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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Medical Devices)
Subject:	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency

Delegations will find attached the Presidency flash for the meeting of the Working Party on Pharmaceuticals and Medical Devices on 21 May 2026. The draft agenda is set out in CM 2822/26.

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Presidency Flash Note
Working Party on Pharmaceutical & Medical Devices

Format 1+1

21 May 2026 10:00

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1. Adoption of the agenda

The Presidency will invite delegations to adopt the agenda set out in CM 2822/26.

2. Medical Devices and In-vitro Devices Regulation (MDR/IVDR)

At the meeting of the Working Party on Pharmaceuticals and Medical Devices on 21 May 2026, we will continue the examination of the Commission proposal for a revision of the MDR and IVDR. The discussion will be focussed on cluster 4 (st7254.26), which will be divided in two blocks:

- Block 1: proposed amendments to the provisions related to **post-market surveillance and vigilance** in Chapter VII, Sections 1 and 2, and Annex III of the MDR and of the IVDR. This block includes the manufacturer's post-market surveillance system, the Periodic Safety Update Report, reporting and analysis of vigilance cases, and the proposed new reporting of actively exploited vulnerabilities and severe cybersecurity incidents.
- Block 2: proposed amendments to the provisions concerning **the generation and documentation of evidence** in Article 32, Chapter VI, Annex II and Annexes XIV-XV of the MDR. This block includes the provisions on clinical evaluation, clinical investigations, post-market clinical follow-up, the Summary of Safety and Clinical Performance and technical documentation. It also includes the proposed amendments to the definition of 'clinical data' in Article 2(48) MDR and the proposed new definition of 'combined studies' in Article 2(73) MDR and Article 2 (75) IVDR, which is also included in the European Biotech Act (proposed new Article 2(44) of the Clinical Trials Regulation). Combined studies will be subject to the proposed new Article 14c of the Clinical Trials Regulation.

Like in previous meetings, the Commission will briefly explain the main elements of their proposed amendments at the beginning of each of those blocks.

Proposed amendments related to the generation and documentation of evidence regarding *in vitro* diagnostics in Article 29, Chapter VI, Annexes II, XIII and XIV of the IVDR will be discussed at the CWP meeting on 3 June 2026 as part of the discussions dedicated to IVDR specific topics. The discussions on 3 June 2026, however, will focus on IVDR specific issues and not repeat topics equally relevant for the MDR already discussed at the meeting on 21 May.

Did you know that…

Traditional sweets from Cyprus reflect the island's blend of Greek, Middle Eastern, and Ottoman culinary influences?



Many are made with nuts, honey, rosewater, citrus, syrup, and fragrant spices, often served with Cypriot coffee as gesture of welcome. Traditional Cypriot sweets are deeply tied to family traditions/gatherings, religious festivals, and island's hospitality.

Here are some of the most beloved traditional Cypriot sweets:

- **Loukoumia,** also known as Cyprus Delight, are soft, chewy, jelly-like cubes. They are made from sugar, water, and starch and usually flavoured with rosewater, bergamot, lemon, or mastic and dusted with powdered sugar. The town of Yeroskipou is especially famous for its loukoumia production.
- **Daktyla**, meaning "fingers," are rolled pastries filled with almonds, cinnamon, and sugar. They are baked and then dipped in syrup, creating a crunchy and sweet dessert popular during holidays.
- **Soutzoukos** is made by dipping strings of almonds or walnuts repeatedly into thickened grape must until a chewy coating forms. It resembles a sweet sausage and is especially associated with mountain villages and grape harvest season.
- **Palouzes** is another grape-based sweet made from freshly pressed grape juice thickened with flour or starch and flavoured with rosewater or nuts. It is smooth, rich, and deeply connected to rural winemaking traditions.
- **Glyko tou Koutaliou** literally means "spoon sweet." Fruits, nuts, or even vegetables are preserved in thick syrup and traditionally served on a spoon alongside cold water or Cypriot coffee. Common varieties include walnut, cherry, watermelon rind, bergamot, and grape.



- **Kattimerka** are fried pastries somewhat similar to pancakes or dough fritters. They are commonly drizzled with honey or syrup and sprinkled with cinnamon.
- **Shamishi** are crispy pastries filled with semolina custard, fried until golden, and coated in syrup. They are especially popular at fairs and celebrations.
- **Pasteli** is a chewy bar made from carob syrup and sesame seeds, reflecting Cyprus's historical carob production.