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AGENZIA ITALIANA DEL FARMACO

New Regulation approved by the Board of Directors

AIFA launches crackdown on conflict of interest. But opens the way for free opinions and consultations by high-profile professionals

"*Giving the Agency the possibility of using high-profile professionals for opinions and consultancy, without falling into the trap of conflict of interest. At the same time, strengthen the limits for heads and employees, with the obligation extended to both to declare any conflicts of interest that lead to suspension from the proceedings in which the conflict arises*". This is how **AIFA's administrative director, Giovanni Pavesi**, explains the salient new features of the new conflict of interest regulation, adopted by decision of the Agency's Board of Directors after accepting ANAC's suggestions and still awaiting any technical comments from the supervising ministries.

"*We had no obligation to intervene with a regulation on conflicts of interest, but we wanted to do so in order to follow the path that Europe is tracing in this regard in the pharmaceutical sector. But above all*, - explains **AIFA President Robert Nisticò**, presenting the regulation at the Agency's headquarters to its Heads - *we thought of protecting the health of citizens by ensuring effective prevention of conflicts of interest, without this turning into a noose for the good performance of the Agency, but preventing the interests of those who work or collaborate there from even appearing to prevail over the main interest, which is the protection of public health*".

The list of relationships and activities that constitute "direct secondary interests" is long: relationships of dependence, consultancy or collaboration in any capacity, even free, with a "sensitive" entity; transfers of money in any form by private individuals operating in the pharmaceutical sector; extra-institutional teaching activities and interventions as speakers at events always organised by sensitive entities; possession of stock titles, stock options or any other co-interest or participated interest in companies in the pharmaceutical sector; property rights, including patents relating to medicines or active ingredients; participation in strategic, scientific and management committees organised or financed by sensitive entities; social positions, even if unpaid, in scientific societies financed by companies or any other private entity operating in the pharmaceutical sector.

The list of secondary interests that arise when these concern relatives or people in any way close to AIFA employees, heads and collaborators is similar.

Employees and Heads are required to submit the Declaration of Conflict of Interest (DOI) to the superior Head. The members of the CdA, Cdr, OIV (Independent Evaluation Body), CSE (Scientific and

Economic Committee for Medicine) and the General Directors in turn submit the Declaration of Conflict of Interest to the Committee of Guarantors, which supports those responsible for assessing the conflict of interest in particularly complex cases. The Committee includes Lorenzo D'Avack, as president, and Pierluigi Navarra and Giuseppe Fabrizio Maiellaro as members.

The Regulation identifies three levels of risk:

1) Absent or irrelevant, according to which involvement in the Agency's activities is permitted without limitations;
2) Relevant, according to which limitations are provided, such as the obligation to abstain in those phases of the procedure in which there is a declared interest;
3) High, the existence of which excludes the performance of any institutional activity.

A firm restriction, accompanied by an opening to the possibility of making use of "high professional skills of an irreplaceable nature", essential for the proper functioning of the Agency.

With the exception of members of the Board of Directors, a specific authorisation is also required from the hierarchical superior for participation, on behalf of the Agency, as a speaker, teacher, moderator or similar in events sponsored by entities operating in the pharmaceutical sector.

Violation of the obligations set out in the Regulation entails suspension of activity from three months to one year for experts, consultants, collaborators and members of working groups not directly dependent on AIFA. For employees, however, disciplinary proceedings will be triggered.

"*With the new Regulation* - says **Pavesi** - *AIFA is moving in line with the recent decision of the European Court of Justice, which by overturning an EMA decision not to approve a medicine, in the presence of a possible conflict of interest, has established that the European Agency itself 'is required to monitor in order to ensure that the experts it consults do not find themselves in a conflict of interest'. A risk from which AIFA wants to protect itself* - concludes the Administrative Director - *also with a new internal code of conduct that expands the duties of the Agency's staff, with a view to preventing illicit activities, with particular attention to the use of information technology, media and social media*".