



Report of the State Comptroller of Israel | May 2022

Ministry of Health

Expansion of the Health Services Basket – The Addition of Medications and Technologies



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Background

The National Health Insurance Law, 1994, determines, among other things, the medical services the members of the Health Maintenance Organizations (HMO) in Israel are entitled to that are included in the Health Services Basket (the Basket). The expansion of the Basket allows for the addition of new technologies – medications, medical devices, medical equipment, and medical, diagnostic, and therapeutic procedures (Medications and Technologies). It is also designed to enable the continued fulfillment of the objectives underlying the Law, to realize the latent possibilities in these Medications and Technologies and the scientific developments, and to provide patients with a service corresponding to these developments.

The Basket Committee examines new Medications and Technologies and recommends to the Minister of Health, which should be added to the Basket within the given budget. The budget is determined every year in the ongoing discussions between the Ministry of Finance and the Ministry of Health, according to the Government's State Budget priorities. From 1998 to 2021, a sum of about NIS 8 billion was allocated for expanding the Basket. The Ministers of Health and Finance appoint the Basket Committee's members, including representatives from the medicine, ethics, and social fields. Members of the Committee include representatives from the Ministry of Health, the Ministry of Finance, the HMOs, and the public.

The Basket updating process is anchored in a designated procedure from 2010 – "Procedure for Updating the Health Services Basket – February 2010", that determines the work procedures, the composition of the Basket Committee, and the operation criteria. The process for expanding the Basket lasts about one year and is divided into several stages: publication of a Request for Proposals; submitting requests; professional processing of the proposals and holding Technologies Forum discussions at the Ministry of Health; discussions of the Basket Committee and the sub-committee; and Government approval for the expansion of the Health Services Basket.



Key figures

**NIS 58
billion**the Health Services
Basket budget for
2021**NIS 500
million**the annual addition to
the Health Services
Basket in each one of
the years 2017–2021**15%**the average rate of
requests rejected by
the Technologies
Forum¹ from 2018 to
2021 and did not
reach the Basket
Committee for
discussion**109–160
Days**the delay in business
days until the
protocols publication
from 2018 to 2020**62%**the financial part of
the ten most
expensive
Medications and
Technologies added
to the Basket from
2016 to 2021**31%**the quantitative part
of the free-of-charge
Medications and
Technologies included
in the Basket from
2016 to 2021**NIS 506
million**of the addition to the
Basket were
accumulatively
allocated from 2015 to
2021 for medications
for "orphan diseases"²**71**the number of risk
allocation
agreements and
unilateral
undertakings from
2016 to 2021

Audit actions

 From November 2020 to October 2021, the State Comptroller of Israel conducted an audit on the Health Services Basket expansion by adding Medications including: adding procedure of new Medications and Technologies to the Basket; transparency of the activity of the Basket Committee and its associated bodies; pricing of the Medications and Technologies and the risk allocation agreements; drawing conclusions from the decisions implementing method of the Basket Committee and control over the matter. The examinations were conducted at the Ministry of Health in the Medical Technologies, Information and Research Unit, the Supervision of Health Maintenance Organizations,

- 1 The Technologies Forum at the Ministry of Health examines all the requests submitted for expansion of the Basket and determines whether they comply with the conditions required for transferring them for continuation of discussion.
- 2 "Orphan diseases" are rare diseases. This is a group of severe, progressive, degenerative, life threatening, chronic and low frequency diseases. There is no worldwide uniform definition for these diseases.



and Complementary Health Services Division; in four HMOs: Clalit Healthcare Services, Maccabi Healthcare Services, Meuhedet Health Fund, and Leumit Health Services, and at the Ministry of Finance. Supplementary examinations were conducted in the medical professional unions at the Israeli Medical Association and the Public Complaints Commission at the Ministry of Health.

Key findings



Determination of the technological component budget addition in the Basket

– several attempts have been made over the years to anchor in law³ the mechanism for updating the technological coefficient. It was raised that in most years, the annual technical update addition rate to the Health Services Basket, out of the entire cost of the Basket, was smaller than recommended by the committees: in 21 (about 90%) out of the 24 years from 1998 to 2021, the addition rate was less than 1.5%, the lowest threshold recommended by the committees; in four (about 15%) out of these 24 years it was even smaller than 0.8%, the rate defined by the German Committee as necessary for preserving the quality of the medical services provided by the Basket.



Combining the services included in the Third Schedule to the Law in the Health Services Basket update

– since 2015 and until the completion of the audit in October 2021, there were no Government decisions concerning the update of the Services Basket regarding the Third Schedule to the Law, services provided by the Ministry of Health⁴. The approval that the sum allocated for the expansion of the Basket should also be used for funding this addition is retroactively granted every year when the Government approves the Basket Committee's recommendations. In each of the years from 2015 to 2021, an average of about 2.5% of the annual budget – about NIS 74 million – were added to the Health Services Basket and were designated for funding the services included in the Third Schedule.



Transparency in the approval process of the Health Services Basket expansion

– it was found that the transparency model in the expansion of the Health Services Basket is deficient:

- **Technologies Forum** – from 2018 to 2021, the Technologies Forum rejected 46% of the requests for the inclusion of technologies that are not medications and 9%

3 This coefficient is designed to keep the Basket updated with novelty Medications and Technologies which enable a considerable improvement in the quality of life of many patients and may even save their lives, and whose effectiveness has already been proven in clinical trials.

4 For example: personal preventive medicine; devices for rehabilitation, walking and mobility.



of the requests for the inclusion of medications, yet the rejection details are not presented to the Basket Committee. Thus it does not have a complete situation report concerning the submitted requests, and bodies related to the expansion of the Basket process cannot conclude about the characteristics of the rejected requests.

- **The sub-committee**⁵ – all its members are Government and HMOs' representatives, and there is no representative from the public; even journalists are not allowed at its discussions, although they are allowed to attend the discussions of the Basket Committee. In addition, the sub-committee's protocols are not published to the public.
- **The Basket Committee** – in 2018–2020, the protocols of its discussions are published after delays of 109 to 160 business days, adversely affecting transparency and may hinder submitters of rejected proposals from submitting updated requests as soon and as relevantly possible.



Financial evaluation as a decision-supporting tool in updating the Health Services Basket – the "Procedure for Updating the Health Services Basket – February 2010", determines that a financial evaluation should be submitted when requesting the addition of Medications and Technologies to the Basket, and the "Procedure for Submitting a Request to Include a Preparation ('Medication') in the Health Services Basket," requires to be followed as much as possible. Yet the Basket Committee decides based on a professional evaluation, with no financial evaluation, as opposed to standard practice in advanced countries worldwide. Only one financial evaluation was submitted to the Basket Committee in 2018–2020.








Evaluating the anticipated number of patients according to the diseases records – although the diseases records⁶ (to which information about the number of patients is added and monitored) may serve as an essential database for a well-founded evaluation of the patients' number of recorded diseases and their development stages, it was found that according to the existing regulation, even in mandatory cases to provide information, the registrars cannot enforce or impose any sanctions on bodies which do not fulfill their reporting duty. Thus, the national databases for recording diseases information, are not necessarily updated, and cannot serve as a reliable source for morbidity evaluation rate and a reliable allocation of the specific addition.

5 The sub-committee collects data according to which it prices the budgetary addition required for the Medications and Technologies submitted and presents the pricing to the Basket Committee.

6 Diseases records – are kept, among other places, at the Gertner Institute for Epidemiology and Health Policy Research Ltd., at the Israel Center for Disease Control, and at the Information Division at the Ministry of Health. Likewise, unofficial records are kept on behalf of professional associations at the Israeli Medical Association and at the HMOs, which keep designated records.



-  **Use of therapeutic alternatives – "class effect"⁷** – despite the ongoing principle argument regarding the definition of medications as a class, the Ministry of Health has not determined guidelines for the definition of medications as a class effect.
-  **Addition of medications to the Services Basket without any extra cost** – from 2016 to 2021, the rate of free medications included in the Basket was about one-third of the annual technological update. It was found that the adding process for these medications is similar to the adding process of any medication or other technology to the Basket; even though no extra cost is involved, the process is carried out once a year and only then is it possible to approve their addition to the Basket.
-  **Risk allocation agreements** – notwithstanding the complexity of the process of formulating risk allocation agreements, the Ministry of Health has no procedure or guidelines to regulate it, including the need to identify cases requiring signing risk allocation agreements; the need for advisory bodies; determining who is the responsible party; the method of including the HMOs in deciding the terms of the agreements; the necessary control processes when performing the process and after that, and determining the schedules. It was found that the sub-committee's work procedure draft, circulated for the HMOs remarks in August 2021, partially deals with the subject and, as of the date of the audit's completion, had not been approved; the Ministry of Health does not analyze the risks to which the HMOs will be exposed when the agreement expires when the discounts the HMOs received under the agreement will end, and it does not examine expired agreements to learn about the prices after the agreement has expired. Neither does the Ministry examine the extent the agreements are exhausted – some were used to a greater extent than the determined forecast, and some to a lesser extent, to draw conclusions that can be applied in future agreements.
-  **Ministry of Health monitoring the HMOs' use of the Basket additional budget and concluding** – the Ministry of Health relies upon data delivered by the HMOs when pricing the Medications and Technologies in the sub-committee, but it does not examine the extent to which they are used after their addition to the Basket. This may overprice a medication or technology at the expense of other Medications and Technologies that consequently were not added to the Basket. This may under-budget a medication or a technology. A draft report on allocation compared to use was submitted to the then (2018) Director-General of the Ministry of Health about 10 years after the examination period (2007–2009), and the Ministry published the final report three years later, in January 2022. Only in 2021 did the Ministry begin to examine the years 2010 and later.
-  **Oncological medications and expensive Medications and Technologies** – it was found that the additional cost of the 10 Medications and Technologies was the highest cost from 2016 to 2021 relative to the total addition cost (they constitute 62% of the cost of the entire addition, about NIS 1.7 billion out of approximately NIS 2.7 billion).

7 Medications defined as class effect are medications belonging to the same therapeutic group, even if they do not contain the same active ingredient.



Though the addition for the oncological medications was 37% of the total addition for these years, the Ministry of Health did not control their use and efficiency, to conclude for future addition decisions of costly Medications and Technologies.



Public participation – the Ministry of Health's inclusion of the public in the Health Services Basket expansion process should be commended.

Transparency in the media and the Ministry of Health website – journalists, who can report to the public about the discussions at the end of the process, are allowed to be present at the discussions of the Basket Committee. The Basket Committee also publishes its critical decisions on the Ministry of Health website shortly after the discussions.

Key recommendations



It is recommended that the Ministries of Health and Finance, in conjunction with the HMOs, examine the impact of the determining method of the technological coefficient amount relative to the methods used in developed countries worldwide and whether it should be regulated. Likewise, it is recommended to consider determining a minimal annual update rate of the coefficient, to reduce the planning uncertainty level, enable long-term planning and optimally meet the requirements of technological advancement.



It is recommended that the Ministry of Health examine the appropriate reporting mechanism of the Technologies Forum's decisions, and determine this as part of the Health Services Basket Updating Procedure – who should be given notice of the decisions and how these notices will be drafted. This will enable to study of the considerations underlying the Forum's decisions on whether a suggested medication or technology is appropriate or inappropriate for discussion by the Basket Committee. Increasing the transparency of the process will optimize the work of all the bodies involved and the public's trust in the process.



It is recommended that the Ministry of Health determine criteria and the appropriate ways for the financial evaluation of Medications and Technologies. It is recommended that this be carried out in consultation with the relevant bodies. It is further recommended that the Ministry consider expanding the manpower, providing financial evaluations, and updating its procedures accordingly.

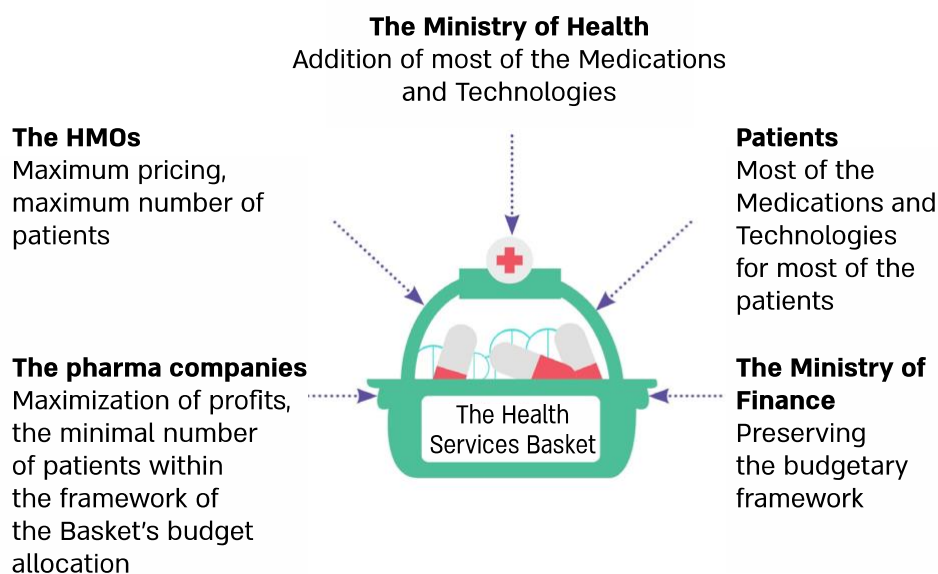


It is appropriate that the Ministry of Health, in conjunction with the HMOs, systematically examine the financial effects of adding medications without any cost to the Health Services Basket, including considering learning from other countries. Following the

examination findings, they should consider discussing their addition on a separate fast track without having to convene the Basket Committee. It is further appropriate that the Ministry, in conjunction with the HMOs, periodically control the financial implications of adding medications without any cost to the Health Services Basket.

- 💡 The risk allocation agreements are complex, and professional knowledge and expertise are required in drafting them; therefore, it is recommended that the Ministry of Health finish formulating the relevant procedure, considering all the stages of the process, including the monitoring and tracking process of the agreements implementation, and concluding from their implementation.
- 💡 It is recommended that the Ministry of Health draw conclusions and formulate recommendations for improving the work processes of the Basket Committee and the sub-committee. Likewise, it is recommended that the Ministry determine the minimum frequency for control over allocation compared to uses and implement the previous control recommendations. Regarding the supplementary control by the Ministry on the budget allocation from 2010 to 2020, it is recommended that it relate to the HMOs' remarks in the previous controls, draw conclusions from the arising findings, and examine them within this framework.

Factors influencing the addition to the Health Services Basket





Summary

The expansion of the Health Services Basket allows the addition of advanced Medications and Technologies to the Basket out of public funds. The decision to prioritize the requests is ethical, accompanied by deliberations, as each request is essential. Still, due to budgetary constraints, it is impossible to include all the requested Medications and Technologies in the Health Services Basket. It is recommended that amendments and improvements are made in the Basket's expansion process to better exhaustion of the Health Services Basket budget to the entitled public. In light of this report's findings, given the Basket Committee has been acting for over twenty years with no complete control reports, it is of great importance that the Health Council and the Ministries of Health and Finance examine all the Committee's activities to improve its functioning. Thus, the patients can get the most out of the health services included in the Basket.