



Council of the  
European Union

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#### COVER NOTE

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 2 October 2015

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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No. Cion doc.: C(2015) 6601 final ANNEXES 1-4

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Subject: ANNEXES I to IV to the Commission Delegated Regulation (EU) No .../. of  
XXX supplementing Directive 2001/83/EC of the European Parliament and  
of the Council by laying down detailed rules for the safety features  
appearing on the packaging of medicinal products for human use

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Delegations will find attached document C(2015) 6601 final ANNEXES 1-4.

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Encl.: C(2015) 6601 final ANNEXES 1-4



Brussels, 2.10.2015  
C(2015) 6601 final

ANNEXES 1 to 4

## **ANNEXES**

**I to IV**

**to the**

**Commission Delegated Regulation (EU) No .../...**

**supplementing Directive 2001/83/EC of the European Parliament and of the Council  
with regard to the detailed rules for the safety features appearing on the packaging of  
medicinal products for human use**

{SWD(2015) 188 final}

{SWD(2015) 189 final}

## ANNEX I

### List of medicinal products or product categories subject to prescription that shall not bear the safety features, referred to in Article 45(1)

Name of active substance or product category	Pharmaceutical form	Strength	Remarks
Homeopathic medicinal products	Any	Any	
Radionuclide generators	Any	Any	
Kits	Any	Any	
Radionuclide precursors	Any	Any	
Advanced therapy medicinal products which contain or consist of tissues or cells	Any	Any	
Medicinal gases	Medicinal gas	Any	
Solutions for parenteral nutrition having an anatomical therapeutical chemical ('ATC') code beginning with B05BA	Solution for infusion	Any	
Solutions affecting the electrolyte balance having an ATC code beginning with B05BB	Solution for infusion	Any	
Solutions producing osmotic diuresis having an ATC code beginning with B05BC	Solution for infusion	Any	
Intravenous solution additives having an ATC code beginning with B05X	Any	Any	
Solvents and diluting agents, including irrigating solutions, having an ATC code beginning with V07AB	Any	Any	
Contrast media having an ATC code beginning with V08	Any	Any	
Tests for allergic diseases having an ATC code beginning with V04CL	Any	Any	
Allergen extracts having an ATC code beginning with V01AA	Any	Any	

## ANNEX II

**List of medicinal products or product categories not subject to prescription that shall bear the safety features, referred to in Article 45(2)**

Name of active substance or product category	Pharmaceutical form	Strength	Remarks
omeprazole	gastro-resistant capsule, hard	20 mg	
omeprazole	gastro-resistant capsule, hard	40 mg	

### ANNEX III

<b>Notification to the European Commission of medicinal products not subject to prescription judged <u>to be at risk of falsification</u>, pursuant to article 54a(4) of Directive 2001/83/EC</b>					
<b>Member State:</b>			<b>Name of competent authority:</b>		
Entry No	Active substance (Common Name)	Pharmaceutical form	Strength	Anatomical Therapeutical Chemical (ATC) Code	Supporting Evidence <small>(please provide evidence of one or more incidents of falsification in the legal supply chain and specify the source of the information).</small>
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
Note: The number of entries is not binding.					

## ANNEX IV

<b>Notification to the European Commission of medicinal products judged <u>not to be at risk of falsification</u>, pursuant to article 54a(4) of Directive 2001/83/EC</b>					
<b>Member State:</b>			<b>Name of competent authority:</b>		
Entry No	Active substance (Common Name)	Pharmaceutical form	Strength	Anatomical Therapeutical Chemical (ATC) Code	Comments / Complementary information
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
Note: The number of entries is not binding.					