ORDER no. 1575

of 22 December 2014

on amendment of Order of the Minister of Health no. 456/2013 on approval of the List of International Non-proprietary Names of medicinal products at high unavailability risk, as provided to insurants in the health insurance system and agreement on a measure to ensure their market availability in Romania

ISSUED BY: THE MINISTRY OF HEALTH PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, PART I, No. 946 of 23 December 2014

On seeing Approval report no. N.B. 11.520/2014 of the Medicinal Product and Medical Devices Directorate and NAMMD notifications no. N.B. 7.288, 71.247/2014 and 77.894/2014,

taking into account provisions of Article 695 (17) and Article 792 of Law 95/2006 on healthcare reform, as amended,

based on provisions of Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following Order:

ARTICLE I

Order of the Minister of Health no. 456/2013 on approval of the List of International Non-proprietary Names of medicinal products at high unavailability risk, as provided to insurants in the health insurance system and agreement on a measure to ensure their market availability in Romania, published in the Official Gazette of Romania, Part I, no. 197 of 8 April 2013, as amended, is amended as follows:

1. Under Article 1, paragraph (2) is amended as follows:

"(2) Distribution outside Romania of medicinal products included in the List specified in (1) is temporarily suspended as of the date of this Order coming into force to 30 June 2015."

2. The Annex is replaced with the Annex which is integral part of this Order.

ARTICLE II

This Order is to be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health, Dorel Săndesc, State Secretary

Bucharest, 22 December 2014. No. 1.575.

ANNEX 1 (Annex to Order no. 456/2013)

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| No. | International Non-proprietary Name |
| 1. | ASPARAGINAZUM |
| 2. | BLEOMYCINUM SULFAS |
| 3. | BUSULFANUM |
| 4. 4. | CARMUSTINA |
| 5. | CHLORAMBUCILUM |
| 6. | CISPLATINUM |
| 7. | CYCLOPHOSPHAMIDUM |
| 8. | CYTARABINUM |
| 9. | DACARBAZINUM |
| 10. | DACTINOMICINUM |
| 11. | DAUNORUBICINUM |
| 12. | DEXAMETHASONUM |
| 13. | ETOPOSIDE |
| <u> </u> | FLUOROURACILUM |
| <u> </u> | LOMUSTINUM |
| <u> </u> | MELPHALANUM |
| '' 17. | MERCAPTOPURINUM |
| 18. | METHOTREXATUM |
| 19. | PROCARBAZINA |
| 20. | TENIPOSIDE |
| 21. | TIOGUANINA |
| 22. | VINBLASTINUM |
| 23. | PEGINTERFERON alfa-2a |
| 24. | SUNITINIBUM |

| 25. | ENOXAPARINUM |
|-----|----------------------|
| 26. | NADROPARINUM |
| 27. | DALTEPARINUM |
| 28. | TINZAPARINUM |
| 29. | BEMIPARINUM |
| 30. | HEPARINUM |
| 31. | RITUXIMABUM |
| 32. | BEVACIZUMABUM |
| 33. | ERLOTINIBUM |
| 34. | OCTREOTIDUM LAR |
| 35. | VORICONAZOLUM |
| 36. | GOSERELINUM |
| 37. | FULVESTRANTUM |
| 38. | INSULINUM GLARGINUM |
| 39. | INSULINUM GLULIZINUM |
| 40. | HUMAN INSULINS |
| 41. | DEFERASIROXUM |
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