Emergency Ordinance no. 72 of 30 June 2010

on reorganization of health care facilities and amendment of public health legislation (Published in the Official Gazette of Romania, Part I, no. 452/July 2, 2010)

In order to streamline the activity of healthcare institutions in line with the Government's priorities for reform in public administration,

taking into account the urgency of establishing economic and financial measures for institutions funded by the State and under the Ministry of Health, as a result of the severe economic recession threatening the economic stability of Romania, and to ensure compliance with commitments of the Government following negotiation of loan agreements with financial institutions regarding the consolidated general public budget deficit for 2010,

in this context, taking into account budgetary constraints and also allocated funds, expedited rethinking of the entire institutional system as well as reorganisation and reform of public health institutions is mandatory.

Given the current global financial context, provision of premises for the establishment of new institutions adaptable to the economic situation corresponding to the existing financial reality requires expedited adoption of measures to ensure the strengthening of the existing legal framework to this purpose.

Given that failure of immediate action would lead to inability to properly organize their activities and the impossibility of improving conditions for development of public health activities,

whereas failure to adopt immediate measures by an emergency ordinance would lead to difficulties both in terms of organization and operation, and from a financial standpoint, with regards to remaining within the income and expenditure budget,

considering the fact that these elements are of general public interest and represent urgent and extraordinary circumstances whose regulation may not be deferred,

under Art. 115 para. (4) of the Romanian Constitution, republished,

the Government of Romania adopts the current emergency ordinance.

Article I. - Law no. 95/2006 on healthcare reform, published in the Official Gazette of Romania, Part I, no. 372 of 28 April 2006, as amended, is hereby amended as follows:

1. Article 14 will read as follows:

"Article 14 – The National Centre for Organization and Insurance of the I.T. and Informational System in public healthcare, a specialized public institution with legal entity under the Ministry of Health, is abolished as a result of its

takeover and undertaking of its activities by the National Institute of Public Health."

2. In Article 695, paragraph 27 will read as follows:

"27. Competent authority - the National Agency for Medicines and Medical Devices, hereinafter NAMMD;".

3. Throughout the law, the phrase "the National Medicines Agency (NMA)" shall be replaced by "the National Agency for Medicines and Medical Devices".

Article II. - Law no. 176/2000 on Medical Devices, republished in the Official Gazette of Romania, Part I, no. 79 of 24 January 2005, as amended, is hereby amended as follows:

1. Article 6 will read as follows:

"Article 6 - (1) Evaluation activities referred to in art. 3. (3) and the control activities referred to by art. 5 will be conducted by the National Agency for Medicines and Medical Devices, hereinafter NAMMD.

(2) The NAMMD is established as a result of the merger of the National Agency for Medicines and the Technical Office for Medical Devices."

2. In Article 7, the introductory part of paragraph (1) reads as follows:

"Article 7 - (1) For the purposes of the present Act, the NAMMD has the following main tasks:".

3. Article 7 (1) a) will read as follows:

"a) develops specific technical procedures for medical devices, approved by decision of the NAMMD President; ".

4. Throughout the law, the term "the Technical Office for Medical Devices" shall be replaced by "the National Agency for Medicines and Medical Devices."

Article III. – The organization and functioning of the National Agency for Medicines and Medical Devices is approved by Government decision within 15 days from the date of entry into force of this ordinance.

Article IV. - Article III of Law no. 434/2004 for the amendment of Law no. 176/2000 on medical devices, published in the Official Gazette of Romania, Part I, no. 1009 on November 2, 2004, is hereby repealed.

Article V - Government Ordinance no. 125/1998 regarding the establishment, organization and functioning of the National Medicines Agency, published in the Official Gazette of Romania, Part I, no. 329 of 31 August 1998, approved with amendments by Law no. 594/2002, as amended, is hereby repealed.

Article VI. - (1) Within 15 days from the entry into force of this ordinance, public institutions subject to reorganization will have completed the handover protocols.

(2) handover protocols under par. (1) contain unused budgetary credit until the entry into force of this ordinance, staff structures taken over, heritage of institutions for the handover/merger. (3) The National Public Health Institute takes over the heritage of the National Centre for Organization and Insurance of the I.T. and Informational System in public healthcare based on its closing balance sheet, accompanied by a summary trial balance, heritage results account, and other Treasury cash flow statements and annexes, prepared at the end of the year, together with the handover protocol concluded within 15 days from the date of entry into force of this ordinance.

(4) The National Agency for Medicines and Medical Devices Agency takes over the heritage of the National Medicines Agency and the Technical Office for Medical Devices based on their closing balance sheet, accompanied by a summary trial balance, heritage results account, and other Treasury cash flow statements and annexes, prepared at the end of the year, together with the handover protocol concluded within 15 days from the date of entry into force of this ordinance.

Article VII. - (1) The maximum number of positions for units with legal entity under the Ministry of Health, funded entirely by the state budget or funded by their own revenues with subsidies from the state budget, or coordinated by the Ministry of Health, funded entirely by their own revenue, are approved by Government decision, according to law.

(2) Compliance with the maximum number of positions provided in par. (1) is achieved by an Order of the Minister of Health.

(3) Compliance with the maximum number of posts is achieved in the terms and procedure established by the law applicable to each category of staff.

PRIME MINISTER EMIL BOC

Countersigned: Minister of Health, **Cseke Attila**

Minister of Labour, Family and Social Protection Mihai Constantin Şeitan

Minister of Public Finance Sebastian Teodor Gheorghe Vlădescu

Bucharest, June 30, 2010. Nr. 72