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Information Page: The Coronavirus Vaccine Approval

What is the difference between "Approval" and "Emergency Authorization Use," and why does it matter?

The Public Emergency Council for the Covid-19 Crisis recently turned to the Ministry of Health with a demand to change the various Ministry advertisements in which the claim is made that the vaccine was approved by the American Federal Drug Administration (FDA) and that the vaccine passed all stages of testing, similar to all other medications and vaccines.

Council members did not take this step due to their opposition to vaccinations – almost all of the members have been vaccinated. The demand stemmed from council members' stance that, at this time of crisis, the need for professional and ethical conduct, transparency and reliability is especially vital. Accordingly, council members surmised that citizens must receive information regarding the vaccine that is precise and conveyed clearly.

[After legal action](#), the Ministry of Health changed the wording and removed the subtitles from informational videos that claimed that the vaccine was approved by the FDA so that they would correspond more accurately to the necessary definition of "Emergency Authorization Use." This is in light of the fact that **the vaccine is still not approved by the FDA, as it has not completed all of the accepted steps for vaccine approval as required by the FDA.** What actually is the debate about? What difference does it make if the vaccine is approved by the FDA, and what is the meaning of emergency approval?

The American FDA is responsible for the regulation and approval of medications, vaccines, medical equipment and medical treatments. Above and beyond its status as a federal agency of the United States, the FDA serves as a guiding body on a world-wide level. Many countries, Israel among them, depend almost totally on the FDA's approval process for their own national levels of approval. For example, Israel has never approved a vaccine that has not been previously approved by the FDA, except in one instance (the Sci-B-Vac), use of which was halted and results of which [are still being debated in court](#).

[There is no FDA approved vaccine for covid-19 virus.](#) The vaccinations were developed in record time and it was not possible to complete the research needed to receive approval. The permission granted to Pfizer and other companies is solely **Emergency Use Authorization, and the vaccine is defined as "Investigational"**. The permission granted protects the pharmaceutical companies in that damaging side effects caused by the vaccine will be legally defined under the lenient heading, "Investigational Vaccine" and not "Approved Vaccine." This legal defense is the reason why [Pfizer's CEO emphasizes](#) that the vaccine has yet to receive FDA approval. In instances of Emergency Authorization, the FDA directs that [those being vaccinated must be informed](#) regarding:

- The investigational nature of the medication (and that it is not approved via the regular required process).
- The possible benefits and possible risks
- Possible alternatives to treatment
- The patient's full right to refuse treatment.

Moreover, every person must receive a detailed information page that includes various data about the vaccine.

[This information leaflet](#) is translated into 29 languages on the FDA website, including Somali and Yiddish, though unfortunately (for no clear reason), it was not translated into Hebrew.

In conclusion, the difference between full Approval and Emergency Use Authorization is: medications under Emergency Use Authorization, including all currently available corona vaccines, have not yet completed FDA-defined research requirements. In other words, all of the information necessary for full approval has yet to be received, according to [the FDA's own website](#).

For those interested in looking deeper into the matter, the corona vaccines "skipped" a stage in the development process: corona vaccination experiments were meant to be completed in 2023, after two years of long-term follow-up on people receiving the vaccination, in order to determine, among other reasons, if there are medium- or long-term side effects. Due to worldwide pandemic data, the FDA gave emergency permission without this stage. Unfortunately, when primary research results became known, the FDA decided to allow Pfizer to vaccinate the research control group as well, significantly damaging the ability to identify future long-term side effects.



It is important to note the difference between experimental treatment of an illness and a vaccine whose stages of research have yet to be completed. An individual suffering from an illness who chooses to take an experimental medication is a person in pain and suffering who expresses a willingness to take a certain risk considering that there is the possibility of recovery. A person receiving a vaccine that has yet to be approved is a totally healthy individual, therefore the vaccine should require a higher level of safety in order to avoid the worsening of the patient's condition, in accordance with the first rule of medicine – first, do not cause damage (*Primum, non nocere*). This is especially important as the Pfizer vaccination's promising technology, the mRNA vaccine, is an innovative technology that has yet to be incorporated in a vaccine. These are the first vaccines of their kind in the world permitted for use on human beings, and they comprise a new category of vaccination treatment. Accordingly, many questions still do not have answers – from effectiveness to safety. Moreover, in the past, [a number of corona vaccines were rejected due to concern of severe side effects.](#)

It is important to note that the Ministry of Health is an independent body, not subject to the FDA. Thus, for example, the Ministry of Health decided to encourage vaccinations for pregnant women in all stages of pregnancy, despite that many agencies throughout the world are holding back due to a lack of evaluated information from studies on this topic and fear of possible damage to the fetus. Likewise, the Ministry of Health recommended "booster" shots for those recovered from Corona, despite the fact that this has not been recognized as accepted protocol elsewhere in the world.

We would like to emphasize that despite all of the above – it does not mean that a vaccine given Emergency Authorization Use is not safe. **The significance of the above is that, by definition, all of the required safety tests have yet to be completed, and therefore it is not possible to testify to the safety of the vaccine according the accepted and necessary standards required by the FDA for granting approval.**



The Members of the Council* (in alphabetical order)



Dr. Yifat Abdi-Kork

An expert in epidemiology and molecular biology, served as a Consultant to the national health basket public committee and Head of Pharmacoeconomics Department, Israeli Center for Technology Assessment in Health Care, the Gertner Institute.



Prof. Zvika Granot

Professor of Immunology in the Faculty of Medicine at the Hebrew University. An international expert in the field of neutrophil research, is developing new approaches to immunotherapy.



Dr. Bruria Adini

PhD in Health Systems Management, serves as head of the Department of Emergency and Disaster Management at Tel Aviv University. Former Head of the IDF Emergency Preparedness Division (Lt. Col.) and Senior Consultant to the Ministry of Health's Emergency Division.



Dr. Michal Hemo Lotem

Pediatrician, Entrepreneur and author on leadership at medical futurism. Served as Vice President of Innovation at the Sheba Medical Center, and as a member of the Prime Minister's Advisory Council. Founded Beterem - Safe Kids Israel, and OSHEYA - Women Lead Wellness. Received Prime Minister's special Award for her contribution to children.



Prof. Amos Adler

Professor of Medicine in the Department of Epidemiology and Preventive Medicine, Specialist in Pediatrics and Clinical Microbiology. Director of the Microbiological Laboratory at Sourasky Medical Center Tel Aviv, Treasurer of the Israeli Association for Infectious Diseases.



Prof. Asa Kasher

Professor Emeritus of Professional Ethics and Philosophy at Tel Aviv University. Laureate of the Israel Prize for Philosophy. Member of the European Academy of Sciences and Arts. Wrote dozens of state and public codes of ethics, including the military code of ethics, as well as serving as a member of several national public committees



Prof. Elian Alkrinawi

Professor of Social Work, served as president of the Achva College, head of the Department of Social Work at Ben-Gurion University and as dean of the School of Social Work at Memorial University in Canada. Killam Award winner and beacon lighter at the 2013 Independence Day ceremony.



Prof. Amnon Lahad

Specialist in Family Medicine (ISR) and Public health (US). Head departments of Family Medicine Hebrew University & Clalit Health Services, Jerusalem, Israel. Vice Dean Academia – Family medicine, Hebrew University. Chairman of the National Council for the Health of the Community. Active Family physician in Jerusalem.



Prof. Zvi Bentwich

Professor of Medicine, specialist in Clinical Immunology and Infectious Diseases. Served as Chief of Department of Medicine, and pioneered AIDS medicine in Israel. Currently Head of Center for Tropical Diseases and AIDS at Ben-Gurion University. President of NALA Foundation for the Control of Neglected Tropical Diseases in Developing Countries and Board Member of Physicians for Human Rights in Israel.



Prof. Retsef Levi

Professor of Operations Management at the MIT Sloan School of Management. An international expert in safety, risk management and analytics-driven design and optimization of health systems and biologic drugs manufacturing systems. He is leading several large-scale research collaborations across the world with leading industry enterprises and government organizations. He has consulted multiple state governments during the COVID-19 pandemic.



Dr. Orna Blondheim

Specialist in Pediatrics and Neonatology as well as Director of Health Systems. She served as the director of the Schneider Children's Hospital and served 16 years as CEO of Emek Medical Center



Prof. Udi Qimron

Chair of the Department of Clinical Microbiology and Immunology at Tel Aviv University. Expert in T cells, mucosal vaccines, genetic engineering of bacterial viruses, and CRISPR. Published in Science, Nature and Cell and has won prestigious research grants including the ERC. Partner in the establishment of the SARS-CoV-2 testing laboratories.



Prof. Emerita Rivka Carmi

Professor of Medicine, Specialist in Pediatrics, Neonatology and Medical Genetics. Served as Director of the Genetic Institute at Soroka Hospital, Dean of the Faculty of Medical Sciences at Ben-Gurion University, Chairman of the Dean of Medical Schools Association, President of Ben-Gurion University and Chairman of the Board of Universities.



Dr. Amir Shachar

Specialist in internal medicine, cardiology, emergency medicine and health administration. Established and managed the Department of Emergency Medicine at Sheba Hospital, was deputy director of Meir Hospital and currently heading the ER at Laniado Hospital. Founded the Emergency Medicine department at Tel Aviv University.



Prof. Aaron Ciechanover

Serves as a Distinguished Professor at the Faculty of Medicine in the Technion-Israel Institute of Technology. Awarded with the chemistry Nobel Prize, as well as the Lasker Award, the Israel Prize, and the EMET Prize. He is a member of the US National Academies of Sciences (NAS) and Medicine (NAM), the Israeli National Academy of Sciences and Humanities, and the Pontifical Academy of Sciences at the Vatican.



Prof. Mordechai Shani

Professor of Medicine and Medical Management, Specialist in Internal Medicine. Winner of the Israel Prize. Served twice as Director General of the Ministry of Health and Director of Sheba Hospital, as well as Chairman of the Medicines Committee. Founded and managed the School of Public Health at Tel Aviv University, and also established and managed the National Institute for Health Policy Research.



Prof. Eran Dolev

Professor of Medicine, Military Medicine and Medical History, Specialist in Internal Medicine, Director of Health Systems and Ethics in Medicine. He served as Surgeon General of the IDF, as Director of the Internal Medicine Department, and as Chairman of the Ethics Bureau of the Medical Association and Head of the International Review Board of Tel Aviv University.



Prof Emerita Zahava Solomon

Lt. Col (ret). Recipient of the Israel Prize, the Emet Prize and The Laufer Award. Her research in Social Work and Psychiatric Epidemiology focuses on man - made trauma. Served as head of research in mental health IDF. Head of the School of Social Work and director of the Trauma I-Core, TAU and DSM-4 (APA) committee.



Prof. Asher Elhayany

Professor of Medicine, Specialist in Family Medicine and Public Administration. He served as the CEO of Meir Hospital, the director of the Central District at Clalit Medical Centre, and as the director of the United Health Fund. He served as chairman of the National Council for Health in the Community. Family doctor in the Negev.



Dr. Yoav Yehezkeili

Specialist in Internal Medicine and Medical Management. Lecturer in the Department of Emergency and Disaster Management at Tel Aviv University. Lt. Col. Res., One of the founders of the epidemic treatment team and evaluation programs for extreme biological incidents. Served as a hospital's deputy director, district physician, director of the primary care division in the HMOs. Medical consultant to KI research institute.



Prof. Eitan Friedman

Professor of Medicine in the Department of Genetics and Biochemistry, Specialist in Internal Medicine and Medical Genetics, PhD from the Karolinska Institute in Sweden. Established the Ontogenetic Unit and Clinic for High-Risk Women at Sheba Hospital, serves as chair of the Ministry of Health's Supreme Helsinki Committee.

*The opinions expressed are the individual opinions of the members, and do not necessarily represent the opinions of the institutions to which the members are affiliated.