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חטיבת טכנולוגיות רפואיות, מידע ומחקר

Medical Technology, Health Information and Research Directorate

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Subject: **MTIR directorate joins two FDA-led multinational initiatives focusing on oncology and generic drugs**

The Medical Technology, Health Information and Research (MTIR) Directorate has joined two multinational initiatives led by the US Food and Drug Administration (FDA) focusing on oncology drugs and generic drugs.

FDA-led Project Orbis is a platform for multinational regulatory dialogue aimed at reviewing designated oncology drug applications. Project Orbis members include the MHRA, TGA, SwissMedic, Health Canada, ANVISA and HSA, which the MTIR directorate has also promoted bi-lateral collaborations with. The Orbis Project will enable the submission of application to the MOH concurrently to their submission to the FDA. A specific guideline for sponsors on this matter will be issued in the next few weeks.

The FDA's Generic Drug Cluster, whose members include the MHRA, SwissMedic, EMA and Health Canada, will focus on policy issues and harmonization of regulatory requirements in the field of generic drugs.

Membership in these two initiatives joins a list of multinational and international forums, which the expert teams of the directorate have been taking part in over the past few years, such as the International Council for Harmonisation (ICH), the International Pharmaceutical Regulators Programme (IPRP) and the International Coalition of Medicines Regulatory Authorities (ICMRA).

This is another step in the long process of broadening the directorate's international regulatory collaborations, in order to secure the position of Israeli regulation as innovative, professional and forward thinking, and as a strong stake holder on the international regulatory front.