



Council of the European Union
General Secretariat

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (Biotech Act)
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 5 March (afternoon) and 6 March 2026. The draft agenda is set out in CM 1739/26 .



Presidency Flash Note
Working Party on Pharmaceutical & Medical
Devices
Format 1+2

5 March (afternoon) - 6 March 2026

The Presidency intends to hold substantial discussion on the Biotech Directive on 5 March (afternoon) and 6 March.

On 5 March (afternoon), the discussion will focus on GMMs. Delegations are encouraged to invite attachés from the WP on the Environment to this agenda item or to coordinate their position with them.

On 6 March, the Working Party will be devoted to the part concerning organs.

The Presidency's objective is to go through the text of the Directive on both days in order to gather comments from Member States and subsequently return with a compromise proposal for the next meeting. MS will also have the opportunity to send written comments until 11 March.

The planning of the meeting is as follows:

5 March 2026 14:30

1. Adoption of the agenda

The Presidency will invite delegations to adopt the agenda set out in CM 1739/26.

2. BTA Directive regarding the placing on the market of Genetically Modified Micro-organisms (GMMs)

Under this agenda item, the Commission will explain the key amendments proposed regarding the Directive on the deliberate environmental release and placing on the market of genetically modified organisms (Directive 2001/18/EC). The amendments address the placing on the market of genetically modified micro-organisms as or in products and aim at adapting regulatory requirements to latest scientific evidence and the specificity of microorganisms while maintain the safety standards of the GMO legislation. The Commission will address questions that were received from the Member States in writing after the last CWP.

6 March 2026 10:00

3. BTA Directive regarding the processing of Organs

Regarding the EU directive on organ transplantation, the Biotech Act introduces legal clarity on the possibility of processing organs ex-vivo (in between their collection from a donor and their transplantation into a recipient). Such processing practices are increasingly applied in order to maintain and improve organs, allow for more transplants, and eventually increase treatment options for over 50,000 EU citizens on the transplant waiting lists.

Did you know that...

Zivania (or *zivana*) is a traditional Cypriot pomace brandy distilled from grape pomace and local dry wines made from Xynisteri and Mavro grapes. Its name comes from the Cypriot Greek word *zivana* (ζιβανα), meaning “pomace.”

It is clear and colorless, with a light raisin aroma, typically 45% ABV (legally up to 60%), and contains no sugar or acidity.

Production dates to the late 15th century under the Venetian rule, which introduced distillation to Cyprus which eventually led to the creation of this unique drink. In 1949, British colonial authorities banned its production to favor British distilleries, though locals continued illegally until legalization in 1998. After **Cyprus** joined the EU in 2004, zivania was recognized as a Protected Geographical Indication (PGI), meaning it can only be traditionally produced in Cyprus.

There are several types of zivania, varying in production technique and additional ingredients (Classic, Flavored and Aged Zivania). Beyond being a drink and cultural symbol, zivania is used in folk medicine for wound disinfection, massages, compresses, and relief of colds, sore throats, and toothaches. Recently, it has also become popular in modern cocktails.

