the Price List of Prescription Drugs, 5775-2015, KT 7108 8556 (Isr.) (announcing special update in June 2015). Additional updates were made in Mar. 2008, May 2008, July 2008, Sept. 2008, Oct. 2008, Nov. 2008, Feb. 2009, June 2009, Mar. 2010, June 2010, Sept. 2010, and July 2018. Notice of a Special Update of the Price List of Prescription Drugs, 5769-2009, KT 5965 4384 (Isr.) (update June 2009); Notice of a Special Update of the Price List of Prescription Drugs, 5771-2011, KT 6259 5213 (Isr.)

price list was made at a rate of 5.37%, when the exchange rate of the euro fell by more than 3% compared to its level in December 2014.[119]

At the time of our data analysis (August 2020), twenty-seven price lists were available with publication dates between December 2007 and April 2020.[120] These price lists include both the annual price list published by the Ministry of Health each calendar year as well as the price lists published following a special update.

To examine the changes in the maximum price, we focused on the maximum price per pharmacist (retailer). The use of the nominal value is intended to ensure that the analysis focuses on the policy as it is expressed in the price changes from time to time. The price per pharmacist is immune to sweeping changes in the VAT rate. We also refrained from adjusting the nominal values according to the consumer price index or the exchange rate of the euro (or other foreign currency) so as not to create a dynamic picture of a change in price due to a change in the benchmark.

To examine the changes in drug prices, each time a drug appeared on the price list, we calculated the difference in price from its previous published price. For example, in December of 2007 the price of the drug Arcoxia 120 mg was NIS 47.525

(update Sept. 2010); Notice of a Special Update of the Price List of Prescription Drugs, 5770-2010, KT 6117 4271 (update June 2010) (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5771-2010, KT 6074 2437 (update Mar. 2010) (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5769 No. 5914-2009 2320 (update Feb. 2009) (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5769-2009, KT 5879 1029 (Isr.) (update Nov. 2008); Notice of a Special Update of the Price List of Prescription Drugs, 5768-2008, KT 5853 4890 (update Oct. 2008) (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5768-2008, KT 5842 4473 (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5768-2008, KT 5825 3683 (update July 2008) (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5768-2008, KT 5799 2927 (update Mar. 2008) (Isr.); Notice of a Special Update of the Price List of Prescription Drugs, 5768-2008, KT 5780 2070 (update Mar. 2008) (Isr.); MINISTRY OF HEALTH, ANNOUNCEMENT OF A SPECIAL UPDATE OF PRESCRIPTION DRUGS THAT WILL TAKE EFFECT ON JAN. 7, 2018 (May 31, 2018) (update July 2018) (Isr.), https://www.chamber.org.il/media/158688/407892518.pdf.

119. Notice of a Special Update of the Price List of Prescription Drugs, 5775-2015, KT 7108 8556 (Isr.).

120. This is from 64 price lists published on the Ministry of Health's website. MINISTRY OF HEALTH, TOPICS, BUDGETS & TARIFFS, https://www.health.gov.il/Subjects/Finance/Pages/default2.aspx (last visited Mar. 29, 2022).

(maximum price per retailer),[121] but in March 2008, the price was NIS 44.34 (maximum price per retailer).[122] In this instance, the comparison shows that in a span of three months, there was a decrease of more than 3% in the price of the drug. This method of analysis has a major advantage: it does not limit the analysis to only specific drugs that appear in all publications, and it allows us to examine the changes in relation to all drugs, whether they appeared on the list in December 2007 or were added at a later date.[123] As mentioned above, new drugs are added to the database every year, and some are based on innovative technologies and are patented protected.[124]

The price difference data includes 59,665 observations from the period between December 2007 and April 2020. Analysis of the results shows that in 60% of the observations, there was a decrease in the maximum price of prescription drugs; in 28% the observations, there was an increase in the maximum price set for prescription drugs; and in 12% of the observations, the maximum price of prescription drugs did not change.[125]

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121. *Price List for Prescription Drugs*, MINISTRY OF HEALTH, https://www.health.gov.il/Subjects/Finance/DrugPrice/Pages/default.aspx (last visited Mar. 29, 2022) (cell D160 of spreadsheet for Dec. 5, 2007 price list); *see also* MINISTRY OF HEALTH, ISRAELI DRUG REGISTRY, https://data.health.gov.il/Drugs/index.html#!/byDrug (last visited Mar. 29, 2022) (establishing that the drug's registration number is: 11 30788 44 129, the registrar is: MERCK SHARP & DOHME ISRAEL LTD, manufacturer: MERCK SHARP & DOHME CORP., USA.).

122. *Price List for Prescription Drugs*, MINISTRY OF HEALTH, https://www.health.gov.il/Subjects/Finance/DrugPrice/Pages/default.aspx (last visited Mar. 29, 2022) (cell D160 of spreadsheet for Mar. 1, 2008 price list). We chose the drug Arcoxia, MSD's flagship drug, due to the extensive press coverage it received during the years 2006-2007. *See*, *e.g.*, Itai Gal, *FDA to Ban Sale of Arcoxia, the Successor to Vioxx*, YNET (Apr. 14, 2007), www.ynet.co.il/articles/0,7340,L-3387689,00.html.

123. *See* STATE COMPTROLLER, *supra* note 90, at 434.

124. *See id*. (discussing how adopting the Dutch model is designed to accommodate innovation)

125. Fig. 3, *infra* (demonstrating that a decrease in the maximum price set for prescription drugs was observed in 36,026 of the cases, while in contrast, an increase was recorded in only 16,458 cases).

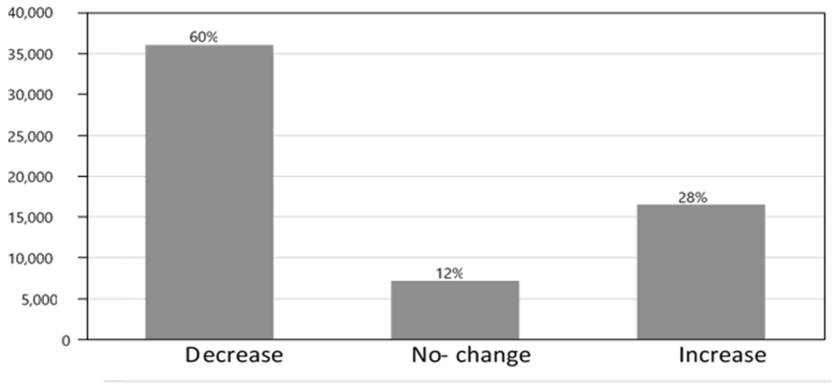

Fig. 3 Price difference observations from the period between December 2007 and April 2020

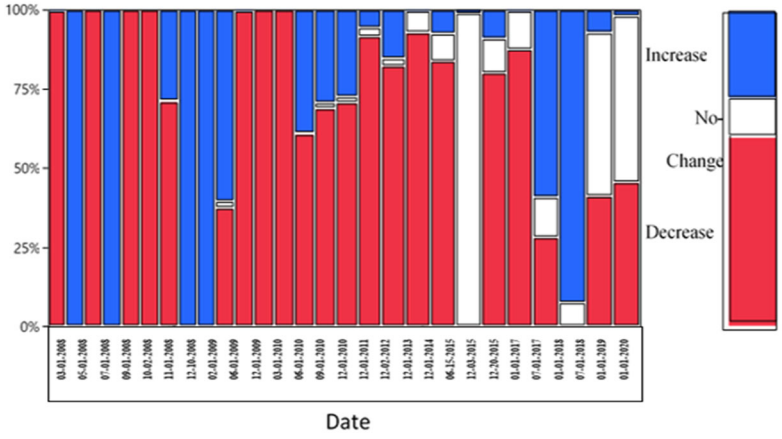

Fig. 4 Changes in drugs price during the years 2008–2020

As illustrated in Figure 4, during the years 2008–2011 there were frequent changes in drug prices. Indeed, there were times when almost all drug prices went up or down.[126] For example, in

126. Thus, in March 2008, May 2008, July 2008, September 2008, October 2008, November 2008, February 2009, June 2009, March 2010, June 2010, September 2010, 100% of the price changes observed were increases, or 100% were decreases. *Infra* tbl.1. It is important to note that in June 2009, a special update of the price list of prescription drugs was made due to a change in the average exchange rate by more than three percent compared to the average

July 2008, the price of all drugs dropped (compared to the previous date).[127]

From 2011 onwards, however, the frequency with which drug prices changed decreased, and as a result, from December 2010, the prices of most drugs have been updated only at the end of the calendar year. The price updates have, in most cases, reflected a drop in drug prices.[128] For example, in December 2011, the price of 69% of drugs decreased, the price of 29% of drugs increased, and the price of about 2% of the drugs remained the same.[129] In December 2012, a decrease in the price of 71% of drugs was observed, while the price of 27% of drugs increased and the price of about 2% of drugs remained unchanged.[130]

	Decrease in the maximum price of the drugs		No-change in the maximum price of the drugs		Increase in the maximum price of the drugs		Total	
Date	Number of observations (drugs)	Percentage	Number of observations (drugs)		Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage
05-12-2007	0	0%	0	0%	0	0%	0	0%
01-03-2008	1822	100%	0	0%	2	0%	1824	100%
01-05-2008	1	0%	0	0%	1834	100%	1835	100%
01-07-2008	1877	100%	0	0%	0	0%	1877	100%
01-09-2008	0	0%	0	0%	1892	100%	1892	100%
02-10-2008	1912	100%	0	0%	0	0%	1912	100%
01-11-2008	1929	100%	0	0%	0	0%	1929	100%
10-12-2008	1340	71%	6	0%	534	28%	1880	100%
01-02-2009	2	0%	0	0%	1871	100%	1873	100%
01-06-2009	0	0%	0	0%	1899	100%	1899	100%
01-12-2009	711	37%	43	2%	1147	60%	1901	100%
01-03-2010	2004	100%	0	0%	2	0%	2006	100%
01-06-2010	2011	100%	0	0%	0	0%	2011	100%
01-09-2010	2046	100%	0	0%	0	0%	2046	100%
01-12-2010	1264	61%	2	0%	805	39%	2071	100%
01-12-2011	1439	69%	40	2%	608	29%	2087	100%
02-12-2012	1613	71%	44	2%	617	27%	2274	100%
01-12-2013	2107	92%	62	3%	125	5%	2294	100%
01-12-2014	1988	82%	61	3%	362	15%	2411	100%

Table 1 Drug Price Changes, 2007–2014

exchange rate on February 1, 2009. Notice of a Special Update of the Price List of Prescription Drugs, 5769-2009, YP 5965 4384 (Isr.).

127. *See infra* fig.4; *infra* tbl.1.

128. *See infra* tbl.1 (showing that a comparison was made between the maximum price of the drugs in the December 2011 price list and the maximum price of the drugs in the December 2010 price list).

129. *Id*.

130. *Id*.

As set forth in Table 1, a similar trend was also observed in December 2010, December 2013, and December 2014.

This stabilization in drug prices can be attributed to the fact that from 2011 onwards, there were almost no special price list updates resulting from currency fluctuations, and in most cases drug prices remained in effect for the entire calendar year.[131] However, one can assume that the 2010 amendment to the Order for the Supervision of Prices of Goods and Services contributed to the decrease in the maximum price of most medications, since that amendment altered the list of reference countries.[132]

As stated above, the citation mechanism was again updated in 2015. As part of this update, the prices of medications for which the maximum price per consumer (including VAT) did not exceed NIS 16 were frozen.[133] Likewise, in June 2015, a special update to the price list was made at a rate of 5.37%, because the exchange rate of the euro fell by more than 3% compared to its level in December 2014.[134] Therefore, as can be seen in the table below (Table 3), in 2015 there were changes in drug prices in both the month of June and the month of December.

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131. *See supra* note 118 and accompanying text.

132. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Temporary Order), 5770-2010, KT 6915 1455 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6915.pdf. The amendment to the supervision order entered into force on November 24, 2010, and immediately afterwards, in the price list published on December 1, 2010, a decrease in the prices of about 61% of the drugs was observed, and an increase in the price of about 39% of the drugs, with only the price of two drugs remaining unchanged, compared to the previous date. *See infra* tbl.2; s*ee also* Press Release of Moshe Kahlon, The Minister of Finance Signed an Order for a Significant Reduction in the Price of Medicines, https://www.gov.il/he/departments/news/press_230518_b.

133. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Temporary Order), 5775-2015, KT 7550 1880 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-7550.pdf (entering into force on June 1, 2015); s*ee also* Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Temporary Order), 5776-2016, KT 7612 702 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-7612.pdf (entering into force on December 4, 2015).

134. Notice of a Special Update of the Price List of Prescription Drugs, 5775-2015, YP 7108 8556 (Isr.), https://www.nevo.co.il/Law_word/law10/yalkut-7108.pdf. *See also* PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 40; § 3(c) Supervision Order for the Prices of Commodities and Services (Application of the Law on Preparations), 5761-2001, KT 6085 414, as amended (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6085.pdf.

	Decrease in the maximum price of the drugs		Increase in the maximum price of the drugs		No-change in the maximum price of the drugs		Total	
Date	Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage
15-06-2015	2347	93%	172	7%	4	0%	2523	100%
03-12-2015	2166	84%	225	9%	193	7%	2584	100%
20-12-2015	0	0%	2605	99%	21	1%	2626	100%
01-01-2017	2056	80%	277	11%	228	9%	2561	100%
01-07-2017	2315	88%	320	12%	7	0%	2642	100%
01-01-2018	740	28%	330	13%	1549	59%	2619	100%
01-07-2018	4	0%	204	7%	2525	92%	2733	100%
01-01-2019	1090	41%	1362	52%	183	7%	2635	100%
01-01-2020	1242	46%	1428	53%	50	2%	2720	100%

Table 2 Drug Prices Changes, 2015-2020

The order for the Supervision of Prices of Goods and Services was updated again in January 2017,[135] March 2018,[136] and June 2018.[137] Among other things, the list of reference countries was again revised such that the maximum price would be the average of the three lowest prices found in Belgium, Hungary, Spain, France, Great Britain, Germany, and the Netherlands.[138] These updates further provided that in the event that no price

135. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Amendment), 5777-2017, KT 7755 478 (Isr.) (entering into force on January 1, 2017), https://www.nevo.co.il/Law_word/law06/tak-7755.pdf.

136. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Amendment), 5778-2018, KT 7972 1174 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-7972.pdf (entering into force on January 4, 2018).

137. Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Amendment No. 2), 5778-2018, KT 8021 2180 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-8021.pdf (promulgated on June 14, 2018).

138. § 1A(a), First Addendum, Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations,) 5761-2001, KT 6559 536 (Isr.), https://www.nevo.co.il/Law_word/law06/tak-6559.pdf.

were found in three countries, the maximum price would be determined according to the average prices in two countries, or in one country, as the case may be.[139]

Indeed, the table above illustrates that there were frequent changes in the maximum price of prescription drugs between January 2017 and January 2019.[140] These changes, too, can be attributed in part to changes in the price control model.

In the next stage of our analysis, we focused exclusively on prescription drugs that appear on the first and last date of the period under review (December 5, 2007 to January 4, 2020) and are repeated (almost) at all the times in between (hereinafter: ***the repeat drugs***).[141] This analysis is designed to ensure: (a) that there is no separate pattern for the repeat drugs; (b) that the findings previously observed were not affected by the fact that the list of drugs included in the price list changes from time to time (i.e., that the changes are not affected by the addition of products to the list of drugs appearing in the price list, or their removal).

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139. § 1A(b), Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) (Amendment No. 2), 5778-2018, KT 8021 2180 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-8021.pdf (entering into force on January 1, 2019).

140. In January 2017, the maximum price of 80% of the drugs decreased, 9% of the drugs increased and 11% remained unchanged compared to the previous date. In July 2017, the maximum price of 88% of the drugs decreased and 12% remained unchanged compared to the previous date. In January 2018, the maximum price of 28% of the drugs decreased, 59% of the drugs increased and 13% of the drugs remained unchanged compared to the previous date. In January 2019, the maximum price of 41% of the drugs decreased 7% of the drugs increased and 52% of the drugs remained unchanged. In January 2020, the maximum price of 46% of the drugs decreased, 2% of the drugs increased and 52% of the drugs remained unchanged. *Supra* tbl.2.

141. The number of repeat drugs ranged from 958 to 966 drugs during the period.

The different series of the repeat drugs includes 16,332 observations from the period under review. As set forth in the chart below (Figure 5), an alternative analysis of the series of price differences of repeat drugs shows a pattern similar to the changes reviewed above. Especially at the beginning of the period under review, frequent changes in medication prices occurred, but from 2011 onwards, the frequency of these changes diminished. In general, from December 2010 onwards, the price of most drugs stabilized and was updated only at the end of the calendar year.

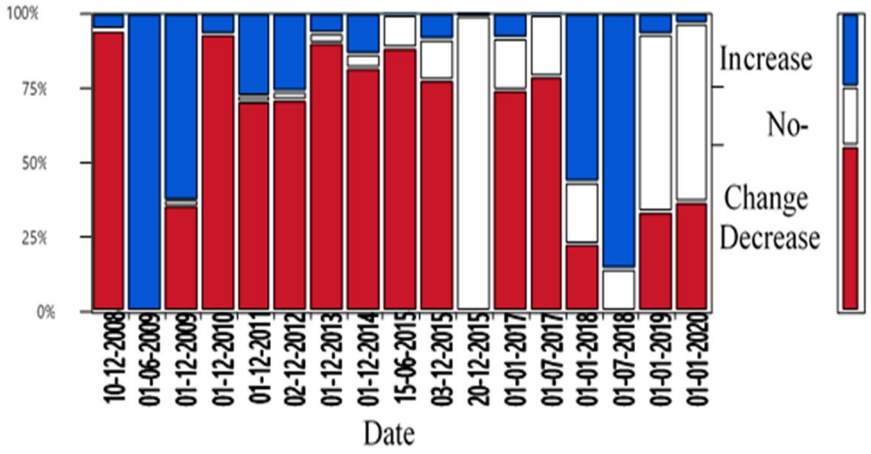

Fig. 5 Changes in the Repeat Drugs Price During the Years 2008–2020

Moreover, analysis of all observations shows that in 56% of cases there was a decrease in the maximum price of prescription drugs; in 25% of cases there was an increase in the maximum price set for prescription drugs; and in 20% of cases the maximum price of prescription drugs did not change.[142] In other words, maximum prices tended to decrease over this period. The following table (Table 3) presents data on the distribution of the change in prices of the repeat drugs for all points between December 2007 and April 2020.

142. A decrease in the maximum price set for prescription drugs was observed in 9,115 of the cases. In contrast, an increase was observed in only 4,005 cases.

	Decrease in the maximum price of the drugs		Increase in the maximum price of the drugs		No-change in the maximum price of the drugs		Total	
Date	Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage	Number of observations (drugs)	Percentage
05-12-2007	0	0%	0	0%	0	0%	0	0%
10-12-2008	903	94%	7	1%	48	5%	958	100%
01-06-2009	2	0%	0	0%	960	100%	962	100%
01-12-2009	340	35%	18	2%	602	63%	960	100%
01-12-2010	891	93%	2	0%	65	7%	958	100%
01-12-2011	676	71%	16	2%	265	28%	957	100%
02-12-2012	679	71%	28	3%	251	26%	958	100%
01-12-2013	869	90%	35	4%	61	6%	965	100%
01-12-2014	786	82%	44	5%	131	14%	961	100%
15-06-2015	855	89%	110	11%	1	0%	966	100%
03-12-2015	749	78%	135	14%	81	8%	965	100%
20-12-2015	0	0%	962	99%	5	1%	967	100%
01-01-2017	713	74%	170	18%	77	8%	960	100%
01-07-2017	757	79%	201	21%	2	0%	960	100%
01-01-2018	217	23%	201	21%	540	56%	958	100%
01-07-2018	0	0%	138	14%	821	86%	959	100%
01-01-2019	323	34%	569	59%	67	7%	959	100%
2020-01-01	355	37%	576	60%	28	3%	959	100%

Table 3 The Changes in Repeat Drug Prices During the Years 2007–2020

In summary, there was a decrease in the maximum price of all prescription drugs in the years 2017–2020. As mentioned, changes to the model of drug price control, and especially changes to the list of reference countries explains, at least in part, the decline in the maximum price of prescription drugs.[143] Indeed, the prices of medicines vary from country to country in the European Union,[144] and in fact, OECD data show that price variation can reach up to 60%.[145]

Another important factor bearing on average drug prices is

143. *See* PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 12–15.

144. Lipschitz, *supra* note 30, at 13.

145. *Id.*; *see also* ORG. FOR ECON. CO-OPERATION & DEV. [OECD], PHARMACEUTICAL PRICING POLICIES IN A GLOBAL MARKET 30–32 (2008).

whether they are patent-protected. As noted above, the pharmaceutical market comprises both brand-name drugs and generic drugs. **Brand-name drugs** are developed by a pharmaceutical company.[146] The process of developing a new drug generally takes many years and involves an extremely large investment.[147] Accordingly, these drugs receive strong protection under patent law designed to encourage investment in the research and development of new medications. Patent protection grants the patent holder a limited monopoly,[148] allowing it to charge a higher price for the drug than it could in a competitive market.[149] It also prevents the unauthorized sale or distribution of the patented drug throughout the period of the patent's validity (usually twenty years).[150]

Generic drugs, on the other hand, are "replicas" of brand-name drugs, meaning they contain an active ingredient that is identical in strength, quality, and dosage to the active ingredient in the brand-name drug.[151] Once the patent protection period for a brand-name drug has expired, any pharmaceutical company may manufacture a generic drug that is a copy of the brand-name drug. Because the manufacturer of a generic drug was not required to invest the same resources in research and development as the brand-name manufacturer, generic drugs are much cheaper than brand-name drugs.[152] Moreover, the introduction of a generic drug creates competition that reduces

146. Dan Wagener, *What's the Difference Between a Man-Made Drug and a Generic Drug?*, GOODRX HEALTH, https://www.goodrx.com/healthcare-access/medication-education/brand-vs-generic-drugs-whats-the-difference (last updated Dec. 22, 2021).

147. Olivier J. Wouters, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market*, 323 JAMA 844 (indicating that the average cost to bring a drug to market is estimated at over $900 million, with a mean time of over eight years). *See also* HCJ 5379/00 Bristol-Myers Squibb Co. v. Minister of Health, 55(4) PD 447, 452, 461(2001).

148. *See* CivA 665/84 Sanofi Ltd. v. Unipharm Ltd. 41(4) PD 729, 742–43 (1987) (Isr.); *see also* Tal Band, *On Patents and Morals: The Question of Access to Medicine*, *in* THE MORAL BOUNDARIES OF INTELLECTUAL PROTECTION 71, 78 (Michael Birnhack & Or Cohen-Sasson eds., 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3843608.

149. *See* Band, *supra* note 148, at 78; Valérie Paris & Allison Colbert, *Innovation, Access, and Value in Pharmaceuticals*, *in* OECD, NEW HEALTH TECHNOLOGIES 81, 82 (2017).

150. *See* §§ 49A, 52, Israeli Patent Act, 5727-1967, SH 510 148 (Isr.), https://fs.knesset.gov.il/6/law/6_lsr_209311.pdf.

151. Wagener, *supra* note 146.

152. *Id.*

the cost of the original drug.[153] In light of the above, it is clear that when considering the price of drugs over time, the existence and expiration of patent protection take on great significance.

To understand the relationship between the expiration of patent protection and the maximum price set by the Ministry of Health, we examined the changes in the maximum prices set for a number of leading drugs close to the expiration date of the patents involved. We created a list with details of brand-name drugs for which patent protection expired between December 2007 and January 2020, including drugs whose patent term was extended beyond 20 years by an extension order.[154] Thereafter, to examine the rate of change in the maximum price set for these drugs around the date patent protection expired, we cross-referenced the names of these drugs with the information appearing in the Ministry of Health price lists.[155] We then compared the maximum prices published for those drugs before and after the expiration of patent protection. Our findings showed a moderate decrease of 5.7% in the average drug price near the expiration date, when the price of nearly 70% of those drugs decreased, as compared to the prices of drugs whose patent protection was not expiring during that period, most of

153. *Id*.

154. *See* § 49A, Israeli Patent Act, 5727-1967, SH 510 148 (Isr.), https://fs.knesset.gov.il/6/law/6_lsr_209311.pdf. An extension order constitutes an exception to the general twenty-year term of patent protection measured from the date of filing. These extensions compensate the company that developed the drug for the period during which the patent was registered, but marketing authorization for the drug protected by the patent had not yet been granted. An extension order gives the patent owner an additional monopoly period and can delay competition from generic drug companies. *See generally Id.* §§ 64A-Q (covering extension of patents under the law).

155. The data on the brand-name drugs we examined included the patent number, the expiration date of the extension order, and the chemical substance present in the drug (the active ingredient listed on the Ministry of Health website). Search results for the active ingredient in the existing drug database on the Ministry of Health website, https://israeldrugs.health.gov.il/#!/byDrug, led to the creation of a new drug list (the "new drug list"). Then, with respect to each drug in the new drug list, we determined whether it was a brand-name or a generic drug based on the information on the Ministry of Health website and Patent Authority websites. Next, we cross-referenced the information in the new list of drugs with the information in the Ministry of Health price lists published between December 2007 and April 2020 to ascertain the rate of change in the maximum prices set for brand-name drugs around the expiration date of extension orders. After cross-referencing the information, we removed from the list brand-name drugs with expiration dates in the future and examined the price change around the expiration date of the extension order in relation to each remaining brand-name drug that appeared in both the new drug list and the Ministry of Health price lists.

which increased at a rate of up to 5%. The figure below shows the distribution of the change in drug prices near the expiration of patent protection.

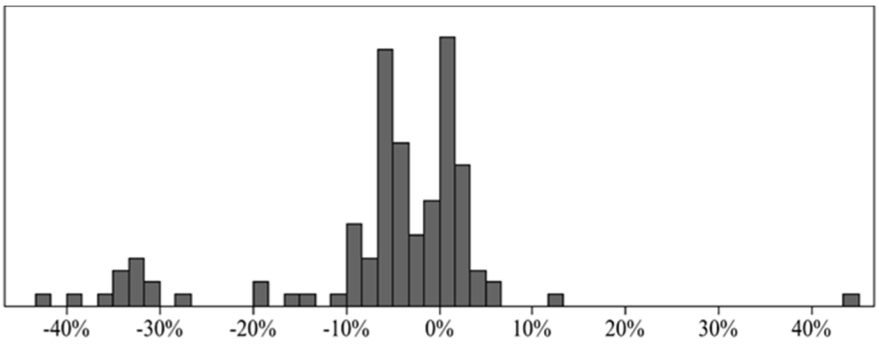

Fig. 6 Changes in "the repeat drugs" price during the years 2008–2020

Although this data concerns decreases in the maximum price set by the Ministry of Health, and not decreases in the price at which the HMOs actually purchase the drugs, our results appear consistent with a study of 2005 United States drug price data by Silverman et al., which found that the first generic manufacturer to enter the market priced the generic drug at a discount of about 6% on average from the price of the original drug.[156]

Finally, it is important to note that because maximum drug prices in Israel are based on comparisons with prices in a number of European reference countries, there may be

156. *See* Rachel Silverman et al., *Tackling the Triple Transition in Global Health Procurement*, CTR. FOR GLOB. HEALTH 42 (2019), https://www.cgdev.org/sites/default/files/better-health-procurement-tackling-triple-transition.pdf. This study also showed that the entry of second and successive generic competitors significantly reduced the price of generic drugs, a 48% reduction on average. *Id. See also* RYAN CONRAD & RANDALL LUTTER, U.S. FOOD & DRUG ADMIN., GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES 2–3 (2019), https://www.fda.gov/media/133509/download (demonstrating that more recent studies indicate a higher decline in drug prices with the introduction of the first generic drug); IMS Inst. for Healthcare Info., *Price Declines After Branded Medicines Lose Exclusivity in the U.S.*, IQVIA 2 (2016) https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf?la=en&hash=642B9A40F3F176CE93E8E9F791EE2BE4975C8580&_=1513600175779 (finding a price decline by an average of 51% from the original drug price in the first year after loss of exclusivity, and a 77% decline after six years).

significant decreases in the maximum drug prices in Israel near the expiration of patent protection in the reference countries, and not necessarily near the expiration of patent protection in the State of Israel.

B. CHANGES IN THE PRICES OF OVER-THE-COUNTER DRUGS

In the second phase of the quantitative study, we examined changes in the prices of over-the-counter drugs over time.

As a public service, the Ministry of Health periodically publishes a price list of over-the-counter preparations. In each price list, next to the name of the product is the following data: code, active ingredient, strength, dosage form, package size, maximum price per consumer, and maximum price per consumer including VAT.[157] As mentioned above, the price list reflects the fixed prices for drugs on the day of publication.[158]

At the time of data analysis (August 2020), we had twelve price lists available for over-the-counter medications. The price lists were published between April 2011 and July 2019. Each of the price lists includes between 589 and 684 medicines. To examine the changes in the maximum price, the variable chosen for analysis was the maximum price to the consumer.

Date	**No. of observations (Over-the-Counter Drugs)**
04-04-2011	684
01-02-2012	639
01-09-2012	621
03-02-2013	622
02-06-2013	608
10-09-2013	618
01-02-2014	628
01-02-2015	607
01-10-2015	619
05-06-2016	589
06-02-2018	597
07-01-2019	602
Total	**7434**

Table 4 Over-the-counter drug prices between April 2011 and January 2019.

157. *See Price List for Prescription Drugs*, MINISTRY OF HEALTH, https://www.health.gov.il/Subjects/Finance/DrugPrice/Pages/default.aspx (last visited Mar. 29, 2022).

158. *Id*.

The analysis was based on changes in the maximum consumer price of drugs whose price was published at least twice. At each point, the published price was compared to the previous published price. The series of price differences includes 6,268 observations over the period of January 2011 to January 2019.[159] Contrary to what we observed with respect to prescription drugs, the maximum prices of which generally decreased over time, the data concerning over-the-counter drugs shows that in the period between January 2011 and January 2019, the prices of almost all over-the-counter drugs remained unchanged. In fact, 97% of the drugs that were repeatedly observed were listed at the same price.[160]

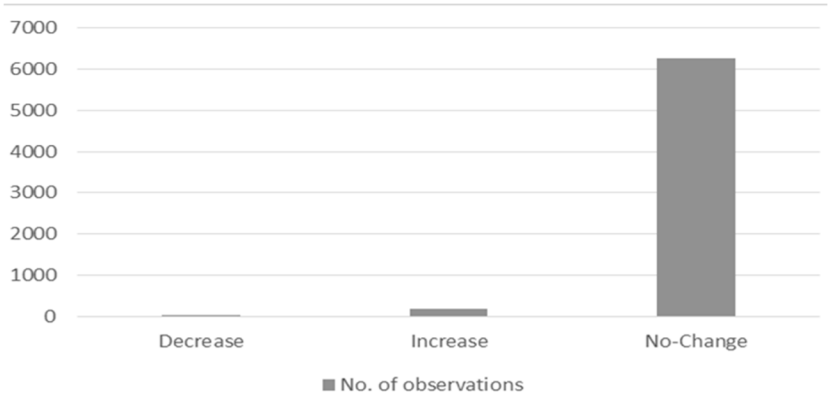

Fig. 7 Changes in "the repeat drugs" price during the years 2008–2020

In conclusion, the data confirm that the citation method has succeeded in bringing about price reductions over the years.[161] However, it is important to note that the maximum price for the consumer (or retailer) is, as its name implies, a maximum price. HMOs can purchase most drugs at a lower price than the maximum, and presumably do so in practice.[162] In fact, the HMOs regularly negotiate and receive discounts that are not

159. Unlike prescription drugs, the price lists for over-the-counter drugs do not publish a maximum price per retailer. *Id.*

160. In all of the observations, only 29 instances of reduced prices and 186 instances of increased prices were recorded.

161. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 25.

162. THE PRO. COMM. FOR HEARING COMPLAINTS, *supra* note 79, at 11.

made public.[163] Moreover, a 2007 agreement between the Ministry of Health, the Ministry of Finance, and the organization Pharma Israel stipulates that as a condition for including a new drug in the basket of covered drugs, pharmaceutical companies must agree that the sale price to HMOs and public hospitals will not exceed 95% of the maximum retail price in 2006–2007, 95% of the maximum retail price in 2008, and 94% of the maximum retail price from 2009 onwards.[164]

Still, the maximum price set by the Ministry of Health has an impact on several levels. First, the consumer's portion of the cost to purchase medications is determined on the basis of the maximum price to the consumer, not on the basis of the actual purchase prices of the HMOs.[165] Therefore, the lower the maximum price of a drug, the lower the deductible of the insured,[166] although in some cases the consumer's total cost may be higher than the cost to the HMO.[167] Second, the maximum price serves as a reference for updating prices in contracts between the HMOs and the pharmaceutical companies. Pharmaceutical companies tend to enter into long-term agreements with the HMOs and update the contract price in accordance with the maximum price updates set by the Ministry of Health.[168] Third, non-covered medications and medications

163. Angel et al., *supra* note 16, at 4.

164. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 9. Requests we submitted to all of the HMOs under the Freedom of Information Law seeking data regarding their actual drug purchasing costs and the effect on those costs of the legislative amendment opening the Israeli market to parallel imports were denied on the ground that this information is protected as trade secrets. Accordingly, we were unable to examine this data. Our inquiries to the organization of manufacturers and marketers of over-the-counter drugs, in order to obtain information on prescription drug data, were also unsuccessful. Accordingly, we focused on data from the Ministry of Health regarding the maximum price to the consumer and other data to which we had access, especially YARPA price lists. Yarpa Computers Ltd., is a software company that provides computer services for inventory management for most pharmacies and in doing so receives the drug prices from the drug marketers and implants them in the software. Since the company provides services to many pharmacies, the prices shown in the software are market prices.

165. BARUCH LEVY & YOSSI ZULFAN, KNESSET RSCH. AND INFO. CTR., DOCUMENT ON THE COLLECTION OF PAYMENT FOR MEDICINES IN THE HMOS, (2003), fs.knesset.gov.il/globaldocs/MMM/f2ae4ca5-9632-e811-80de-00155d0a0235/2_f2ae4ca5-9632-e811-80de-00155d0a0235_11_10180.pdf.

166. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 25.

167. THE PRO. COMM. FOR HEARING COMPLAINTS, *supra* note 79, at 11; Lipschitz, *supra* note 30, at 14

168. THE PRO. COMM. FOR HEARING COMPLAINTS, *supra* note 79, at 11.

supplied to people who do not have insurance coverage such as foreign workers, diplomats, and tourists, are sold at the full authorized price, i.e., the maximum price established by the Ministry of Health price list.[169] The changes in the maximum price therefore have a real effect on household expenses and the HMOs. Finally, the maximum price is used to estimate the cost of medications entering the basket of covered medications, since the cost of such medications is calculated by doubling the estimated consumer portion of the medication's cost.[170] Therefore, reducing the maximum price of medications allows more drugs to enter into the basket of health services.

IV. THE LEGAL BASIS FOR PARALLEL IMPORTS OF DRUGS IN ISRAEL

A. LEGISLATION

At the same time as changes were implemented in the pharmaceutical price control mechanism in Israel, pressure from the Ministry of Health and the HMOs led the Israeli legislature to open the pharmaceutical market up to parallel imports. The assumption was that this change in Israel's parallel import policy would stimulate competition and lead to a decrease in drug prices that would benefit the insured, the HMOs, and the hospitals.[171] To this end, the Pharmacists Ordinance[172] was amended, and the Pharmacists (Preparations) (Amendment) Regulations were established.[173]

Prior to these developments, only those who held a registration certificate could import drugs into Israel. However, following the amendment to the Pharmacists Ordinance, importation was no longer conditioned on possession of a registration certificate, as the amendment authorized anyone

169. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 26.

170. *Id.*

171. *Id*. at 10. For further background information on the regulatory changes, see generally *Unmodified Minutes No. 226 of the Meeting of the Labor and Welfare Committee*, 14th Knesset, Meeting Dated July 1, 1998 Regarding the Pharmacists (Medical Products) Regulations (Amendment), 5758-1998, https://oknesset.org/meetings/2/0/2057277.html; *see also* HCJ 5379/00 Bristol-Myers Squibb Co. v. Minister of Health, 55(4) PD 447, 455–56 (2001) (Isr.).

172. Pharmacists Ordinance [New Version], 5741-1981, 5761 DMI 693 (1981) (Isr.), https://www.nevo.co.il/Law_word/law18/35.pdf.

173. Pharmacists (Medical Products) Regulations (Amendment), 5760-2000, KT 6040 646, https://www.nevo.co.il/Law_word/law06/TAK-6040.pdf.

with an "import license" to import a registered preparation or "compatible drug."[174] An import license is defined in the Pharmacist Regulations (Preparations) as follows: "A permit for the import and marketing of a registered drug not in the possession of the registration holder or a permit for the import and marketing of a 'compatible drug.'"[175] That is, the amendment allows parallel importation of drugs by those who do not operate within the official distribution channels of the manufacturer. The new regulations provide two avenues for import approval: (1) a registered drug; and (2) a "compatible drug."[176]

1. Import License for Registered Drugs

Procedure 33 regulates the manner in which applications for an import license for registered drugs are submitted and handled.[177] Generally, the importation of pharmaceuticals or pharmaceutical materials can be done by a pharmaceutical factory, a pharmaceutical trade house, or a pharmaceutical warehouse of a medical institution.[178] The applicant must submit an application to the import department,[179] which must enclose: a photocopy of the drug's registration certificate of the drug, an importer/manufacturer's license, a registered power of attorney, and a responsible pharmacist declaration form.[180]

2. Impact License for "Compatible Drugs"

Procedure 35 regulates the manner of submitting an

174. § 47C, Pharmacists Ordinance [New Version] 5741-1981 (Isr.).

175. § 1, Pharmacist Regulations (Preparations), 5746-1986, KT 6040, 645 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-6040.pdf.

176. *Id.* at § 5A-C; *see also* 35 Medicines and Cosmetics Guidelines, Procedure for Approving the Import of a Compatible Preparation (Jan. 1, 2001) [hereinafter Procedure No. 35], https://www.health.gov.il/hozer/DR_35.pdf.

177. 33 Medicines and Cosmetics Guidelines, Procedure for Approving the Import of a Compatible Preparation (Nov. 2000), https://www.health.gov.il/hozer/DR_33.pdf.

178. *Id.* § 3.1.1.

179. *Id.* § 3.1.2.

180. *Issuance of Import Permits for Registered Preparations*, MINISTRY OF HEALTH, www.health.gov.il/Subjects/PharmAndCosmetics/ImportDrugsAndPreparations/Pages/ImportPreparationsRegisteredOrUnregistered.aspx (last visited Mar. 29, 2022) (listing the required documents to apply for an import license for registered drugs).

application for approval to import a registered drug without the permission of the registration holder, i.e.: a "compatible drug."[181] "Compatible Drug" is defined in Section 47C(b) of the Pharmacists Ordinance as a drug identical to a registered drug from the same manufacturer, or a drug identical to a registered drug from another manufacturer.[182] Importing a "compatible drug" is based on the existence of a registered preparation in Israel (from the same manufacturer). In general, an import license for a compatible preparation will be granted if all the following conditions are met: (A) The drug will be imported through a drug store or a recognized institution that meets adequate conditions for the storage of drugs; (B) the importer has proven that the drug has been stored and transported under proper conditions;[183] (C) the drug is purchased directly from the manufacturer or from a seller authorized by the authorities in one of the recognized countries, as defined in the Pharmacists Regulations;[184] (D) the importer has a detailed certificate of analysis from the manufacturer of the drug (for the specific batch); (E) if the drug is manufactured on a site other than the one registered, the importer must have additional approvals regarding the conditions of production and marketing of the drug;[185] (F) the importer must present a sample of the drug for

181. Procedure No. 35, *supra* note 176, § 3.

182. § 47C(b) Pharmacists Ordinance [New Version], 5741-1981; *see also*, §1, Pharmacist Regulations (Preparations), 5746-1986, KT 6040, 645 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-6040.pdf.

183. Procedure No. 35, *supra* note 176, § 3.1. This is done by presenting a delivery note, supplier's invoice, or any other document, establishing that the product was purchased from the previous supplier in the marketing chain all the way back to the production site.

184. These countries are: USA, Canada, EU member states, Switzerland, Norway, Iceland, Australia, New Zealand, Japan and Israel, as well as authorized dealers (wholesalers) in recognized countries. Imports from EU countries will be done only after the EU has completed the approval of the product registration systems in the acceding countries. *Id*. § 2.

185. The required approvals include: proof of production and marketing of the drug in the recognized country; proof of proper production conditions; and confirmation that the method of manufacture of the drug is the same as that of the reference drug. *Id.* § 3.1. Drugs containing ingredients derived from human or animal origin, or that used such ingredients during production, must also be accompanied by a document stating that the preparation meets European guidelines for the reduction of the risk to animal substances (TSE). The TSE statement includes details of the animal substances. *Id.* § 3.1; *see generally Background & Legal Framework*, EUROPEAN DIRECTORATE FOR QUALITY OF MEDS. & HEALTHCARE, https://www.edqm.eu/en/certification-background-77.html (last visited Mar. 29, 2022) (overviewing legal requirements for TSE compliance).

which the approval is sought, in the packaging as it is sold in the country from which it will be imported, including a label and leaflet; (G) the importer must also provide a sample of the reference product as it is sold in Israel, including a label and a leaflet; and (H) the drug will be marketed with a label and leaflet to the consumer in accordance with the provisions of the regulations.[186]

It is important to note that the above procedure generally applies to the import of a registered drug or a "compatible drug," but in specific cases, a drug can be imported without registration by individual order and with the approval of the Pharmacy Division, pursuant to Section 29 of the Pharmacists Regulations.[187]

B. COURT RULINGS AND THE DOCTRINE OF THE EXHAUSTION OF RIGHTS IN ISRAEL

Shortly after the amendment of the Pharmacists Ordinance and the enactment of Pharmacists Regulation (Preparations), six international manufacturers with patent rights in medications imported into Israel filed a petition against the Ministry of Health.[188] This petition (the "Bristol-Myers case") brought the issue of parallel importation of medications to the doorstep of the Supreme Court of Israel.[189]

At the heart of the drug manufacturers' challenge to the validity of the new regulations were four main claims.[190] The first concerned the administrative procedure for adopting the regulations.[191] The second, substantive argument was that the granting of a permit for parallel importation infringed the drug manufacturers' patent rights, since parallel importation of a patent-protected drug without the consent of the patent owner constitutes patent infringement.[192] The third argument asserted

186. Procedure No. 35, *supra* note 176, § 3.3.

187. *See* § 29, Pharmacist Regulations (Preparations), 5746-1986.

188. HCJ 5379/00 Bristol Myers Squibb Co. v. Minister of Health, 55(4) PD 447 (2001) (Isr.).

189. *Id.* at 452.

190. *Id.* at 460.

191. *Id.*

192. *Id.* at 461. The petitioners relied on the provision of Section 49(a) of the Patent Law, which states that: "A patent holder is entitled to prevent any other person from using without his permission or illegally the invention for which a patent has been granted . . . ." *Id.* (citing § 49A, Israeli Patent Act, 5727-1967, SH 510 148) (author's translation).

that granting a permit for parallel imports violates the rights of the registration holder in the registration file, which amounts to a violation of the international obligations of the State of Israel.[193] The fourth argument was that the regulations presented a risk to public health because the inspection arrangements of parallel imports are inadequate.[194] In the drug manufacturers' view, severing the direct connection between the manufacturer and the importer makes parallel imports difficult to inspect and thus increases the risk that counterfeit medications will be imported.[195]

The court's analysis of the petitioners' infringement claim focused on Israeli law's approach to the doctrine of exhaustion of intellectual property rights.[196] Under the doctrine of exhaustion, the sale of a protected product by the manufacturer extinguishes the patent holder's ability to control the import and distribution of the product through enforcement of the patent, since its patent rights are "exhausted" by the sale of the patented product.[197] There are two basic approaches to the doctrine of exhaustion of patent rights: national exhaustion and international exhaustion.[198] Under the first approach, the right of a patent holder to control the importation and distribution of its product is exhausted with the first sale of the product within its national territory.[199] Thus, for example, if a product is patented in the State of Israel and then sold outside of Israel, the patent holder has not yet exhausted its intellectual property rights because the product has not yet been sold in Israel. Under international exhaustion principles, however, the patent holder's intellectual property rights are exhausted even by the protected product's sale outside of the national territory.[200]

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193. *Id.*

194. *Id.* at 463.

195. *Id.*

196. *Id.* at 464–70. See generally Gilad Noam, *Developed Countries, Developing Countries and Intellectual Property Protection: International Aspects of Intellectual Property Protection*, 10 HAMISHPAT 187 (1995), for a discussion of international aspects and comparative law on this issue.

197. Margreth Barrett, *The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods*, 27 N. KY. L. REV. 911, 911–12 (2000).

198. The TRIPs Agreement does not mandate either approach. *See* Agreement on Trade Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 6, Apr. 15, 1994, 1869 U.N.T.S. 3, 33 I.L.M. 1197.

199. HCJ 5379/00 Bristol Myers Squibb Co. v. Minister of Health, 55(4) PD at 464.

200. *Id.*

Accordingly, parallel importation is permitted in jurisdictions that follow the international approach to exhaustion but prohibited in jurisdictions that follow the domestic approach.[201]

In the Bristol-Myers case, the Supreme Court did not clearly decide whether parallel imports are consistent with Israeli patent law.[202] It noted that Israeli patent protection is territorial but held that "from the principle of territoriality alone, it cannot be concluded that the principle of national exhaustion applies to the issue of parallel imports."[203] Nevertheless, Justice Englard's opinion observed that Israeli law "tends to lean in favor of adopting the principle of international exhaustion."[204] In other words, the marketing of a patent-protected product anywhere in the world, with the patent holder's approval, will exhaust the patent holder's rights.[205] A review of Israeli case law confirms this observation and illustrates that adoption of the international approach to exhaustion creates normative harmony.[206]

The Supreme Court of Israel first confronted the question of parallel imports in a trademark case handed down in the 1950s.[207] In that case, the Gramophone Company filed a lawsuit against the Symphony Company to prohibit the importation and marketing of records bearing protected trademarks pursuant to the Trademarks Ordinance, claiming that these activities violated of Gramophone's right to "exclusive use" of the trademarks.[208] The Supreme Court rejected the claim, concluding that importation and marketing of trademarked products do not violate the right of "exclusive use" of trademarks, so long as the importer or marketer does not intend to gain "exclusive rights" to the products of their own.[209]

In a later case from the 1970s, a manufacturer with a registered trademark for a chemical product used in agriculture sued an importer that purchased the product from the

201. *Id.*
202. *Id.* at 469.
203. *Id.* at 468 (author's translation).
204. *Id.* at 469.
205. *See id.* at 469–70.
206. CivA (DC CT) 23067-11-09 Spin Master Ltd. v. Toy Empire Ltd., Nevo Legal Database (Nov. 11, 2012) 8–14.
207. CivA 155-56, Gramophone Co. Ltd. London v. Symphony Ltd., 11(2) PD 821 (1957).
208. *Id.* at 822.
209. *Id.* at 823.

manufacturer's American subsidiary and imported it to Israel.[210] The manufacturer argued that the unauthorized parallel imports violated its right to use the trademark and threatened the reputation it built through its own investments and efforts.[211] The Court ruled that since the product bearing the trademark was an "original" product originating from the manufacturer, there was no risk of deception or damage to reputation.[212] Accordingly, the trademark owner had no right to prevent the use of "original" goods that it produced.[213]

Israel's Supreme Court confronted the issue of parallel importation again in 1990, when it considered whether an exclusive distributor of Cross and Parker pens could prevent a wholesaler of office supplies from importing the pens from abroad.[214] The distributor argued that it had a proprietary right in the product's reputation based on its investments in promoting the product and that by allowing parallel imports, the importer would reap the benefit of that reputation without making similar investments.[215] The Court rejected these claims, concluding that the distributor had no proprietary right in the product's reputation, which belonged exclusively to the product manufacturer, and could not prevent parallel importation on that basis.[216] Additionally, the Court held that absent special provisions in the distribution agreement, the manufacturer had no right to monitor and control the distribution of the product after it was sold, and that the manufacturer was presumed to have included the value of the product's reputation in the price of the product.[217] The Court examined the advantages of parallel imports, which encourage free competition and lower costs for consumers, and also considered the constitutional right of the parallel importer to freedom of occupation.[218] The Court added that only in cases of unscrupulous conduct or other circumstances such as tortious conduct, trademark

210. CivA 471/70 Y.R. Gagei S.A. v. Pazkim Ltd., 24 PD 705, 706 (1970).

211. *Id.* at 707.

212. *Id.* at 707–08.

213. *Id.*

214. CivA 371/89 Leibowitz v. Eliyahu Ltd., 44(2) PD 309, 315 (1990) (Isr.).

215. *Id.* at 321. The distributor also claimed unsuccessfully that the parallel importation amounted to unjust enrichment and breach of contract. *Id.* at 316.

216. *Id.* at 321.

217. *Id.* It was also determined that the parallel import does not violate the exclusivity of the distribution contract between the manufacturer and the official importer, but at most only reduced its value. *Id.*

218. *Id.* at 327.

infringement, deception, or similar acts on the part of the parallel importer will the enrichment be deemed to outweigh the values of free competition and freedom of occupation.[219]

Israeli lower courts have held that the international approach to exhaustion applies in the context of copyright as well. In a 2007 decision involving Dyson vacuum cleaners, the court applied international exhaustion principles in rejecting a challenge to the parallel importation of that product.[220] And in *Spin Master v. Toy Empire Ltd.*, a 2012 case concerning parallel imports of children's toys, the Central District Court confirmed this approach, holding that that "the new [copyright] law explicitly chooses that the exhaustion of rights be international and not national."[221]

Finally, in a 2012 decision in *Suissa v. Tommy Hilfiger* ("The *Hilfiger* Case"),[222] the Supreme Court held squarely that the doctrine of international exhaustion applied to intellectual property law in Israel.[223] The Court concluded that "the recognition of 'parallel imports' in Israeli law means that the doctrine of exhaustion is applied in a format based on 'international exhaustion.'"[224] The Court further explained that the international approach to exhaustion was preferable in view of the centralization of the Israeli economy, which is isolated from its immediate environment and depends on imports in many industries, as well as the ability of the Israeli consumer to purchase products from abroad via the Internet.[225]

In conclusion, despite differences among the branches of intellectual property, an examination of Israeli case law reflects normative harmony with respect to the doctrine of international exhaustion in view of the significant competitive benefits of

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219. *Id*.

220. CivC (DC Hi) 1089/05 Dyson Ltd. v. Y. Shalom Ltd., Nevo Legal Database (Nov. 14, 2007), 13–14 (Isr.); *see also* CivC (DC CT) 25756-06-10 Koninklijke Philips Electonifs v. Electronikah Ravey (2002) Ltd., Nevo Legal Database (Dec. 19, 2010) (Isr.). The District Court rejected a lawsuit to stop parallel imports of televisions to Israel, emphasizing that because it was dealing with original products, the parallel import operation is permitted in light of the doctrine of exhaustion of rights. *Id.* at 13–16.

221. CivA (DC CT) 23067-11-09 Spin Master Ltd. v. Toy Empire Ltd., Nevo Legal Database (Nov. 11, 2012) 10 (author's translation).

222. CivA 7629/12 Suissa v. Tommy Hilfiger Licensing LLC., Nevo Legal Database (Nov. 16, 2014) (Isr.).

223. *Id.* at 11.

224. *Id.* (author's translation).

225. *Id.* at 12; *see also* CivC (DC TA) 27455-02-17 Latfud v. Foodstock, Nevo Legal Database (Apr. 4, 2017) 3 (quoting CivA 7629/12 Suissa, at 11) (Isr.).

allowing parallel imports.[226]

C. THE VOLUME OF PARALLEL IMPORTS IN ISRAEL

Although one of the stated aims of amending the Pharmacists Ordinance was "increasing competitiveness in the pharmaceutical economy by expanding the possibility of marketing drugs other than through the registration holder,"[227] an examination of data from the Ministry of Health over the past two decades shows that the opening of the Israeli pharmaceutical market to parallel imports through this legislative change has given rise to almost no applications for parallel imports by players in the Israeli market. This means that in practice, regulations have hardly been implemented over the years, and there is almost no parallel import activity in the Israeli pharmaceutical market.

For example, on May 19, 2002, a background document was submitted to the Knesset's Labor, Welfare and Health Committee for a discussion on the issue of the Pharmacy Division and parallel imports.[228] This document states that from the amendment of regulations regarding the parallel import of medications (September 2000), until the date the document was compiled, approximately 38 applications had been submitted for approval of medicines for parallel import, "of which 82% are applications from a recognized institution (HMO) and the rest from a drug store."[229] It was also reported that "out of the 21 applications submitted in 2001, only about half were approved. Out of about 17 applications submitted by May 2002, about half were approved, and the rest are still under review."[230] These data are in line with the conclusions of the Committee for

226. The Haifa District Court observed that there would be "no logic" in applying different exhaustion principles to the related areas of intellectual property. CivC (DC Hi) 1089/05 Dyson Limited v. Y. Shalom Ltd., Nevo Legal Database (Nov. 14, 2007) 12 (Isr.).

227. Draft Bill for Law of Arrangements in the State's Economy (Legislative Amendments to Achieve the Budgetary Goals for the Fiscal Year 1999) (No. 2), 5759-1998, HH (Knesset) 2785 (Isr.) (author's translation), https://fs.knesset.gov.il/14/law/14_ls2_567778.pdf.

228. SARAH ZOWNER, KNESSET SPEECH SYS., BACKGROUND DOCUMENT FOR THE DISCUSSION: THE PHARMACY DIVISION AND PARALLEL IMPORTS (May 19, 2005), fs.knesset.gov.il/globaldocs/MMM/c9e88303-9332-e811-80de-00155d0a0235/2_c9e88303-9332-e811-80de-00155d0a0235_11_9573.pdf.

229. *Id.* at 3 (author's translation).

230. *Id.* (author's translation).

Examining the Model of Controlling the Prices of Prescription Drugs from 2016, according to which the degree of competition in the pharmaceutical market in Israel is "limited and deficient."[231]

At the beginning of 2020, we submitted a request to the Ministry of Health pursuant to the Freedom of Information Law seeking up-to-date data on the number of parallel importers operating in the Israeli market and on the volume of imports. The data we received shows that from the amendment of the Pharmacists Ordinance in the early 2000s until March 2020, a total of four parallel imports—or in the language of the law, "Compatible Product Imports"[232]—have been carried out. This figure appears extremely low and indeed, it is lower than the figures provided the 2002 report described above. In any case, it is clear that there is almost no parallel importation of medications in the State of Israel.[233]

In the following parts we examine the situation in the European Union, the United States and developing countries. We also try to understand the reasons for the very limited number of parallel importers operating in the Israeli pharmaceutical market and the main barriers to entry into this market.

V. COMPARATIVE REVIEW

A. THE EUROPEAN UNION

As in Israel, the cost of drug treatment is increasing in EU countries, which have adopted a series of policies aimed at curbing drug costs.[234] Parallel importation of medications is one of the main ways to lower the prices of patented source medications and controlling the growing health care costs in Europe.[235]

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231. PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 25.

232. Correspondence with Mr. Eli Marom, Deputy Director of the Pharmacy and Enforcement Division, Ministry of Health, dated Sept. 3, 2020.

233. See Correspondence with Mr. Eli Marom, *supra* note 232. Various volumes of imports exist as far as imports are concerned under the provisions of section 29. See § 29, Pharmacist Regulations (Preparations), 5746-1986, KT 6040, 645 (Isr.), https://www.nevo.co.il/Law_word/law06/TAK-6040.pdf.

234. Lipschitz, *supra* note 30, at 10–12.

235. *See* Esco Aguiar & Kasper Ernest, *Savings from Parallel Imports in Europe: A Review of the Recent Studies*, AFFORDABLE MEDICINES EUROPE 6 (Jan. 2020), https://affordablemedicines.eu/wp-content/uploads/2020/01/

The desire to harmonize regulations and standards regarding the safety and efficacy of drugs distributed in the EU has led to the establishment of a centralized procedure for approving and licensing medications for marketing.[236] Nevertheless, drug pricing is determined by each country individually. In this respect, the pharmaceutical market is an exception to the EU's general efforts to integrate the European market and allow free movement of goods under principles of free trade.[237] The uniqueness of the pharmaceutical market is also reflected in the extensive regulation of medications and medical treatment; the involvement of intermediaries in the process of purchasing medications, including hospitals, health funds, insurance companies, and physicians; extensive state intervention in the negotiation of drug prices and purchases; and restrictions pursuant to patent law and intellectual property law in general.[238]

While most jurisdictions follow either the international or the national exhaustion doctrine, the EU has adopted a doctrine of regional exhaustion, which distinguishes between sales made in one of the member states of the EU and transactions made outside of the EU.[239] Under this approach, intellectual property rights are exhausted only when a transaction was made in an EU country.[240] Because transactions outside of the EU do not exhaust patent rights, generally only parallel imports from one of the EU countries are allowed in the territories of the EU.[241]

Affordable-Medicines-Europe-Studies-on-Savings-2020-2.pdf. Additional measures EU countries have taken to curb rising drug costs include regulating the maximum price of drugs based on the price of the same product in other countries, reducing VAT on drugs, controlling expenses, promoting rules for the use of generic drugs, controlling the time of entry into the market of drugs eligible for public funding, price freezing, and the use of public procurement (public tender). *See generally* Giuseppe Carone et al., European Comm'n, *Cost-containment Policies in Public Pharmaceutical Spending in the EU* (May 14, 2014) (describing carious price control strategies in the European pharmaceutical market), https://op.europa.eu/en/publication-detail/-/publication/b18e7de2-d60a-4640-8092-b83e9e85fb7a/language-en.

236. *See* Margaret K. Kyle, *The Single Market in Pharmaceuticals*, 55 REV. INDUS. ORG. 111, 112–13 (2019).

237. *Id.* at 112.

238. *See, e.g.*, *id.* at 111–13.

239. *Id.* at 124.

240. *Id.*

241. Rajnish Kumar Rai & Srinath Jagannathan, *Parallel Imports and Unparallel Laws: An Examination of the Exhaustion Doctrine through the Lens of Pharmaceutical Products*, 21 INFO. & COMMC'NS TECH. L. 53, 69 (2012); Kamal Saggi, *Regional Exhaustion of Intellectual Property*, 10 INT'L J. ECON.

Article 30 of the Treaty of Rome prohibits the imposition of quantitative import restrictions among member countries.[242] Yet the principles of patent law, which guarantee proprietary protection to patent holders—including control over the import of patent-protected products—are ostensibly at odds with this provision.[243] To reconcile this conflict, Article 36 of the Treaty of Rome clarified that the commitment to free trade "shall not be an obstacle to prohibitions or restrictions in respect to importation . . . which are justified on grounds of . . . industrial and commercial property."[244]

Nevertheless, the European Court of Justice ("ECJ") has held that the doctrine of exhaustion restricts the proprietary protections reserved under Article 36. For example, in the 1971 *Deutsche Grammophon* case, the defendant purchased records distributed by the German plaintiff's subsidiary in France, imported them back into Germany, and sold them at a lower price.[245] The ECJ interpreted Article 36 narrowly and ruled in the defendants' favor.[246] The court reasoned that the plaintiff's effort to enforce its intellectual property right to prevent marketing in the EU member state would thwart the Rome Agreement's purpose of encouraging free trade among EU member states.[247]

In the 1974 *Centrafarm* case, the ECJ expanded the principle established in *Deutsche Grammophon* to copyright and patent law.[248] The defendant had a patent in the Netherlands and also operated a licensed marketer who sold the patent-protected product in the UK.[249] The plaintiff purchased the patented product from the UK marketer and imported it to the

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THEORY 125, 126 (2014); *see also* Kyle, *supra* note 236, at 124.

242. Treaty Establishing the European Economic Community art. 30, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter Treaty of Rome].

243. Michael A. Gold, *European Patent Law and the Exhaustion Principle*, 1992 U. CHI. LEGAL F. 441, 441 (1992).

244. Treaty of Rome, *supra* note 242, art. 36.

245. Case 78/70, Deutsche Grammophon Gesellschaft mbH v. Metro-SB. Großmärkte GmbH & Co. KG, 1971 E.C.R. 487, 490.

246. *Id.* at 499–500.

247. *Id.* at 500. In another case, *De Peijer*, the ECJ decided that parallel importation within the EU is legal and permissible with regard to importing medicines from pharmacies in another EU country for consumers' personal use, provided that the medicine is available in the country to which the medicines are imported. *See* Case 104/75, de Peijer, 1976 E.C.R. 613.

248. Case 15/74, Centrafarm BV v. Sterling Drug Inc., 1974 E.C.R. 1148.

249. *Id.* at 1149.

Netherlands to market and sell.[250] The defendant sought to ban the import of the patent-protected product into the Netherlands by asserting its patent rights in that country.[251] The court held that the defendant's patent right was exhausted when the patent-protected product was sold in the United Kingdom, another EU member country.[252] Accordingly, the defendant had no right to restrict imports to the Netherlands or other countries in the EU. Once again, the tribunal reiterated the supremacy of the principles of free trade over the proprietary right of the patent owner.[253]

Merck & Co. Inc. v. Stephar BV involved a patent infringement case challenged the marketing in Italy of a product that was patent-protected in the Netherlands but ineligible for patent protection in Italy.[254] In this case, the ECJ ruled that a patent holder who markets his products in two EU member states cannot prevent parallel imports between the two markets, notwithstanding differences in the property protections afforded in the respective countries.[255] The court held that when the patent owner voluntarily released its product to a market where patent protection could not be obtained, it exhausted its patent right.[256]

Later, in *Merck & Co. Inc. v. Primecrown*, the ECJ interpreted Articles 30 and 36 of the Rome Agreement in the context of a patent infringement claim challenging the parallel importation of products from different European countries.[257] The court adhered to its previous rulings in *Centrafarm* and *Merck v. Stephar* but clarified that the doctrine of exhaustion applies only when the patent owner made the initial sale voluntarily.[258] If the patent owner can establish, however, that it was required by law to market the protected product, it will not be deemed to have exhausted its rights and can prevent

250. *Id.*
251. *Id.*
252. *Id.* at 1151, 1162.
253. Gold, *supra* note 243, at 444.
254. Case 187/80, Merck & Co. Inc. v. Stephar BV, 1981 E.C.R. 2064, 2065.
255. *Id.* ¶ 14; *see* Rai & Jagannathan, *supra* note 241, at 69.
256. *See* Case 187/80, *Merck & Co.*, ¶¶ 13–14. *But cf.* Valentine Korah, *The Limitation of Copyright and Patents by the Rules for the Free Movement of Goods in the European Common Market*, 14 CASE W. RSRV. J. INT'L L. 7, 20, 29–33 (1982) (criticizing the reasoning in *Merck & Co., Inc.*).
257. Joined Cases C-267/95 & C-268/95, Merck & Co. Inc. v. Primecrown Ltd., 1996 E.C.R. I-6285.
258. *Id.* at I-6387.

parallel importation.[259]

As these cases illustrate, pharmaceutical companies can rarely prevent parallel imports of drugs from other EU countries. Moreover, state control over drug prices restricts these companies' ability to raise prices to reduce the incentives for parallel importation. Accordingly, pharmaceutical companies have instituted a variety of other policies in an effort to prevent competition from parallel importers. For example, GlaxoSmithKline Spain ("GSK Spain")[260] implemented a dual pricing policy in which it marketed medications at the regulated price in Spain and at higher prices outside of Spain, reducing the incentive for parallel imports. [261] But the ECJ has ruled dual pricing violates competition law and the principles of free trade in the EU. [262]

Pharmaceutical companies may also try to reduce drug inventories in countries where drug prices are low to decrease the incentive for parallel importation. In 2008, GSK's Greek subsidiary, Syfait, imposed unilateral restrictions on the quantities of drugs marketed in Greece, where drug prices are lower than those of other European countries.[263] The ECJ held that notwithstanding the uniqueness of the pharmaceutical industry and the company's desire to safeguard its economic interests, the company was not entitled to exploit its dominant position with the goal of harming parallel imports.[264]

Cases such as these illustrate that to promote integration and free trade in the European Union, European regulators and courts tend to allow parallel imports from other EU countries,

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259. *Id.* at I-6389.

260. Joined Cases C-501/06, C-513/06, C-515/06 & C-519/06, GlaxoSmithKline Servs. Unltd. v. Comm'n, 2009 E.C.R. I-9374.

261. *Id.* ¶¶ 3–11.

262. *See* Patrick Rey & James S. Venit, *Parallel Trade of Prescription Medicines: The Glaxo* Dual Pricing *Case*, *in* CASES IN EUROPEAN COMPETITION POLICY: THE ECONOMIC ANALYSIS 268, 269 (Bruce Lyons ed., Cambridge Univ. Press 2009). The European Commission has ruled that double pricing infringes Article 81 of the Treaty Establishing the European Community (now Article 101 of the Consolidated Version of the Treaty of the Functioning of the European Union) because it harms free trade between EU countries. *See id.* n.4. The ECJ noted that in light of the unique characteristics of the pharmaceutical industry, the activities of GSK Spain may be covered by the exception in Article 101(3) of the TFEU, but it nevertheless held its double pricing activity unlawful. *See* Joined Cases C-501/06, C-513/06, C-515/06 & C-519/06, GlaxoSmithKline, ¶ 104.

263. Joined Cases C-468/06 to 478/06, Sot. Lélos kai Sia EE v. GlaxoSmithKline AEVE Farmakeftikon Proionton, 2008 E.C.R. I-7139. I-7148.

264. *Id.* at I-7166–67.

including in the pharmaceutical market. Scholars have debated the merits of the EU's regional exhaustion approach, highlighting ways in which it may ultimately disserve the public interest even as it helps control drug prices.[265] What emerges from these discussions is that the impact of parallel imports on EU drug prices needs further examination.[266]

According to a January 2020 report published by Affordable Medicines Europe (AME), parallel drug imports provide economic benefits to EU countries as an alternative to, and challenge to, the originator manufacturers.[267] The report shows that over the years, EU countries have increased their health spending, which now represents a substantial part of their overall budgets.[268] For the past four decades, parallel imports have been a major source of competition for originator manufacturers.[269] Although the volume of parallel imports is limited, parallel importation nevertheless reduces drug prices and leads to savings for EU countries.[270]

Data published in this report reveal that the volume of parallel trade in medications across the EU stands at about 5,500 million euros per year, but the share of parallel import of the pharmaceutical market as a whole has been decreasing over the years.[271] As of 2018, parallel imports account for about 2.9% of all sales in the European pharmaceutical market.[272] Parallel

265. Gold, *supra* note 243, at 446; Kyle, *supra* note 236, at 124–25; Rai and Jagannathan, *supra* note 241, at 69–70; *see generally* Benoit Durand, *Competition Law and Pharma: An Economic Perspective*, *in* EU LAW OF COMPETITION AND TRADE IN THE PHARMACEUTICAL SECTOR 1 (Pablo Figueroa & Alejandro Guerrero eds., 2019) (arguing that parallel imports are a form of arbitrage that sell products in different price according to demand, and when there are large differences in demand, pharmaceutical companies may stop supplying to low-price countries reducing customer welfare).

266. Durand, *supra* note 265, at 20–21.

267. Aguiar & Ernest, *supra* note 235, at 6, 13. Affordable Medicines Europe (AME)'s website includes various studies on parallel imports in Europe. *Reports and Studies*, AFFORDABLE MEDS. EUR., https://affordablemedicines.eu/reports-and-studies/ (last visited Mar. 29, 2022).

268. *Id.* at 3.

269. *Id.* at 13.

270. Mendez's 2017 study found that eliminating parallel imports would raise both original drug prices and, less significantly, generic drug price. The study also found that if parallel imports are banned, government spending on health services would increase and consumer welfare would decrease. Susan J. Mendez, *Parallel Trade of Pharmaceuticals: The Danish Market for Statins*, 27 HEALTH ECON. 333, 334 (2017).

271. *See* Aguiar & Ernest, *supra* note 235, at 4.

272. *Id.*

imports vary from country to country.[273] For example, as of 2016, the rate of parallel imports in the pharmaceutical market ranged from 1.6% to 25.5%.[274] As can be seen from the figure below, the volume of parallel imports in selected European countries is as follows:

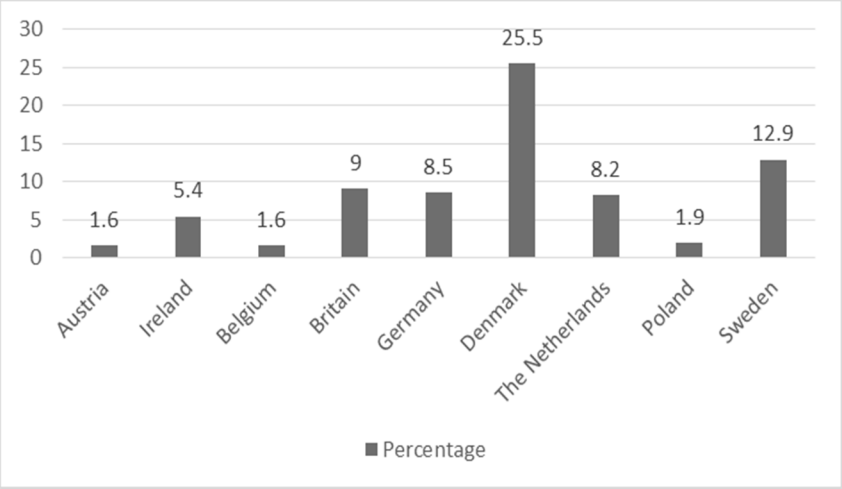

Fig. 8 The Volume of Parallel Imports in Selected European Countries as a Share of Total Market Sales[275]

According to an earlier report by the AME, the total direct and indirect savings from parallel imports in Germany, Sweden, Denmark, and Poland in 2018 was about 3.2 billion euros.[276] Direct savings reflect the price difference between the drug marketed by the official importer and the drug marketed by the parallel importer, while indirect savings result from competitive pressure, since the price of medications marketed by the manufacturer tends to go down when there is competition from parallel imports.[277] Moreover, additional indirect savings come

273. *Id*. at 11.

274. *The Pharmaceutical Industry in Figures: Key Data 2018*, EUR. FED'N PHARM. INDUS. & ASS'NS 5 (2018), https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf.

275. *Id.*

276. According to the editors of the Affordable Drugs Report, the reported savings are based on conservative calculations and are likely greater, especially with respect to Germany and Sweden, where data reflect sales from parallel imports in pharmacies but excludes sales in hospitals. *See* Aguiar & Ernest, *supra* note 235, at 6, 17.

277. *Id*. at 11. In a 2003 study, West and Mahon estimated that the direct

from potential competitive pressure. This refers to the savings generated by the manufacturer's decision to lower prices preemptively to prevent competing importers from entering the market.[278]

The AME estimates that indirect savings resulting from parallel imports are immeasurably greater than the direct savings. Thus, the table below illustrates the savings realized in representative countries:

	Indirect Savings (in million Euros)	Direct Savings (in million Euros)	Total (in million Euros)
Germany	2,600	202	2,802
Sweden	175	60	235
Denmark	51	31	82
Poland	57	67	124
Total	2,883	360	3,243

Table 5 Savings Resulting from Parallel Imports in Selected European Countries [279]

It is important to note that for the parallel importation of medications, the importer must apply for an import license from the European Medicines Agency (EMA) or the regulator in the particular country, and the procedure can be long and tedious.[280] The centralized procedure through the EMA is simpler because

savings to five countries—the United Kingdom, Germany, Sweden, the Netherlands, and Denmark—in 2002 amounted to about 635 million euros. *See* Peter West & James Mahon, The European Association of Euro-Pharmaceutical Companies: Benefits to Payers and Patients from Parallel Trade 67 (York Health Econ. Consortium, May 2004), https://affordablemedicines.eu/portfolio-item/report-number-3/.

278. Aguiar & Ernest, *supra* note 235, at 11. *But see* Shen Guo et al., *Impact of Parallel Trade on Pharmaceutical Firm's Profits: Rise or Fall?*, 14 EUR. J. HEALTH ECON. 345, 346–47 (2013) (arguing that parallel imports may lead to a rise in drug prices in foreign markets).

279. Aguiar & Ernest, *supra* note 235, at 16.

280. *Frequently Asked Questions About Parallel Distribution*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution (last visited Sept. 15, 2021).

it reduces transaction costs when imports from several countries are involved, and provides uniform production of a drug to be sold in all EU countries.[281]

The increasing use of the centralized procedure has led to an increase in the number of licenses and the number of companies engaged in parallel importation.[282] Additionally, the entry of weaker economies and lower drug prices into the EU (such as Romania and Bulgaria) has made these countries a source of parallel imports.[283] However, the number of countries that are the target markets for parallel imports remains limited. Of the parallel import licenses granted throughout the EU in 2017, Germany led with 11,844 licenses granted, followed by the United Kingdom (5,486), Ireland (3,749), Sweden (2,925), Denmark (2,094), the Netherlands (2,080) and Malta (1,267).[284] In the other EU countries, the number of import licenses granted was fewer than a thousand, and was zero in several countries.[285] It is important to note that the EMA and its partners in the European medicines regulatory network have put measures in place to help prevent and mitigate possible disruptions to the supply of medicines in the EU during the COVID-19 pandemic. Although most medicine shortages are normally dealt with at the national level, during the COVID-19 pandemic the EMA has acted as a central coordinator in supporting Member States' activities in this area.[286]

B. UNITED STATES

Parallel importation of drugs into the United States is a complex process subject to both patent law and FDA regulations. The U.S. Patent Act does not explicitly address the issue of

281. Kyle, *supra* note 236, at 126–27.

282. *Id.*

283. In June 2020, Affordable Medicines Europe published a report about trade flows of parallel imported medicines. In the report they claim that medicines do not always go from lower income countries to higher income countries. For example, Norway exports more per capita than any other EU country. Esco Aguiar & Kasper Ernest, *Trade Flows of Parallel import*, AFFORDABLE MEDS. EUR. 10 (June 2020), https://affordablemedicines.eu/wp-content/uploads/2020/06/Trade-Flow-Study-FINAL-big-file.pdf.

284. Kyle, *supra* note 236, at 126 tbl.9.

285. *Id.*

286. *See Availability of Medicines During COVID-19 Pandemic*, EUR. MEDS. AGENCY, https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/availability-medicines-during-covid-19-pandemic (last visited Mar. 29, 2022).

patent exhaustion, but the doctrine emerged from *Bloomer v. McQuewan*, where the Supreme Court held that upon the sale of a patent-protected product, the product leaves the control of the patent holder, and the purchaser can do with it whatever the purchaser sees fit.[287] In recent years, the Supreme Court has addressed the doctrine in three major judgments: (1) *Quanta Computer, Inc. v. LG Electronics Ind.*;[288] (2) *Bowman v. Monsanto Co.*;[289] and (3) *Impression v. Lexmark Int'l, Inc.*[290]

In *Quanta Computer*, the Court reiterated the rule that patent holders exhaust their rights to a product when the product is sold by them or by someone on their behalf.[291] The court further held that the doctrine of exhaustion applies to patent-protected processes (in that case, a method of operating a computer system), as long as the product sold substantially embodies the patent.[292] In other words, the lawful sale of a product that embodies the essence of the patent-protected process, and that has no significant use other than the adoption of the process or method, exhausts the rights of the patent owner.[293]

However, the doctrine of exhaustion does not extinguish a patent owner's right to prevent others from producing additional copies of the protected product. Thus, in *Bowman,* the Court held that a farmer who buys patented seeds may not reproduce them through planting and harvesting without the patent holder's permission.[294]

The Supreme Court again confronted the issue of exhaustion of patent rights in *Impression,* a case concerning the sale of toner cartridges for laser printers.[295] Lexmark manufactured and sold its patented cartridges to consumers in the United States and around the world.[296] One of the advantages of Lexmark's cartridges was that when the ink ran

287. Bloomer v. McQuewan, 55 U.S. 539, 549 (1852).

288. Quanta Comput., Inc. v. LG Elecs., Inc., 553 U.S. 617, 628 (2008).

289. Bowman v. Monsanto Co., 569 U.S. 278, 280 (2013).

290. Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1529 (2017); *see generally* Ofer Tur-Sinai, *Exhaustion in the Service of Progress*, 37 CARDOZO ARTS & ENT. L J. 87, 91–97 (2019) (analyzing the *Impression Products* decision).

291. *Quanta Comput.*, 553 U.S. at 625.

292. *Id.* at 628.

293. *Id.* at 625.

294. *Bowman*, 569 U.S. at 283.

295. *Impression Prods., Inc.*, 137 S. Ct. at 1529.

296. *Id.*

out, they could be refilled and reused.[297] This characteristic created a business opportunity for other companies such as Impression to buy empty Lexmark cartridges, refill them, then resell them to consumers at a lower price than Lexmark offered.[298] When Lexmark discovered that Impression was purchasing empty cartridges from consumers outside the United States and importing them back into the United States to refill and resell, it sued Impression for patent infringement.[299] The Supreme Court rejected the claim, concluding that Lexmark's sale of the cartridges in the U.S. and elsewhere exhausted its patent rights, notwithstanding restrictions Lexmark included in its contracts with buyers purporting to restrict resale.[300] Reiterating the principle that the lawful sale of a protected product exhausts the patent holder's rights, the Court held that the patent owner cannot enforce contractual restrictions on use or resale of a protected product by way of a patent infringement claim.[301] Moreover, the Court explicitly embraced the international exhaustion regime, holding that even a sale outside the United States exhausts the exclusive rights of the patent holder, meaning that a patent holder cannot rely on patent law to prevent the importation of protected products sold legally outside the United States.[302]

One might expect the Court's decision in *Impression* to have had a significant impact on the parallel importation of drugs into the United States—a country where drug prices are among the highest in the world.[303] However, provisions of the Federal Food, Drug and Cosmetic Act ("FD&C Act") create a barrier to parallel importation of pharmaceuticals by prohibiting the importation of "new drugs" (which in this context includes foreign versions of drugs) without FDA approval.[304]

For example, if an international pharmaceutical company markets a drug in the United States that has received FDA approval and also markets another version of the same drug in

297. *Id.*
298. *See id.* at 1530.
299. *Id.*
300. *Id.* at 1533.
301. *Id.*
302. *Id.* at 1531.
303. Kelsey Myers, *Free Trade and Pharmaceuticals: Canadian-American Pharmaceutical Trade and American Access to Affordable Drugs*, ST. OLAF COLL. ECON. DEP'T'S OMICRON DELTA EPSILON J. ECON. RSCH., Spring 2018, at 48, 49.
304. 21 U.S.C. §§ 331(d), 355(a).

Europe and Israel, then the foreign version will be considered a new drug whose importation is prohibited.[305] Importation is similarly prohibited, if the version marketed outside the United States is manufactured in a facility other than the one in which the American version is manufactured, or according to a different specification.[306] If even the packaging or label is different from those used in the version that has received FDA approval, importation is prohibited.[307] Moreover, if a drug is manufactured in the United States and exported to another country, only the original manufacturer can import it back into the United States (reimportation).[308] In short, the U.S. market is closed to the parallel importation of any drug not approved by the FDA.

In recent years, there have been several attempts to address rising drug prices in the United States and allow parallel importation of drugs. For example, a bill was proposed in 2000 that became known as the Medicine Equity and Drug Safety Act (MEDS).[309] Among other things, the bill proposed making changes to the FD&C regulations, which, if adopted, would have allowed pharmacists or wholesalers across the United States to import certain prescription drugs without the manufacturer's approval.[310] Although this option could have lowered drug prices in the United States,[311] this importation scheme was not enacted.[312]

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was enacted.[313] Section 1121

305. United States v. Genendo Pharm., N.V., 485 F.3d 958, 960 (7th Cir. 2007) (affirming FDA's seizure of imported version of Lipitor as an "unapproved new drug" under § 355(a)).

306. *See id.*

307. *Id.* (holding that a parallel import of the drug Lipitor is the same as introducing a "new drug" to the market).

308. 21 U.S.C. § 381(d)(1); *see also* Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,798 (proposed Dec. 23, 2019) (to be codified at 21 C.F.R. pts. 1 and 251).

309. Medicine Equity and Drug Safety Act, S. 2520, 106th Cong. (2000).

310. *Id.* § 3.

311. *See Imported Drugs Raise Safety Concerns*, FOOD & DRUG ADMIN, https://www.fda.gov/drugs/drug-information-consumers/imported-drugs-raise-safety-concerns (Mar. 1, 2018).

312. 148 CONG. REC. 13217 (letter to President Clinton from Donna Shalala, Secretary of Health and Human Services, 2000); *see also* Importation of Prescription Drugs, 84 Fed. Reg. at 70,799 (explaining why efforts to enact parallel importation failed).

313. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

of this Act amended the provisions of the FD&C Act.[314] In its current version, Section 804 of the FD&C Act authorizes the U.S. Department of Health and Human Services (HHS) to enact regulations that allow pharmacists and wholesalers to import certain prescription drugs from Canada.[315] To date, however, regulations under the provisions of section 804 of the FD&C have not been enacted for the following reasons, among others: (a) the FDA could not guarantee the safety and efficacy of drugs imported in this way; (b) concerns that the opening of the U.S. pharmaceutical market to parallel imports of prescription drugs will result in the entry of counterfeit drugs or of a non-compliant drug supply into the United States;[316] (c) concerns that such an import plan will not result in a significant reduction in costs to American consumers.[317]

In January 2019, a bill was brought before Congress concerning the importation of drugs from Canada.[318] The initiative is designed to enable U.S. citizens to purchase cheaper drugs from Canada.[319] In addition, in December 2019, the FDA proposed amending the regulations enacted to implement the FD&C so that states or other (non-federal) government agencies can submit proposals for an import program to the FDA for review and approval.[320] Such import plans may be submitted in conjunction with a pharmacist, wholesaler, or other non-federal government entity.[321] As of the writing of this article, however, these statutory and regulatory initiatives have not been adopted.[322]

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314. *Id.* § 1121.

315. 21 U.S.C. § 384(b).

316. *See, e.g.*, Press Release, U.S. Dep't of Just., Paul Daniel Bottomley Pleads Guilty in U.S. Federal Court (Apr. 24, 2013), https://wayback.archive-it.org/7993/20170723081601/https://www.fda.gov/ICECI/CriminalInvestigations/ucm349880.htm; Press Release, U.S. Dep't of Just., Canadian Drug Firm Admits Selling Counterfeit and Misbranded Prescription Drugs Throughout the United States (Apr. 13, 2018), https://wayback.archive-it.org/7993/20180725182130/https:/www.fda.gov/ICECI/CriminalInvestigations/ucm605139.htm.

317. Importation of Prescription Drugs, 84 Fed. Reg. at 70,799; *see generally* HHS TASK FORCE ON DRUG IMPORTATION, U.S. DEP'T OF HEALTH & HUM. SERVS., REPORT ON PRESCRIPTION DRUG IMPORTATION (Dec. 2004) (reporting on the concerns about importing drugs from foreign markets).

318. Safe and Affordable Drugs from Canada Act of 2019, S. 61, 116th Cong. (2019).

319. *See id.*

320. Importation of Prescription Drugs, 84 Fed. Reg. at 70,796.

321. *Id.*

322. *S.61*, CONGRESS.GOV, https://www.congress.gov/bill/116th-congress/

C. DEVELOPING COUNTRIES

The Center for Global Development published a report in 2019 that examined the pharmaceutical market in developing countries.[323] The report's findings reveal a bleak picture of the pharmaceutical market in poor countries with weak economies.[324] The study showed that despite the impressive achievements of the world health system in the last twenty years, including the development of drugs to treat diseases such as AIDS, malaria, and tuberculosis, these life-saving drugs may be unavailable in low-income developing countries.[325] One of the main reasons is the inefficiency in the procurement processes for medications in developing countries.[326] In addition, these countries often pay more for drugs compared to established and developed countries. The cost of buying drugs is a significant part of developing countries' healthcare costs.[327] In fact, in some countries the cost of purchasing drugs and related products is estimated at about 50 billion dollars a year.[328] Despite the involvement and contributions from various health organizations, developing countries still pay the highest drug prices in the world due to market failures, cumbersome regulation, and rigid government policies that make parallel drug imports and generic drug production difficult in these countries.[329]

Moreover, research shows that there is little competition in

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senate-bill/61?q=%7B%22search%22%3A%5B%22S.+61%22%2C%22S.%22%2C%2261%22%5D%7D&s=4&r=7 (last visited Mar. 29, 2022).

323. *See* Silverman et al., *supra* note 156. The Center for Global Development (CGD) is an organization whose stated goal is to work to reduce global poverty and improve the quality of life, among other things, through economic research. *Our Work*, CTR. FOR GLOB. DEV., https://www.cgdev.org/our-work (last visited Mar. 29, 2022).

324. *Id*. at xiii ("In Low- and Middle-Income Countries, Prices for Basic Generic Medicines Can Vary and Far Exceed Wealthy-Country Prices."). In the report, the reference is to low- and middle-income countries, which are called developing countries.

325. For example, in 2017, more than 21 million people live with AIDS and receive drug treatment for the disease, compared to the 685,000 people who received the drug in 2000. *See* Silverman et al., *supra* note 156, at 4.

326. *See id*. at xi. It should be noted that the report did not focus on the end consumer, but rather on the state's process of purchasing drugs from the manufacturer.

327. *See id.* at 2.

328. *Id*.

329. For more information on the factors that prevent reductions in drug prices, see *id*. at xvii–xviii, 5.

the supply of medications in developing countries, as these markets are controlled by a single supplier or a small number of suppliers, which directly affects the prices that buyers and consumers pay.[330] In some developing countries, the main supplier of a drug or medical treatment may control more than 85% of sales (for example, cancer and diabetes drug suppliers in Zambia).[331] The main reasons for the shortage of suppliers are the governments' preference for domestic production, high transaction costs, and anti-competitive conduct on the part of existing suppliers.[332] Given the paucity of suppliers in the market, proposals have been made to address bureaucratic obstacles and inefficiencies, which hinder and prevent the entry of generic drug manufacturers into the market.[333]

While the report from the Center for Global Development does not directly address the issue of parallel imports, it illustrates that pharmaceutical markets without parallel imports tend to reflect very high drug prices. Any entry of a competitor into a market with a small number of suppliers should have the effect of lowering drug prices and increasing access to medications. Parallel imports seem to be an important and vital path for achieving these goals in developing countries.

In conclusion, a review of the pharmaceutical market in the European Union, the United States, and developing countries shows a universal desire to lower drug prices. The use of parallel imports is common in the European market and manages to lower the prices of medications with the help of a regional approach to exhaustion. Nevertheless, this tool has rarely been used in the Israeli pharmaceutical market. To understand the reason for this, we devote the next part of this article to exploring possible barriers to parallel imports in the Israeli market.

VI. POSSIBLE BARRIERS TO PARALLEL IMPORTATION

As noted above, the goal of legislative and regulatory amendments authorizing parallel drug imports into Israel was to stimulate competition in the Israeli pharmaceutical market and lower healthcare costs. An influx of parallel drug imports

330. *Id.* at 17–20.
331. *Id.* at xvi.
332. *Id.* at 17–20.
333. *See id.* at 17–19, 24–25.

was expected, in part, because entry barriers are generally lower for new importers than for new manufacturers.[334] Any new supplier typically must make initial investments to understand the relevant market and identify products suited to local consumers.[335] In addition to these investments, new manufacturers must also establish a production and development system for their products, which is a time-consuming and resource-intensive process.[336] Although establishing an importation operation also involves significant investments of time and money, both are generally lower than those faced by new manufacturers, as importers benefit from the manufacturers' earlier production investments in what is known as the "hitchhiker" or "free rider" phenomenon.[337] Moreover, parallel importers' ability to purchase products at lower prices in supplier countries and sell them at higher prices in consumer countries gives them a significant advantage over the consumer countries' official importers.[338] Differences in drug prices around the world were expected to make Israel's pharmaceutical market particularly attractive to parallel importers. But as our findings show, there has been, with few exceptions, no parallel drug importation into Israel.

In previous parts, we discussed the relevant legal landscape, examined the impact of changes in Israeli law on drug prices, and summarized the extent of parallel imports into the State of Israel. The following part will address some of the key barriers to parallel imports, emphasizing the impact of these barriers on the Israeli pharmaceutical market.

A. LEGISLATIVE BARRIERS TO PARALLEL IMPORTATION

1. Import Standardization

In the past decade, consumer awareness in Israel has increased, and concerns about the high cost of living have received public attention. In response, a number of public committees were appointed to examine the main reasons for

334. THE ISRAELI COMMITTEE FOR THE INCREASE OF COMPETITION AND REMOVAL OF BARRIERS TO IMPORTS § 4.1 (2014) [hereinafter LANG COMMITTEE], https://www.chamber.org.il/media/144457/33.pdf.

335. *Id.*

336. *Id.*

337. For further discussion, see *id.* § 4.3.1.

338. *Id.* § 4.1.

Israel's cost of living. One issue that routinely emerged from these committees' reports was the existence of Israeli import barriers, particularly those resulting from strict regulation.

For example, the Committee for Socio-Economic Change: Cost of Living and Competitiveness, headed by Prof. Manuel Trajtenberg (the "Trajtenberg Committee"), noted regulation in the field of import standardization as a major barrier to imports to Israel.[339] The Committee observed that official Israeli standards for many products are fundamentally different from the standards accepted around the world, and that the Israeli standards sometimes require changes in production lines.[340] Israel's unique standards thus increase import costs (which are ultimately passed on to consumers) and make importing products cumbersome and time-consuming.[341] The State Comptroller's 2014 report similarly found that Israel's delay in adopting international standards was a major obstacle to the importation of goods of various types into the country.[342]

The 2014 report of the Committee for Increasing Competition and Removing Barriers in the Field of Imports, chaired by Amit Lang (the "Lang Committee"), identified the lack of uniform criteria for establishing a legal import policy as another major barrier to importation.[343] The legal process entails obtaining permits and licenses from several independently-run government ministries, each of which sets its own requirements to ensure product safety in terms of public health, the environment, and so on.[344] Because some products require unique testing and reliance on results from international laboratories is not permitted, an excess burden is therefore passed on to consumers.[345] The report also found that authorities may be influenced by professional and special interests that are incompatible with the objectives of free importation—including the preservation of local jobs and production facilities—which

339. MANUEL TRAJTENBERG, REPORT OF THE COMMITTEE ON SOCIO-ECONOMIC CHANGE (2011) [hereinafter TRAJTENBERG COMMITTEE]. http://www.hurvitz-institute.tau.ac.il/wp-content/uploads/2016/07/tracht.pdf.

340. *Id.* at 179–80.

341. *Id.*

342. MINISTRY OF ECONOMY, REGULATORY BARRIERS RESTRICTING IMPORT OF GOODS: ANNUAL REPORT 65A, 419, 421 (2014), https://www.mevaker.gov.il/sites/DigitalLibrary/Documents/2014-65a-208-Asdara.pdf; *see also* TRAJTENBERG COMMITTEE, *supra* note 339, at 179–80.

343. LANG COMMITTEE, *supra* note 334, §§ 3.1, 3.5.

344. *Id.* § 3.1.

345. *Id.*

may lead to intentional restrictions on imports.[346] Additionally, the absence of a competent body responsible for defining broad policy objectives and advising the relevant ministries on how to carry them out resulted in each ministry establishing import requirements without regard to their implications on broader questions such as competition and cost of living.[347] Finally, close supervision prior to customs clearance and labeling requirements for products sold in Israel creates additional import barriers.[348]

The Lang Committee report noted that, in some cases, regulators set out unique procedures and regulations for products imported through parallel importation to address perceived concerns that parallel imports are intended to circumvent regulatory requirements.[349] These added requirements increase import barriers.

Although these committee reports do not directly address parallel drug imports, the major barriers they discuss apply equally in the Israeli drug market and affect the volume of parallel drug imports. Ministry of Health regulations provide that a party seeking to import medications through parallel imports must meet myriad strict requirements. For example, it must prove that the preparation was stored and transported under proper conditions[350] and that it was purchased directly from the manufacturer or a dealer authorized by the authorities in one of the recognized countries, as defined in the Pharmacists Regulations.[351] Moreover, the importer must present a sample of the product for which the approval is being requested in the packaging as marketed in the country from which it will be imported (including the label and leaflet), as well as a sample of the reference product as marketed in Israel (including the label

346. *Id.*

347. *Id.*

348. *Id.* § 3.3.

349. *See id.* § 3.5.

350. This is done by presenting a delivery note, supplier's invoice, or any other document, which provides information about the marketing chain from the previous supplier all the way to the production site. Procedure No. 35, *supra* note 176, § 3.1.

351. Imports will only be made from manufacturing sites in countries recognized by the Ministry of Health according to the pharmacists' regulations: USA, Canada, EU member states, Switzerland, Norway, Iceland, Australia, New Zealand, Japan and Israel, as well as authorized dealers and wholesalers in recognized countries. Imports from EU countries will be done only after the EU has completed the approval of the product registration systems in the acceding countries. *Id.* § 2.

and leaflet).[352] Finally, the importer is required to market the drug with a consumer label and leaflet in accordance with the provisions of the regulations.[353] All of these requirements impose costs on the parallel importer that constitute a significant barrier to parallel imports.[354]

Accordingly, even when the Israeli standards are consistent with those accepted worldwide, the information required for importation may be unavailable to parallel importers, either due to lack of contact with the various parties in the supply chain or the manufacturer's desire to prevent parallel imports that could harm its contract with the official importer.[355] These issues further complicate the process and extend the time required for the importer to obtain a parallel import license for drugs.[356] Furthermore, in interviews we conducted with key players in the European pharmaceutical market, we learned that, in many cases, the official importer does not have a copy of the approvals required for parallel importers. Although the official importer can apply to the manufacturer for these approvals, it will usually refuse to do so, for fear that it will harm their relationship. Therefore, in practice, the official importer is often unable to provide the parallel importer with the necessary approvals.[357]

There is no doubt that stringent regulatory requirements are appropriate to ensure the quality and safety medications marketed in Israel. Nevertheless, the requirements highlighted above impose additional costs on importers that impair the viability of parallel imports and constitute a barrier to the parallel importation of drugs,[358] especially since Israel does not

352. *Id.* § 3.

353. *Id.* § 3.

354. LANG COMMITTEE, *supra* note 334, §§ 3.3–.6. It is interesting to note that rigid bureaucracy and strict safety and quality standards are barriers in other countries. In the United States, for example, drug quality and safety standards constitute a major barrier to importation. For further discussion, see, for example, Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 625, 643–47 (2005).

355. LANG COMMITTEE, *supra* note 334, § 3.6.

356. *See id.* § 3.2; TRAJTENBERG COMMITTEE, *supra* note 339, at 166.

357. Interview with Officials Within the European Pharmaceutical Industry, Including Representatives of the AME (May 2020) [hereinafter AME Interview].

358. In a June 2020 conversation, we learned that the Pharmacy Division's requirements for adjusting pharmaceutical packaging and translating the leaflet represent a barrier to parallel imports in the pharmaceutical market. Interview with Head and Deputy Head of Pharmacy Division of the Ministry of Health (June 2020).

have extensive trade relations with its neighbors.[359] Therefore, import costs to Israel are relatively high.[360]

2. Price Control

In an unregulated market, parallel importers are expected to have a significant marketing advantage over official importers, as they can capitalize freely on price differences in different countries by purchasing products in countries where the price is low and selling them in countries where the price is high.[361] But Israel's price control mechanisms discussed in a previous section may impair the economic viability of parallel imports and reduce the ability of parallel importers to operate in the Israeli pharmaceutical market.[362]

Indeed, the Committee on Medical Cannabis studied the effect of price controls on medical cannabis products and reported that they represent a significant barrier to entry into the industry, and even push out small entities whose production costs are higher and have built-in disadvantages.[363] When there is price control, small players do not reach a level of profitability that justifies remaining in the industry.[364] While this report does

359. Some refer to Israel as an "island economy." *See*, *e.g.*, Michal S. Gal, *Market Conditions Under the Magnifying Glass: The Effects of Market Size on Optimal Competition Policy*, 50 AM. J. COMP. L. 303, 305 (2002).

360. Michal (Shitzer) Gal & Hila Nevo, *Regulating Concentration Groups*, 10 DIN U'DEVARIM 237, 249 (2017) (Isr.).

361. Margaret K. Kyle, *Competition Law, Intellectual Property, and the Pharmaceutical Sector*, 81 ANTITRUST L.J. 1, 20 (2016).

362. Incentives vary depending on the existence or absence of parallel imports. *See* Guo et al., *supra* note 278, at 346–4.. Other factors that affect the price offered to a retailer by the official importer include the bargaining power given to HMOs, and a decision to lower the price in order to prevent competing importers from entering the market. These may also lead to a decrease in the viability of parallel imports and the parallel importer's incentive to enter the Israeli pharmaceutical market. *See generally* Nissim Cohen, *Regulation in the Health System: Control over the Activity of the HMOs*, VAN LEER INST. (2014), http://hazan.kibbutz.org.il/hafrata/nisim_can_-_rgoltzia_shl_merct_habriaot_19_2_14.pdf (discussing the connection between the State Health Insurance law and its private aspects).

363. MINISTRY OF HEALTH, SUMMARY OF THE DELIBERATIONS OF THE PRICES COMMITTEE ON THE SUBJECT OF MEDICAL CANNABIS 31 (2020) [hereinafter COMMITTEE ON MEDICAL CANNABIS], https://www.gov.il/BlobFolder/dynamiccollectorresultitem/decision_14012020-b/he/decision_and_directives_Decision_14012020_b.pdf. For further information on the dimensions of limited competition in Israel, see PRESCRIPTION DRUG PRICING MODEL, *supra* note 26, at 24–25.

364. COMMITTEE ON MEDICAL CANNABIS, *supra* note 363, at 10, 31.

not specifically address challenges faced by parallel importers, the price control mechanisms that govern the Israeli pharmaceutical market function similarly to impair the economic viability of parallel drug imports.[365]

B. CONTRACTUAL BARRIERS

1. Restrictions on the Part of the Manufacturer

A manufacturer wishing to prevent parallel imports may place contractual restrictions in its agreements with various parties in the import chain, or by differentiating the products sold in different markets.[366] In the pharmaceutical market, the manufacturer may prohibit the retailer from selling its products to third parties or restrict its authorization to do so to a particular geographical area.[367] The manufacturer may also employ non-contractual schemes to make parallel importation impossible. For example, it can differentiate among products to adapt them to local markets, including by changing the name or appearance of the product and editing the graphic elements in terms of the location, size and composition on the packaging.[368] The Lang Committee report notes that practices such as these may limit the range of products available for parallel importation, disrupt supply continuity, and create differences between the product provided by the official importer and products imported through parallel import.[369] These differences make parallel importation more difficult, as the parallel imports cannot easily substitute for the official import, thus contributing to the retailer's dependence on the official importer.[370]

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365. Another reason is that the pharmaceutical market in Israel is a centralized market due to the insurance structure that characterizes it. *See* Prescription Drug Pricing Model, *supra* note 26, at 10.

366. LANG COMMITTEE, *supra* note 334, § 4.2.

367. Pharmaceutical manufacturers can enforce these restrictions by comparing the quantity purchased and the sales volume of the retailer or tracking a batch number to locate the source of the drug purchase. *Id*. In a June 2020 conversation, we were told that the drug companies usually locate the source of the goods by tracking the batch number that appears on the drug. Interview with Adv. Yoel Lifshitz (June 2020).

368. LANG COMMITTEE, *supra* note 334, § 4.2.

369. *Id.*

370. *Id.*

2. Restrictions on the Part of the Official Importer

Along with the barriers arising from the manufacturer's business practices, the Lang Committee also reports concerns that official importers may exploit their ties with international manufacturers and retailers to block the entry of new importers, especially parallel importers.[371] Such behavior would harm competition and perpetuate market power.[372] Moreover, the retailer's dependence on a dominant importer makes the retailer unlikely to complain about the importer's abuse of its market power.[373]

It is likely that such conduct occurs in the Israeli pharmaceutical market since it is a small market characterized by a limited number of dominant suppliers.[374] These suppliers tend to enter into long-term agreements with the HMOs,[375] which restrict the ability of HMOs to contract with parallel importers and can prevent them from entering the market.[376]

In addition, the HMOs must ensure a regular supply of medications for the citizens of the State of Israel.[377] Parallel importers may find it difficult to provide a regular supply over time, as they are dependent on other factors, including retailers

371. *Id.* § 4.1.

372. *Id.*

373. *Id.*

374. *Id.* There are drug importers in the market who are also drug manufacturers. Most of them also serve as distributors of the drugs they market, but there are also entities that specialize in drug distribution. THE PRO. COMM. FOR HEARING COMPLAINTS, *supra* note 79, at 6–9.

375. LANG COMMITTEE, *supra* note 334, § 4.1. In all HMO negotiations, parallel imports are used as a bargaining tool between HMOs and drug manufacturers and marketers. Interview with Hadas Rotem Rabinovich, Head of the Pharmacy Division at the Ministry of Health, & Eli Marom, Deputy Head of the Pharmacy Division at the Ministry of Health (June 2020). Similar information was provided to us in talks with European pharmaceutical companies, including representatives of AME. AME Interview, *supra* note 357.

376. For comparison, see Gal & Nevo, *supra* note 360, at 275 (discussing contractual barriers to entry into the infant formula market). *See also* Assaf Weiniger, *Public Inquiries Regarding Prices of Infant Food Compounds*, KNESSET RSCH. & INFO. CTR. 2 (2011), https://main.knesset.gov.il/Activity/Info/MMM/Pages/document.aspx?docId=81536b58-e9f7-e411-80c8-00155d010977&businessType=1.

377. In a June 2020 conversation, it was stated that HMOs are committed to the continuous care of their patients. Interview with Rabinovich & Marom, *supra* note 375. Therefore, the HMOs cannot rely on parallel importers who may have a limited inventory of drugs. Similar information was provided to us in talks with European pharmaceutical companies, including representatives of AME. AME Interview, *supra* note 357.

operating in markets outside Israel.[378] The official importer usually will not encounter this difficulty, as it purchases the drug directly from the drug manufacturer or, alternatively, manufactures the drug itself. Thus, in practice, the official importer can put pressure on HMOs or provide them economic incentives to prevent competitors—including parallel importers—from entering the market.[379] This conduct may deter HMOs from contracting with a parallel importer even if the parallel importer offers more advantageous terms.[380]

C. ASYMMETRY IN INFORMATION

Complete and accurate information is usually a required condition for a perfectly competitive market.[381] Economic theory assumes that rational players in a perfect market can make informed decisions based on reliable and complete information.[382] In the absence of full and equal access to information, however, some players in the import market cannot operate effectively, and the market does not reach optimal equilibrium.[383] However, the pharmaceutical market is not a sophisticated market because it is, in part, dominated by small number of buyers (HMOs) who exercise monopsony power in the purchase of drugs. Moreover, there are information gaps in the Israeli pharmaceutical market between the official importer and those who seek to import drugs through parallel importation, as well as between regulators and HMOs. These information gaps can create an environment that excludes potential players from entering the Israeli market.

It is important to emphasize that information gaps and lack of transparency regarding drug prices are not unique to the Israeli health system, but also exist in many other countries. Accordingly, and in view of rising drug prices around the world, the World Health Assembly (WHA) Health Council approved a decision in May 2019, which encouraged governments and other procurement entities (such as health funds) to share drug pricing information, including patent information, clinical trial

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378. LANG COMMITTEE, *supra* note 334, § 4.2.

379. For a discussion of this issue, see *id.* § 4.3.

380. *Id.*

381. OPENSTAX, PRINCIPLES OF ECONOMICS ch. 8.1 (2016), https://opentextbc.ca/principlesofeconomics/.

382. *Id.* ch. 16.

383. *Id.* ch. 16.1.

results, drug efficacy, and other variables.[384] This decision was intended to improve transparency in the pharmaceutical industry and promote institutional cooperation, while also addressing information gaps and rising drug prices.[385]

A 2011 report by Professor Roni Gamzo to the Director General of the Ministry of Health offers an example of the information gaps created by HMOs and pharmaceutical companies and illustrates how these gaps make it difficult to control and monitor drug prices.[386] The report was intended to examine the issue of product surplus and budget deficits resulting from additions to the basket of health services from 1998 onwards.[387] The report reveals numerous obstacles to obtaining the necessary information from the HMOs, some of which could not provide information for the years under review (1998–2006).[388] Due to the difficulties in accessing information, the report provided a reduced study limited to the year 2006 for which data could be obtained from HMOs regarding drugs that were included in the drug basket under the budget supplement portion of the budget.[389] The report criticized the lack of available information and found that while the budget additions to the basket in 2006 were higher than the fund's uses for that year, similar conclusions should not be drawn with respect to other years and further analysis was required to formulate reliable conclusions regarding the gaps between budgeting and

384. World Health Assembly Res. 72.8, ¶ 1 (May 28, 2019), https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf.

385. *Id.*

386. RONI GAMZO, REPORT TO THE DIRECTOR GENERAL OF THE MINISTRY OF HEALTH 4–5 (2011), https://www.health.gov.il/PublicationsFiles/tt190511.pdf.

387. *Id.*

388. *Id.* at 5. Reasons included: (a) failure to store computerized information or modification and replacement of computer systems; (b) failure to document uses according to the labels but only the total expenditure pertaining to each drug; (c) failure to maintain complete and detailed information on the budget the health services basket committee approved for each technology; (d) discrepancies between the nominal budget data used in the health services basket committee's decision-making and the nominal budget data used to calculate the estimated monetary value of actual transfers to the HMOs; (e) lack of clarity regarding the manner in which the prices of alternative medicines were calculated by the Drug Basket Committee; and (f) absence of a central database regarding medical procedures, resulting in incomplete matches between the medical procedure included in the health services basket, as published in the Ministry of Health's CEO and Medical Director's circulars, and the data found in the Ministry of Health. The report also indicated that information deficits were due to the HMOs' fear of disclosing internal commercial information to external parties. *Id.* at 21.

389. *Id.* at 6.

use.[390]

Although the Ministry of Health has the authority to demand information from HMOs pursuant to the provisions of section 40A of the National Health Insurance Law, the information provided to us by various sources in the industry indicates that HMOs refrain from providing complete information about their drug purchase prices on confidentiality grounds. As mentioned, our attempts to obtain information about drug prices for this study were also unsuccessful.

Complete and comprehensive information on drug market prices helps various entities—including parallel importers—to compare and evaluate drug purchase options in other countries. This information may even be helpful in negotiating drug prices or revealing an economically unwise drug purchase. The lack of such information impairs the legal collection, analysis, and distribution of business information about competing suppliers and the market itself as part of market intelligence. Because HMOs in the Israeli market conduct negotiations with the pharmaceutical companies, it is difficult for drug consumers and potential competitors to assess their viability in the absence of information about these transactions. That is, in the absence of information, the parallel importer must act by way of trial and error.

In 2012, a database of pharmaceutical prices was proposed, which could have, among other things, facilitated the parallel importation of drugs and reduced information gaps in the Israeli pharmaceutical market.[391] But the Antitrust Commissioner rejected a request from Market Watch to establish this database in cooperation and by agreement with drug manufacturers and drug importers.[392] The database was expected to provide drug buyers in Israel (such as health funds and pharmacies) with information on the market share of each drug marketed by each

390. *Id.* at 5–6.

391. *See* Competition Authority, Decision Regarding Non-granting of Exemption from Approval of a Restrictive Arrangement: Market Watch Ltd. Drug Manufacturers and Importers of Humane Drugs to Israel (Aug. 16, 2012).

392. Tadmor Levy & Co., *Pharmaceutical Antitrust in Israel,* LEXOLOGY (Apr. 16, 2019), https://www.lexology.com/library/detail.aspx?g=a3702527-9671-4098-805f-29d2f3bfe686. Market Watch is a company that conducts market research and opinion polls for various clients, including in the field of health. It is a subsidiary of the multinational research company Synovate, which also operates in the fields of health and pharmaceuticals. *Market Watch Israel Overview*, PITCHBOOK, https://pitchbook.com/profiles/company/161168-32#overview.

of the importers or manufacturers entering into the agreement.[393] The signatories agreed to furnish information on their sales once a month so that the database could continuously provide up-to-date information to industry competitors.[394]

The Antitrust Commissioner expressed concerns regarding the competitive effect of the proposed arrangement and declined to authorize it.[395] According to the Commissioner, companies operating in the market may need certain types of information to make effective decisions regarding their production and marketing strategies and to contribute to social well-being.[396] However, in uncompetitive markets, certain information may pose a real danger to competition. He added that up-to-date market share information on each of the competitors may be used as a tool for monitoring and enforcing explicit coordination, or tacit understanding, among competitors.[397] This information may remove the uncertainty that contributes to a competitive process in the market.[398] Accordingly, given the characteristics of the industry in Israel, the Commissioner determined that the requested database raised real anticompetitive concerns.[399]

The scholar Margaret Kyle, in addressing information gaps in the pharmaceutical market, has noted recent calls for greater transparency in drug pricing.[400] Agreements between manufacturers and governments are not always transparent to the public in terms of transaction terms and drug prices.[401] Disclosure of these agreements may reveal vital information including quantity limits, volume discounts, and manufacturer rebates.[402] Lack of information, however, makes it difficult to know the actual price the government pays for each drug.[403] Kyle observes, however, that pricing transparency for medications could harm weaker countries, which receive high discounts as compared to the prices for the same drugs in other countries.[404] On the one hand, information gaps constitute a barrier to

393. *See* Competition Authority, *supra* note 391.
394. *Id.*
395. *Id.*
396. *Id.*
397. *Id*.
398. *Id*.
399. *Id*
400. Kyle, *supra* note 236, at 133.
401. *Id.*
402. *Id.*
403. *Id.*
404. *Id.* at 133–34.

parallel imports, as the lack of information about transactions impairs the ability of importers to assess the viability of their entry into the market. However, on the other hand, too much transparency and detail about transactions and terms of sale in the pharmaceutical market may also harm competition, as the Antitrust Commissioner determined in the Market Watch case.

CONCLUSIONS

The term "parallel importation" describes the practice of importing products by a non-official importer for sale in the domestic market. For many years, Israeli law imposed severe restrictions on parallel imports in the pharmaceutical market, but legislative changes in the early 2000s authorized parallel importation of medications into Israel. Because parallel imports are seen as a tool to encourage competition, the prevailing assumption was that these changes would stimulate competition and curb Israel's alarming rise in drug prices and healthcare expenses. That prediction has not come to pass: parallel drug imports are nearly non-existent in the State of Israel.

This article has examined the issue of parallel imports in Israel from theoretical, comparative, and empirical perspectives. We discussed the unique characteristics of the pharmaceutical market, and the manner in which drug prices in Israel are theoretically determined and supervised. We also conducted a comparative study that examined parallel import policies under European law and American law, as well as in developing countries. The comparative study found that in Europe, parallel importation of medications is one of the primary and accepted ways of lowering drug prices. Even in developing countries, parallel imports have been found to be an important and essential channel for lowering drug prices.

Although our study confirmed that there is almost no parallel importation of medications into Israel, our empirical evidence reveals that the maximum price of most prescription drugs decreased between 2007 and 2020. We note in this connection that the maximum price to the consumer (or retailer) is a *maximum* price, and it is possible that HMOs negotiate for and receive discounts that are not made public. Assuming, however, that HMOs pay less than the maximum published drug prices, it stands to reason that the opening of the Israeli market to parallel imports improved the bargaining power of the players in the pharmaceutical market and indirectly led to price

reductions in the Israeli drug market. Indeed, as we explained, parallel imports tend to produce both direct and indirect savings. While we are unable to say with confidence whether the regulation of drug prices in Israel brings about low prices, it is possible that the citation method yields prices similar to those in European countries, where there exists an active parallel import market for drugs. This requires further economic investigation in future studies.

The last part of our study examined possible barriers that may impair the ability to undertake parallel importation in the Israeli pharmaceutical market. We addressed three main categories: regulatory barriers, contractual barriers, and barriers resulting from asymmetry in information. Additionally, because HMOs must ensure continuity in drug treatment to their patients, they may prefer to rely on an official importer—who can offer a continuous and prolonged supply of drugs—rather than on a parallel importer. Future studies can further examine these barriers empirically and assess their impact on market entry by parallel importers in the Israeli pharmaceutical market.

This study opens up new research horizons on the complex interaction between price regulation and parallel importation in the Israeli pharmaceutical market. While it uncovers the promise of price regulation by demonstrating a consistently downward trend in most prescription drug prices, it does not clearly answer whether such regulation necessarily leads to lower prices. Opening up the market for competition by parallel importation appears to be a reliable strategy for lowering drug prices, yet it has not been used at all in Israel. Understanding why so few entities have taken advantage of the amended regulations to engage in parallel importation requires further scholarly attention.