Council of the European Union

Brussels, 28 April 2023
(OR. en)

8869/23
ADD 2

Interinstitutional File:
2023/0127(COD)

PI 54
PHARM 66
COMPET 381
MI 349
IND 203
IA 87
CODEC 741

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 April 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 222 final
Subject:	ANNEX to the Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

Delegations will find attached document COM(2023) 222 final.

Encl.: COM(2023) 222 final

EUROPEAN
COMMISSION

Brussels, 27.4.2023
COM(2023) 222 final

ANNEX 2

ANNEX

to the

Proposal for a Regulation of the European Parliament and of the Council

on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013

{SEC(2023) 172 final} - {SWD(2023) 117 final} - {SWD(2023) 118 final} -
{SWD(2023) 119 final}

ANNEX II

Standard form for notification pursuant to Article 5(3), points (b) and (c).

Tick the appropriate box	□ New notification □ Update of an existing notification	
(a) Name and address of the maker	…	
(b) Purpose of making	□ Export □ Storing □ Export and storing	
(c) Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place	Member State of making	
	(Member State of first related act (if any))	
(d) Number of unitary certificate having effect in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making	Unitary certificate having effect in the Member State of making	
	(Certificate of Member State of first related act (if any))	
(e) For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export		