

## ORDER

**for approval of the National Medicines Agency Scientific Council  
Decision No. 7 from the 17<sup>th</sup> of January 2003 regarding the change of the  
framing of certain pharmaceutical preparations from *Separanda* or  
*Venena* category, from the Romanian Pharmacopoeia, 10<sup>th</sup> edition**

Taking into consideration the provisions of paragraph (9) of the Art. 10 of the Government Ordinance No. 125/1998 regarding the setting up, organization and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002,

Seeing the Report for approval No. DB 964 from February 5<sup>th</sup>, 2003 of the Pharmaceutical General Direction,

In accordance with the Government Decision No. 22/2001 regarding the organization and functioning of the Ministry of Health and Family, with subsequent changes and completions,

**Minister of Health and Family** emits the following order:

Art. 1. – The Decision No. 7 from the 17<sup>th</sup> of January 2003 of the National Medicines Agency Scientific Council regarding the change of the framing of certain pharmaceutical preparations from *Separanda* or *Venena* category, from the Romanian Pharmacopoeia, 10<sup>th</sup> edition, mentioned in the Annex that is part of the present decision is approved.

Art. 2. – The Directions from the Ministry of Health and Family, the Ministries with own sanitary network, economic agents and all units which conduct activities for medical purposes with the substances and products mentioned in the Annex to the present order will comply with the provisions of the present order.

Art. 3. – The present order will be published in the Official Monitor of Romania, Part I.

Minister of Health and Family  
**Daniela Bartoș**

Bucharest, the 6<sup>th</sup> of February 2003  
No. 95

Published in the Official Monitor of Romania, Part I, no. 149/7 – III – 2003

The term *Separanda* is eliminated from the storage conditions from the following pharmaceutical preparations monographs from FRX:

CAPSULAE CYCLOPHOSFAMIDI  
CAPSULAE RETINOLI ACETATIS  
COMPRESSI ACIDII NICOTINICI  
COMPRESSI DIGITALIS  
COMPRESSI ETHINYLESTRADIOLI  
COMPRESSI HYDROXYPROGESTERONI ACETAS  
COMPRESSI ISONIASIDI  
COMPRESSI METAMIZOLI NATRICI  
COMPRESSI METHYLTESTOSTERONI  
COMPRESSI PHENYTOINI  
COMPRESSI TAMOXIFENI CITRATIS  
COMPRESSI OBDUCTI AMITRIPTYLINI HYDROCHLORIDI  
COMPRESSI OBDUCTI NORTRIPTYLINI HYDROCHLORIDI  
INJECTABILE AMITRIPTYLINI HYDROCHLORIDI  
INJECTABILE COFFEINI ET NATRII BENZOATIS  
INJECTABILE GLYCERYLI TRINITRATIS  
INJECTABILE HYDROXYPROGESTERONI CAPROATIS  
INJECTABILE LIDOCAINI HYDROCHLORIDI  
INJECTABILE PAPAVERINI HYDROCHLORIDI  
INJECTABILE PROCAINI HYDROCLORIDI – 40 mg/ml  
INJECTABILE PROCAINI HYDROCLORIDI – 80 mg/ml  
SIRUPUS BELLADONNAE  
SOLUTIO IODI SPIRITUOSA  
SOLUTIO PHENYLHYDRARGYRI BORATIS 0,2%

The term *Venena* is eliminated from the storage conditions from the following pharmaceutical preparations monographs from FRX:

COMPRESSI DIGOXINI  
COMPRESSI COLCHICINI  
COMPRESSI OBDUCTI LANATOSIDI C  
INJECTABILE DESLANOSIDI  
INJECTABILE DIGOXINI  
INJECTABILE METHYLERGOMETRINI  
HYDROGENOMALEATIS  
SOLUTIO DIGITOXINI 0,1%  
SOLUTIO DIGOXINI 0,05%  
SOLUTIO EPINEPHRINI 0,1%  
SOLUTIO IODI SPIRITUOSA  
SOLUTIO METHYLERGOMETRINI HYDROGENII MALEATIS

*Annex no.II\*) to Decision*

**SEPARANDA**

<b>Active substances</b>	<b>Active substances and pharmaceutical preparations containing them</b>
1	2

<i>Acetazolamidum</i>	<i>Cyclobarbitalum</i>
<i>Acidum aceticum</i>	<i>Cyclobarbitalum calcicum</i>
<i>Acidum hydrochloricum</i>	<i>Diazepamum</i>
<i>Acidum iopanoicum</i>	<i>Glutethimidum</i>
<i>Acidum lacticum</i>	<i>Imipramini hydrochloridum</i>
<i>Acidum nicotinicum</i>	<i>Levomepromazini hydrogenomaleas</i>
<i>Acidum phosphoricum</i>	<i>Lithii carbonas</i>
<i>Aconiti tuber</i>	<i>Maprotilini hydrochloridum</i>
<i>Aminoglutethimidum</i>	<i>Meprobamatum</i>
<i>Aminophyllinum</i>	<i>Nitrazepamum</i>
<i>Amitriptylini hydrochloridum</i>	<i>Phenobarbitalum</i>
<i>Amobarbitalum natricum</i>	<i>Phenobarbitalum natricum</i>
<i>Argenti nitras</i>	
<i>Barbitalum</i>	
<i>Barbitalum natricum</i>	
<i>Belladonnae folium</i>	
<i>Benzocainum</i>	
<i>Bromisovalum</i>	
<i>Butylscopolammonii bromidum</i>	
<i>Chinidini sulfas</i>	
<i>Chinini hydrochloridum</i>	
<i>Chinini sulfas</i>	
<i>Chlordiazepoxidum</i>	
<i>Chloropyramini hydrochloridum</i>	
<i>Clomipramini hydrochloridum</i>	
<i>Coffeinum</i>	
<i>Coffeinum et acidum citricum</i>	
<i>Coffeinum et natrii benzoas</i>	
<i>Colecalciferolum</i>	
<i>Cortisoni acetas</i>	
<i>Cyclophosphamidum</i>	
<i>Dequalinii chloridum</i>	
<i>Desoxycortoni acetas</i>	
<i>Dexamethasonum</i>	
<i>Digitalis purpureae folium</i>	

<p><i>Digitalis purpureae pulvis titratus</i> <i>Dihydralazini sulfas</i> <i>Disulfiramum</i> <i>Ephedrini hydrochloridum</i> <i>4'-Epidoxorubicini hydrochloridum</i> <i>Ergocalciferolum</i> <i>Ethacridini lactas</i> <i>Ethinylestradiolum</i> <i>Ethionamidum</i> <i>Extractum Belladonnae siccum</i> <i>Furosemidum</i> <i>Glycerili trinitratis solutio</i> <i>concentrata</i> <i>Guanethidini sulfas</i> <i>Hydrargyri oxydum flavum</i> <i>Hydrochlorothiazidum</i> <i>Hydrocortisoni acetas</i> <i>Hydrocortisoni hemisuccinas</i> <i>Hydrocortisonum</i> <i>Hydroxyprogesteroni acetas</i> <i>Hydroxyprogesteroni caproas</i> <i>Indometacinum</i> <i>Iodum</i> <i>Ipecacuanhae radix</i> <i>Isoniazidum</i> <i>Isoprenalini hydrochloridum</i> <i>Lidocaini hydrochloridum</i> <i>Mepacrini hydrochloridum</i> <i>Metamizolum natricum</i> <i>Methotrexatum</i> <i>Methyltestosteronum</i> <i>Naphazolini hydrochloridum</i> <i>Natrii fluoridum</i> <i>Natrii iodidum</i> <i>Natrii nitris</i> <i>Nifedipinum</i> <i>Nitrofurantoinum</i> <i>Nortriptylini hydrochloridum</i> <i>Noscapini hydrochloridum</i> <i>Papaverini hydrochloridum</i></p>	
---	--

<p><i>Paracetamolum</i> <i>Pentaerithryli tetranitras dilutum</i> <i>Phenylhydrargyri boras</i> <i>Phenytoinum</i> <i>Podophylli resina</i> <i>Prednisoloni acetas</i> <i>Prednisolonum</i> <i>Prednisoni acetas</i></p>	
--	--



<p><i>Prednisonum</i> <i>Primidonum</i> <i>Procaini hydrochloridum</i> <i>Prochlorperazini hydrogenomaleas</i> <i>Progesteronum</i> <i>Promethazini hydrogenomaleas</i> <i>Propranololi hydrochloridum</i> <i>Pyrazinamidum</i> <i>Resorcinolum</i> <i>Retinoli acetatis solutio oleosa</i> <i>Solutio hydrogenii peroxydi</i> <i>concentrata</i> <i>Sparteini sulfas</i> <i>Tamoxifeni citras</i> <i>Testosteroni phenylpropionas</i> <i>Testosteroni propionas</i> <i>Theobrominum</i> <i>Theophyllum</i> <i>Tinctura Aconiti</i> <i>Tinctura Belladonnae</i> <i>Tolbutamidum</i> <i>Triamcinoloni acetonidum</i> <i>Trifluoperazini dihydrochloridum</i> <i>Trihexyphenidyli hydrochloridum</i> <i>Trimethoprimum</i> <i>Xantinoli nicotinas</i> <i>Zinci chloridum</i> <i>Zinci sulfas</i></p>	
--	--

**VENENA**

<b>Strong active-substances</b>	<b>Stupefiant substances and pharmaceutical preparations containing them</b>
<i>Acenocoumarolum</i> <i>Amfetamini sulfas**</i> <i>Atropini sulfas</i> <i>Bromocriptini mesylas</i> <i>Clonidinum</i> <i>Colchicinum</i> <i>Deslanosidum</i> <i>Digitoxinum</i> <i>Digoxinum</i> <i>Dihydroergotamini mesylas</i> <i>Epinephrinum</i> <i>Ergometrini hydrogenomaleas</i> <i>Ergotamini tartras</i> <i>Histamini dihydrochloridum</i> <i>Lanatosidum C</i> <i>Methylergometrini hydrogenomaleas</i> <i>Neostigmini bromidum</i> <i>Norepinephrini hydrogenotartras</i> <i>Physostigmini salicylas</i> <i>Pilocarpini hydrochloridum</i> <i>Pilocarpini nitras</i> <i>Reserpinum</i> <i>Scopolamini hydrobromidum</i>	<i>Cocaini hydrochloridum</i> <i>Codeini hydrochloridum*</i> <i>Codeini phosphas*</i> <i>Codeinum*</i> <i>Ethylmorphini hydrochloridum*</i> <i>Hydromorphoni hydrochloridum</i> <i>Methadoni hydrochloridum</i> <i>Morphini hydrochloridum</i> <i>Opium</i> <i>Opium pulveratum</i> <i>Pethidini hydrochloridum</i> <i>Pulvis Opii et Ipecacuanhae</i> <i>Tinctura anticholerina*</i> <i>Tinctura Opii</i>

\*pharmaceutical preparations containing these substances are kept to *Separanda*, with the exception of those released without medical prescription (OTC) and magistral preparations stored under normal conditions.

\*\* pharmaceutical preparations containing this substance are kept to *Venena*