

## **A sector inquiry on vaccines by the Italian Competition Authority: the need for a more transparent market on drug costs and prices**

An annual cost of 300 million euro, borne by the National Health System (NHS), expected to double with the approval of the new national vaccine plan. A global market of over 20 billion euro, dominated by an oligopoly of four multinational companies. A deep lack of information on product costs and prices. The need for unambiguous and transparent medical choices, also in order to orient the demand side correctly.

The sector inquiry of the Italian Competition Authority (ICA) on “Markets for vaccines of human use”, particularly those considered essential because qualified by the national vaccine plans as mandatory or recommended, puts the spotlight on this sensitive market. The ICA, chaired by professor Giovanni Pitruzzella, observed several critical issues from a competition viewpoint, some of them related to the general structure of the vaccine industry and the pharmaceutical sector, others more specific to the Italian situation.

With respect to issues of general relevance, the investigation pointed out a highly concentrated oligopoly on a worldwide basis, with four multinational companies - GlaxoSmithKline, Sanofi Pasteur, MerckSharpDohme and Pfizer - which hold more than 80% in value of total sales of vaccines, a pharmaceutical sector that is currently worth over 20 billion euro, and has been growing strongly for years. This trend is largely dependent on the development of innovative products that have much higher prices than conventional vaccines and are covered by highly complex intellectual property rights. This hinders the development of generic versions of vaccines at a higher level than the one noted in other pharma industries; moreover, product differentiation is making harder the substitutability between vaccines intended to prevent the same disease.

Trade policies enacted by the major operators (especially “tiered pricing”, to which are frequently added confidentiality agreements on prices) make it hard for the institutional buyers to properly define their purchases. According to the common perception, however, vaccines continue to be regarded as traditional drugs, cheap and readily available. The ICA therefore suggests precise interventions to be

adopted and shared internationally in order to overcome these competitive critical issues.

With respect to Italy, the ICA has analyzed the supply and demand trends of essential vaccines within 2010-2015, when the costs by the NHS were, on average, 300 million euro per year. The ICA considered in a positive way the ongoing process of public demand aggregation, as it considers it appropriate to balance the concentrated supply (countervailing buyer power). According to the ICA, however, there is a need for greater transparency of information, first of all by means of an easier availability of the procurement data, to be processed in view of benchmark assessments: shared good administrative practices are also needed.

In more detail, the sector inquiry provides direct evidence of the positive effects of competition on price, in the interest of consumers; as a matter of fact, when a commercial contest between different products occurs, prices tend to decrease appreciably, even in the absence of so-called generic versions. The cases of the anti-papilloma virus and hexavalent vaccines, representing respectively the third and second NHS vaccine cost items (23 and 75 million euro), are noteworthy, as there was direct competition between the products of GlaxoSmithKline (Cervarix and Infanrix Hexa) and Sanofi-MerckSharpDohme (Gardasil and Hexyon).

In the case of anti-pneumococcal vaccines, representing the first NHS vaccine cost item (84 million euro), there has been instead an absolute dominance of a single product: Prevenar13 by Pfizer, preferred by the public contracting agencies as it offers a higher coverage for serotype strains than its competitor, Synflorix by GlaxoSmithKline. An official medical decision on the possible medical equivalence between vaccines offering different serotype strains coverage is also at the basis of the possible product substitutability from a commercial viewpoint. In the absence of such public decisions, it has thus witnessed the continuing monopoly of a product, which, even in the face of growing and guaranteed sales volumes to the NHS, has increased its prices over the years.

The ICA therefore stresses the need for the competent medical authorities to adopt clear positions, transparent and independent, as regards (1) the inclusion of products in the national vaccine plans and the resulting basic levels of care to be guaranteed at a national level; (2) the medical equivalence between two products.

To allow a rebalancing of trade relations between supply and demand, the ICA also proposes to include vaccines in public reimbursement classes that require a price bargaining with national public authorities, once such products have been included in the national vaccination plans: this taking into account that such inclusion ensures large and enduring sales volumes, in view of appropriate discounts-quality assessments.

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