Council of the European Union

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WORKING DOCUMENT

From:	Presidency
To:	Delegations
No. prev. doc.:	6070/24, 6789/24, 7355/24
Subject:	Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC *- Exchange of views*

In document 8216/24 INIT, in pages 5-6, the Article 24(4) is deleted. Therefore, the Article 24 should read as follows:

Article 24

Suspension of marketing, withdrawal from the market of a medicinal product, withdrawal of a marketing authorisation by the marketing authorisation holder

1. ~~In addition to the notification made pursuant to Article 116,~~ **T**~~t~~he marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, ~~together with the reasons for such action.~~ **based on the following grounds:**

~~The marketing authorisation holder shall declare if such action is based on the following grounds:~~

(a) the medicinal product is harmful;

(b) it lacks therapeutic efficacy;

(c) the benefit-risk balance is not favourable;

(d) its qualitative and quantitative composition is not as declared;

(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or

(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.

The marketing authorisation holder shall declare on which of the abovementioned grounds the action is based.

Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.

~~The notification of the permanent withdrawal of a medicinal product from the market or of the temporary suspension of the marketing authorisation, or of the permanent withdrawal of a marketing authorisation or of the temporary disruption in supply of a medicinal product shall be made in accordance with Article 116(1).~~

The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency.

~~When a marketing authorisation holder submits a notification pursuant to Article 116, it shall also submit a notification in accordance with paragraph 1 and declare, if any, the grounds listed in paragraph 2.~~

1a. If a marketing authorisation holder submits a notification pursuant to Article 116(1) for centrally authorised products, it shall concomitantly notify, without undue delay, in accordance with this Article [where that notification is also based on any of the grounds listed in paragraph 1]

2. The marketing authorisation holder shall make the notification pursuant to paragraph 1 if the action is taken in a third country and such action is based on any of the grounds set out in **paragraph 1**~~Articles 195 or 196(1) of [revised Directive 2001/83/EC]~~.

3. In the cases referred to in paragraphs 1 and 2, the Agency shall forward the information to the competent authorities of the Member States without undue delay.