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Number ΕΜΠ4

Mechanism for the application and informing physicians for prescribing based on the active substance and exceptions from the prescribing system based on the active substance.

THE ALTERNATE MINISTER OF HEALTH

Having considered:
1. The provisions of par. 5 of article 21 of Law 4052/2012, as amended by the provisions of case 11 of subparagraph IB.2 of Law 4093/2012 (Gov. Gazette 222/A/2012).
2. The provisions of article 90 of the Code of Legislation for the Government and the governmental bodies which was ratified by article 1 of the P.D. 63/2005 (Gov. Gazette A 98).
3. The P.D. 86/2012 (Gov. Gazette 141/A/21.6.2012) "Appointment of Ministers, Alternate Ministers and Deputy Ministers".
4. The Decision No Υ47/3-07-12 of the Prime Minister 9Gov. Gazette 2105/B/12) "Assignment of competencies to the Alternate Minister of Health Marios Salmas" as amended by the Decision No ΔΥ1α/οικ. 78084/25-07-12 (Gov. Gazette 2339/B/2012).
5. The Joint Ministerial Decision ΔΥΓ3/οικ.Γ.Υ.153 (Gov. Gazette 544/B/1.03.2012).
6. The fact that no expense is generated against the State Budget from this Decision, we decide:

1. Pursuant to the provisions of Law 4052/2012 and Law 4093/2012, it is obligatory for physicians to completely prescribe, based on the International Non-proprietary Name of the active substance – INN). Physicians are obliged to select the appropriate medicine, in compliance with the EOF's therapeutic protocols and based on the characteristics, indications and correspondence of the occasionally active substance to the therapeutic choice.

2. During the preparation of electronic prescriptions which record only the active substance, the pharmacists are obliged to grant the cheapest available in the Greek market medicine of the specific active substance. In case the said medicine is unavailable, the pharmacist is obliged to inform the insured person for the cheapest available in the Greek market. In case the person insured chooses to buy a more expensive medicine with the same active substance, he/she is obliged to pay, in excess of his/her participation (if any) the difference from the price covered by insurance in the therapeutic category the said medicine belongs to. The pharmacist and the person insured have no right to change the prescribed medicine with a medicine of another active substance, pharmacotechnical form, dosage or content. Substitution is effected only by a certified pharmacist.

3. The obligation of prescribing based on the active substance applies for all therapeutic categories and medicines included in the positive list of prescribed medicines. Only some very specific cases of medicines or diseases are excluded from the prescribing obligation based on the active substance. These cases are defined based on medical and scientific international data and with regard to the effectiveness and safety of the treatment and the proper management of patients and are particularised in paragraphs 4 and 5 of this decision. In this cases, prescribing can be done with the commercial name and in addition, substitution or change of the medicine must be prohibited by an order of the physician. Medicines are reimbursed in accordance with the applicable provisions.

4. The commercial name may in parallel with the active substance be mentioned in the cases of medicines causing allergies and reactions, which are administered to patients having undergone transplant or immunosuppressed in blood derivatives, insulin, vaccines, biotechnological and combined products, for which substitution or exchange are not practically possible and scientifically correct. In addition, medicines of narrow therapeutic range can be excluded from the prescribing exclusively based on the active substance, such as for example: acenocumarol, carbamazepine, cyclosporine, digoxin, methlydigoxin, phenytoin, tacrolimus, theophylline, warfarin, levothyroxine, ethosuximide, levothyroxine, procainamide, flecainide, lithium, phenytoin, sirolimus, theophylines. In addition, medicines that require medical supervision or special protection measures or special methodology during their administration or high-toxicity medicines (chemotherapeutic and derivatives) such as cabergoline, vigabatrin, stertindole, isotretinoin, acitretin, acetohydroxan, thalidomide, clozapine, pergolide. Special cases of medicines that may also be excluded concern medicines treating epilepsy, psychosis, schizophrenia, asthma, and chronic degenerative autoimmune diseases. Finally, medicines whose administration is effected with devices requiring patient-training can also be excluded. The full list with the accurate names, pharmacotechnical forms and content of the above mediciens is posted at the EOF's official website. The physician must file a justification for each deviation from the prescribing exclusively based on the active substance.

5. The commercial name may in parallel with the active substance be mentioned in the cases of patients suffering from chronic diseases (e.g. cardiovascular diseases)

who are adequately and efficiently regulated. The first prescription of the new patients with a chronic disease as well as the first prescription in possible changes of treatment is always with reference to the active substance.

6. Deviations of all the above regulations of mandatory prescribing based on the active substance and the exceptions of the above paragraphs 4 and 5, cannot exceed 15% of the value of the total prescriptions issued by each physician during the year. In particular, all exceptions in paragraphs 4 and 5 must by fully and adequately justified in writing by the physicians participating in the system of electronic prescribing.

7. In the cases where the commercial name is recorded, the electronic prescription must record the difference in the price from the cheapest medicine of a similar active substance.

8. The prescribing system of HDIKA is adapted within 15 days from the issue hereof so that the prices of medicines and the participation of patients are visible to the physician and the patient during the prescribing process and the application of the above provisions and the inspection of the prescriptions issued by each physician is possible. EOPYY will develop warning mechanisms for each physician when the levels of prescribing with a commercial name reach the target and will introduce mechanisms of automatic prohibition of exceptions when the physician reaches the target and will impose penalties such as suspension of the prescribing right in cases of repeated unjustified transgressions.

This Decision must be published in the Government Gazette.

Athens, November 17, 2012

The ALTERNATE MINISTER
MARIOS SALMAS