

REPORT BY THE GENERAL DIRECTORATE ON THE BASIC PORTFOLIO OF SERVICES OF THE SPANISH NATIONAL HEALTH SYSTEM (NHS) AND PHARMACY ON THE PUBLIC REIMBURSEMENT OF MEDICINES WHERE AN EXPRESS RESOLUTION OF NON INCLUSION IN THE PHARMACEUTICAL PROVISION OF THE NHS HAS BEEN ADOPTED

Law 16/2003, of May 28th, on the cohesion and quality of the National Health System, (the "Cohesion and Quality Law"), sets forth in its 2nd article the general principles of the NHS, being the provision of services to the users of the National Health System in conditions of effective equity and quality one of its foremost principles.

The instrument that guarantees observance of this principle is the common portfolio of services of the NHS, defined, in article 8 of the mentioned Law, as the techniques, technologies or procedures through which healthcare services are made effective. This portfolio is articulated in three chapters: the common portfolio of assistance services, the supplementary common portfolio and the common portfolio of accessory services.

The Autonomous Communities, within their competencies, may approve their own portfolios of services which shall include, at least, the three chapters of the common portfolio of services from the NHS, guaranteeing the provision of the services to all users of the system.

Article 8, paragraph five of the Cohesion and Quality Law establishes the complementary portfolio of services. This is defined as comprising techniques, technologies or procedures not provided in the common portfolio of services of the National Health Systems that the Autonomous Communities may approve in addition the common portfolio of services of the NHS, in which case they must provide the necessary additional resources.

The pharmaceutical provision is included under the common portfolio of services of the NHS, and depending on where the medicine is dispensed, it may belong to the common portfolio of assistance services (this is the case for medicines dispensed in healthcare or social care centres) or to the supplementary common portfolio (this applies to medicines dispensed in pharmacies or day care centres, where the user has some co-payment obligation).

This provision is governed by its specific regulations, among which it is important to highlight Royal Legislative Decree 1/2015, of July 24th, which approves the consolidated text of the Law on the Warranties and Rational Use of Medicine and Health Care Products (the "Medicines Law").

Article 91 of the Medicines Law sets forth the principle of territorial equality and coordination on this matter, recognizing the right of all citizens to receive medicines in conditions of equality in the entire NHS, without prejudice of the measures directed towards optimizing prescriptions and the use medicines and health care products that the Autonomous Communities may adopt in exercise of their competencies.

Article 92 of the Medicines Law sets forth that public reimbursement of medicines and health care products will require its inclusion in the pharmaceutical provision through an express resolution adopted by the competent authority (the General Directorate of the Basic Portfolio of

Services of the Spanish NHS and Pharmacy of the Ministry of Health, Consumption and Social Welfare), setting forth the conditions of price and reimbursement within the National Health System. Such resolution shall apply in the entire national territory and shall be effective in the moment it establishes so, in accordance with article 91.2 of the mentioned Law.

The Medicines Law establishes that the Autonomous Communities may not set, unilaterally, specific reservations on the prescription, dispensation and reimbursement of medicines or health care products (article 91.2), this with the aim of guaranteeing the right of all individuals to have access to the pharmaceutical provision in conditions of equality across the NHS.

On the other hand, under article 17.6 of Royal Decree 1718/2010, of December 17th, on medical prescriptions and hospital dispensing orders, “medicines and health care products that are not included in the public financing may only be acquired and used by hospitals in the National Health System if there exists a prior resolution by the commission responsible for therapeutic protocols or the equivalent body in each autonomous community.” To be able to take the decisions set forth above, the commissions responsible must have been constituted in accordance with the applicable regulation in the autonomous community, must have a procedural manual that ensures the quality of their decisions and must inform of their constitution and decisions to the competent body within the department responsible in the autonomous community.

In accordance with what has been mentioned above, and after consulting with the State’s Attorney within the Ministry of Health, Consumption and Social Welfare¹, the following conclusions are reported:

- Those medicines which have received an express resolution of no reimbursement are medicines that are not included in the pharmaceutical provision of the NHS and are therefore not included in the common portfolio of services of the NHS.
- The Autonomous Communities and the managing entities may not include in its portfolio of services, and therefore may not reimburse with public funds, medicines which have received an express resolution of no reimbursement, since this would produce differences in the conditions of access to medicines and health care products by the NHS, between citizens covered the National Health System for reasons only of territory, which is expressly forbidden by the Medicines Law.
- The objective scope of article 17.6 of the Royal Decree 178/2010 refers to those medicines and health care products not included in the reimbursement of the NHS, but not to those medicines which have received, expressly, a resolution of no reimbursement.

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¹ Report by the State’s Attorney (File 652/2019)