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#### COVER NOTE

|                  |                                                                                                                                                                                                                                              |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| From:            | European Commission                                                                                                                                                                                                                          |
| date of receipt: | 8 May 2017                                                                                                                                                                                                                                   |
| To:              | General Secretariat of the Council                                                                                                                                                                                                           |
| No. Cion doc.:   | D050582/03 - ANNEX 1                                                                                                                                                                                                                         |
| Subject:         | ANNEX to the COMMISSION DIRECTIVE (EU) .../... supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use |

Delegations will find attached document D050582/03 - ANNEX 1.

Encl.: D050582/03 - ANNEX 1



EUROPEAN  
COMMISSION

Brussels, **XXX**  
D050582/03  
**[...]**(2017) **XXX** draft

ANNEX 1

**ANNEX**

**to the**

**COMMISSION DIRECTIVE (EU) .../...**

**supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use**

## ANNEX

### Correlation table

| Directive 2003/94/EC | This Directive | Regulation (EU) nn/yyyy<br><br>[Commission Delegated Regulation supplementing Regulation (EU) No 536/2014 of the European Parliament and the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections] |
|----------------------|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Article 1            | Article 1      | Article 1                                                                                                                                                                                                                                                                                                              |
| Article 2            | Article 2      | Article 2                                                                                                                                                                                                                                                                                                              |
| Article 3            | Article 3      | -                                                                                                                                                                                                                                                                                                                      |
| Article 4            | Article 4      | Article 3                                                                                                                                                                                                                                                                                                              |
| Article 5            | Article 5      | Article 4                                                                                                                                                                                                                                                                                                              |
| Article 6            | Article 6      | Article 5, first paragraph                                                                                                                                                                                                                                                                                             |
| Article 7            | Article 7      | Article 6                                                                                                                                                                                                                                                                                                              |
| Article 8            | Article 8      | Article 7                                                                                                                                                                                                                                                                                                              |
| Article 9            | Article 9      | Article 8                                                                                                                                                                                                                                                                                                              |
| Article 10           | Article 10     | Article 9                                                                                                                                                                                                                                                                                                              |
| Article 11           | Article 11     | Article 10                                                                                                                                                                                                                                                                                                             |
| Article 12           | Article 12     | Article 13                                                                                                                                                                                                                                                                                                             |
| Article 13           | Article 13     | Article 14                                                                                                                                                                                                                                                                                                             |
| Article 14           | Article 14     | Article 15                                                                                                                                                                                                                                                                                                             |
| Article 15           | -              | -                                                                                                                                                                                                                                                                                                                      |
| Article 16           | -              | -                                                                                                                                                                                                                                                                                                                      |
| Article 17           | -              | -                                                                                                                                                                                                                                                                                                                      |

|            |   |   |
|------------|---|---|
| Article 18 | - | - |
| Article 19 | - | - |
|            |   |   |