



NEW RULES ON PRESCRIPTION AND DISPENSING OF MEDICINES

Law no. 11/2012 of 8 March establishes new rules for prescription and dispensing of medicines.

Prescriptions for medicines must now include the International Nonproprietary Name (INN) of the active substance, its pharmaceutical form, the dosage, the presentation and the posology. The prescription may also include a trade name by brand or indication of the name of the holder of the marketing authorisation¹.

The patient has the right to choose any medicine that contains the same active substance INN, pharmaceutical form and dosage as the medicine appearing in the medical prescription, except in cases when the medicine prescribed contains an active substance for which there is no generic medicine or for which only the original of the brand and licences exist and if the prescribing doctor has provided a technical justification to demonstrate that the medicine prescribed cannot be substituted.

In the second case, the prescribing doctor must provide an express, clear and sufficient indication in the prescription of the technical justification that makes it impossible to substitute the medicine prescribed with a trade name. The only technical justifications that are acceptable are:

- a) Prescription of a medicine with narrow therapeutic margin or index in accordance with information provided by INFARMED;
- b) A well-grounded suspicion, reported in advance to INFARMED, of intolerance or adverse reaction to a medicine with the same active substance, by identified by another trade name;
- c) Prescription of medicine with the purpose of ensuring the continuity of a treatment with an estimated duration that exceeds 28 days.

In the case of a medicine aimed at ensuring the continuity of a treatment with an estimated duration that exceeds 28 days, when the patient wants a medicine with a price lower than the one prescribed and this is refused at the pharmacy, he or she may choose to exercise the right, by means of a signed prescription, to substitute the medicine for one with a higher price than the one prescribed.

Upon dispensing medicine, the pharmacist or the duly qualified staff of the pharmacy must inform the patient of the existence of the medicines available at the pharmacy with the same active substance,

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Clients Choice Award - International Law
Office, 2008, 2010*

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International Tax Review - Tax Awards
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¹ - On the contrary, under article 2 of Law no. 14/2000, of 8 August, as amended by Law no. 11/2012, of 8 March, for the purposes of subsidisation by the National Health Service, the prescription of medicines may only include the indication of the trade name, by brand or holder of the marketing authorisation, in the case of prescription of medicine with an active substance for which there is no subsidised generic medicine or for which there is only the original brand and licences or in the case of technical justification by the doctor as to the fact that the medicine prescribed cannot be substituted.

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Pharmacies must always have available for sale at least three medicines with the same active substance (...) they must dispense the one with the lowest price unless the patient chooses another one.

pharmaceutical form, presentation and dosage as the medicine prescribed, as well as providing information about any medicines subsidised by the National Health Service that have the lowest available market price.

Finally, pharmacies must always have available for sale at least three medicines with the same active substance, pharmaceutical form and dosage, from among the medicines that have the five lowest prices in each homogenous group and they must dispense the one with the lowest price unless the patient chooses another one.



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