#### Article 36

# Overdue obligations of hospitals

- 1. The validity of the provisions of article 69 of Law 4174/2013 (A' 170) is extended until the publication hereof.
- 2. Par. 1 of article 15 of law 3918/2011, as in force, is substituted as follows:
- "1. The validity of the provisions of articles 1, 2, 3, 4, 5, 6, 11 and 12 of law 3918/2011 commences from 1.1.2016. The validity of articles 8, 9 and 10 commences with the approval of the Total Procurement and Services Programme, of the year 2016".

#### Article 37

# Settlement of overdue service provision obligations

For the purposes of securing the public interest, the protection of public health and due to sublime necessity, the expenditures required for the settlement of obligations under the provision of services to NHS hospitals are deemed lawful, which were rendered to hospitals from the already established contracting companies either at the contractual prices or at the prices of the Prices Observatory of the EPY, if these are lower after the end of their mutual agreement, in the period from September 1, 2012 until the date of publication hereof.

## **Article 46**

# Amendment of the provisions of l. 2859/2000, of the P.D. 113/2010 and of Law 3986/2011

- 1. At the end of case b, of par. 2 of article 7 of the VAT Code (law 2859/2000, A; 248), the following clause is added as follows:
- "b) Good, medicinal products, cloths or other articles for the coverage of needs are deemed as gifts and are also exempted, with the exception of those subjected to special consumption taxes, which are free of charge granted to public law legal entities or non-profit private law legal entities which have lawfully been established in Greece and have provenly a philanthropic or public benefit purpose, in order to be exclusively distributed for the service or relief of sensitive social groups without any consideration, if these articles do not endanger public health. Such articles are those which are not suitable for sale or utilization mainly due to errors or defects or

deficiencies in the packaging, marking or weighting, or due to withdrawal from the market or due to the fact that the expiration date is closing in".

- b. At the end of par. 4 of article 7 of the VAT Code, the following clause is added as follows:
- "By decision of the Minister of Finance, especially for the case of clause 3 of paragraph 2 of article 7 of this Code, the manner and procedure for proving the distribution is set out, with the entry of the data of the legal entities or persons participating in the donations and of the quantities of the gifts per type of article, as well as any other detail necessary for the implementation thereof".
- 2. The P.D. 113/2010 (C' 194) "Assumption of obligations by the Directors" is amended as follows:
- a. In article 2 of the P.D. 113/2010, a paragraph 3 is added as follows:
- "3. Exception from the obligation of paragraph 2, is exclusively permitted for the expenditures exceptionally enforced during the financial year, from the provisions of the law or from a final court order, for which the relevant or adequate available credit have not been provided for, so that the undertaking may be conducted before the expenditure is spent. In these cases, the prompt reform of the Budget of the current financial year is required, in accordance with the applicable provisions, in order to secure the credit and to conduct the undertaking of the obligation, which, for this reason, will have exceptionally a date after the date the invoice is received, the date of the communication of the court order or other equivalent document".
- b. Clause 6 of par. 3 of article 7 of the P.D. 113/2010 is substituted as follows:
- "The number, the date of receipt, according to the provisions of par. 3 of subparagraph Z.5 of Law 4152/2013 (A' 140) and the amount of the voucher proving the existence of the debt:.
- c. In subparagraph c of par. 6 of article 7 of the P.D. 113/2010, the words "from the date the invoice or another document of equal force is issued" are substituted with the words "from the date of receipt, according to the provisions of par. 3 of subparagraph Z.5 of Law 4152/2013 (A' 140)".
- 3. Par. 2 of article 5 of law 3986/2011 (A' 152) is amended as follows:
- a. The existing paragraph 2 is renumbered as case (a) of the same paragraph.
- b. At the end of paragraph 2, a case (b) is added as follows:
- "b. Following the suggestion of the BoD of TAIPED, the Hellenic Republic is able, with an Act of the Cabinet, to decide the countersigning as third party to the contracts

for the exploitation of assets, only as to the terms thereof under which the Hellenic Republic undertakes to indemnify for acts or omissions of the bodies thereof, as provided for in the relevant agreement. The same act defines and authorises the competent bodies to countersign the above agreements as to the specific terms, after the conclusion of the preliminary audit by the Auditing Board provided for in par. 4 of article 9 hereof.

### Article 51

1. Amendment of Article 12A of the L.D. 96/1973

Article 12A of the L.D. 96/1973 is substituted as follows:

"1. The wholesale license holders for medicinal products used by humans which are marketed in Greece, secure the proper and continuous supply of the market with the said medicinal products so as to cover the needs of the patients in Greece.

If a deficiency in a medicinal product is noticed and it is the result of a breach of the obligations of the wholesaler license holder or of the marketing authorisation holder, then a monetary fine is levied, by decision of the Minister of Health, in the aggregate with any other legal sanction provided for, upon the occasionally liable person, ranging from the amount of Euro thirty thousand ( $\leq 30,000$ ) to Euro one million ( $\leq 1,000,000$ ) according to the severity of the violation.

2. The authenticity data of the exported medicinal products are recorded at real time, under the care of the wholesale license holders for medicinal products, by electronic means at EOF's Database. If a breach of the above obligation is discovered, then a fine ranging from the amount of Euro one hundred thousand (€100,000) to Euro one million (€1,000,000), according to the severity of the violation. The release of a batch of a medicinal product is prohibited, if the authenticity details thereof have not been previously declared in the above System of Electronic Data Filing of EOF.

The wholesale license holders for medicinal products, after the prohibition due to deficiencies, of the exports of specific medicinal products, are obliged to declare at EOF's website, their stock for the said medicinal products and immediately disperse them in the market at first demand. Whoever, despite the prohibition set out in the preceding clause, exports or collects medicinal products for the purposes of exporting them, is levied with a fine ranging from Euro one hundred thousand (€100,000) to

Euro one million ( $\leq$ 1,000,000), according to the sewrity of the violation, in the aggregate with the other sanctions provided for.

- 3. The wholesale license holders for medicinal products, who perform exports in countries of the European Union sell directly and only to the persons holding a license to sell medicinal products, according to the law of the destination member-state. The patent medicinal products exported must have obtained a marketing authorisation in the destination state by their exporter and in parallel, medicinal products exported in third countries outside the European Union, must obtain the approval of EOF".
- 2. Regulations for dealing with exceptionally emergency and unanticipated needs of the non-profit entity under the name "HENRY DUNANT NON-PROFIT PUBLIC BENEFIT FOUNDATION".
- 1. The deadline of article 1 of the of the Act of Legislative Content "Regulations for dealing with exceptionally emergency and unanticipated needs of the non-profit entity under the name "HENRY DUNANT NON-PROFIT PUBLIC BENEFIT FOUNDATION" which was ratified by article 1 of law 4227/2014 (A'4) "Ratification of the Act of Legislative Content 'Amendment of par 1 of article 2 of Law 4163/2013 of the Act of Legislative Content dated 11.10.2013", with which the deadline of article 2 of law 4163/2013 (A' 155) "Ratification of the Act of Legislative Content "Amendment of article 1 of the Act of Legislative Content" dated 30.10.2012 was extended, which was ratified by article 1 of law 4118/2013 "Ratification of the Act of Legislative Content 'Regulations for dealing with exceptionally emergency and unanticipated needs of the non-profit entity under the name "HENRY DUNANT NON-PROFIT PUBLIC BENEFIT FOUNDATION" and other provisions' (A' 32) which extends the deadlines of paragraphs 1 and 2 of article 1 of the Act of Legislative Content titled "Amendment of Article 1 of the Act of Legislative Content dated 30.10.2012" which was ratified by article 1 of law 4118/2013 Ratification of the Act of Legislative Content 'Regulations for dealing with exceptionally emergency and unanticipated needs of the non-profit entity under the name "HENRY DUNANT NON-PROFIT PUBLIC BENEFIT FOUNDATION", which were extended with article 1 of the Act of Legislative Content dated 29.04.2012, which was ratified by article 1 of Law 4163/2013, is extended from their expiration until 30.4.2014.
- 2. The members of the Board of the Hellenic Red Cross who were appointed by court order, as well as the members non-profit entity under the name "HENRY DUNANT NON-PROFIT PUBLIC BENEFIT FOUNDATION" who were elected by the above

administration, as well as the managers or liquidators thereof shall not be prosecuted for the acts, omissions or dents of the union or the foundation, which were performed or generated prior to their appointment and they bear no penal, civil or other liability for these, regardless of the time they were assessed.

- 3. Regulation of issues concerning the organising, operation and competencies of the OFFICE of the State Legal Council, in EOPYY.
- Cases (b) and (c) of par. 2 of Article 19 of law 3086/2002 (A' 324) as in force, are substituted as follows:
- "b. The competency of the Office of the Legal Counsel of the State Legal Council has undertaken the general supervision of the self-existent Department of Legal Affairs of EOPYY and the granting of opinion, according to the procedure, that governs the State Legal Council, in case of queries, filed by the President of EOPYY.
- c. By joint decision of the Minister of Finance and the Minister of Health, and following the opinion of the Chairman of the State Legal Council, the issues for the organising and operation of the Office are determined, together with the manner and the procedure for the exercise of the supervision, the procedure and the bodies for accepting the granting of opinion on legal issues, the procedure and the bodies suggesting and granting opinions for the acceptance of decisions, the exercise of legal remedies and means, the acknowledgment of claims, in and out-of-court settlements and any other relevant issue and detail.
- 4. Electronic health file
- 1. The Personal Electronic Health File (AHFY) for all Greek citizens is enacted.
- 2. AHFY contains a brief health background of each citizen, as part of the medical file, as well as the information of case (m) of article 3 of law 4213/2013. By decision of the Minister of Health and following the suggestion of the National Board for the Governing of Electronic Health (ESDHY), a unified national template form of AHFY is established, regarding the content, the preparation manner, the identification of the person and the access of the medical information of the file, in accordance with law 2472/1997 and law 3471/2006, as in force.
- 3. The content of the AHFY as to the brief health background is unified at a national level and obligatory.
- 4. The AHFY is prepared by the family physician or the medical personnel of the healthcare unit, in which the patient is treated. The family and other physicians are

obliged to keep and update the electronic files of the patients, with the electronic information required for the monitoring, treatment and rehabilitation of patients.

5. The data of the AHFY constitute a property of the citizen and are securely kept, under the care of the Ministry of Health, in accordance with the applicable legislation on personal data protection. Access to the information of the AHFY is granted to the citizen, his/her occasional family physician, as well as the treating professional physician, during the hospitalization or visit of the citizen in a public or private healthcare unit.

## **Article 52**

In case f of article 22 of law 3052/2012, as today in force, a second paragraph is added as follows:

"EOPYY is entitled to off-set, by decision of the Board of Directors, the amounts owed by the marketing authorisation holders of patent medicinal products, which result from the rebate obligation set out in par. 1a of this article and their obligation to pay the claw back set out in par. A of article 11 of this law, against their equal debts to the Marketing Authorisation Holders, from the procurement of patent medicinal products for the pharmacies thereof, the NHS Hospitals, the subscribed providers and the Agencies and Organisations supervised by the Ministry of Health, as well as the Public Law Legal Entitles and the Private Law Legal Entities subjected to its authority.