EUROPEAN
COMMISSION

Brussels, XXX
Annexes Del. Act Safety Features
[…](2015) XXX draft

ANNEXES 1 to 4

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 with regard to the detailed rules for the safety features appearing on the packaging of medicinal products for human use

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

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					
Member State:			**Name of competent authority:**		
Entry No	**Active substance (Common Name)**	**Pharmaceutical form**	**Strength**	**Anatomical Therapeutical Chemical (ATC) Code**	**Supporting Evidence** (please provide evidence of one or more incidents of falsification in the legal supply chain and specify the source of the information).
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

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					
Member State:			**Name of competent authority:**		
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.					