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To insurance Undertakings
with head offices in Italy

TO THEIR PREMISES

To their Branches in Italy
of insurance Undertakings with
head offices in a Third Country with respect
to the European Economic Area

TO THEIR PREMISES

To the Insurance intermediaries registered
in the Single Register of Intermediaries
kept by IVASS

TO THEIR PREMISES

Subject EU Directive no. 2016/97 on insurance distribution and the EIOPA preparatory guidelines on product oversight and governance (POG) arrangements by insurance undertakings and insurance distributors.

1. The evolution of European legislation on POG

1. Art. 25 of Directive no. 2016/97/EU on the distribution of insurance (so-called IDD Directive) introduces Product Oversight and Governance (POG) arrangements for manufacturers and distributors that provide any type of insurance product for sale to customers. Such provisions - similar to Directive no. 65/2014/EU (so-called MiFID2 Directive) - introduce safeguards for consumer protection starting from the *design* and the launch of the product, to ensure that the interests of the reference market, i.e. the *target* market of customers for whom the product is intended (so-called *target market*) are properly taken into account. The protection safeguards extend throughout the duration of the product's life, providing a monitoring over time to ensure that the same continues to respond to the interests of the customers for whom it has been designed.
2. The legislation on *product governance* introduced by the European legislation on insurance falls under the broader provisions of *governance* of insurance undertakings defined in the *Solvency II* Directive, which requires management of the activities of the insurance undertaking in a sound and prudent manner through the adoption of an adequate risk management system. Therefore the legislation on the *governance* of insurance undertakings, integrated by the POG legislation, must be understood as a unitary process, to manage in a consistent manner in relation to all the undertaking's products in a more general framework of consumer protection.
3. The European regulatory framework is still in the process of definition: the implementation of the IDD Directive is scheduled for 23 February 2018 and the related Delegated Acts of the European Commission are in the process of public consultation.

4. In the meantime, on 13 April 2016 EIOPA published on its website the "*Preparatory Guidelines on product oversight and governance arrangements by insurance undertakings and insurance distributors*". These *Preparatory Guidelines* (hereinafter referred to as the "guidelines") - adopted pursuant to article 9, paragraph 2 and article 16 of the Establishing Regulation of EIOPA1 - have the purpose of providing the national Authorities with indications in order to facilitate the preparation of the European insurance market for the application of the IDD and of the related Delegated Acts, allowing a harmonisation of the financial and insurance markets that guarantees a *level playing field* with regard to the specificities of the individual sectors.
5. The guidelines are divided into two separate sets, connected to each other and directed, respectively, to the manufacturers and distributors of life and non-life insurance products falling within the scope of application of the IDD Directive, with exclusion of insurance products relating to large risks. They shall establish a separate and integrated set of guidelines to make each operator accountable for his/her own area of competence and on the basis of the role they play in the design and distribution of the products and must be applied in a manner proportional to their complexity and risk, as well as to the nature, scale and complexity of the activity carried out by the subject to be regulated.
6. In the general context of the legislation governing the POG, "manufacturer" shall mean both the insurance undertaking and the insurance intermediary (so-called "*manufacturer de facto*") which provide insurance products for sale to customers; "distributor" shall mean both the undertaking that sells directly and the insurance intermediary that distributes insurance products created by others.
7. The *Technical Advice on possible delegated acts concerning the Insurance Distribution Directive* (hereinafter referred to as "*Technical Advice*") sent on 1 February 2017 by EIOPA to the European Commission provides indications about the figure of the *manufacturer de facto*. In particular, an insurance intermediary is regarded as a "manufacturer" when he/she plays a decision-making role in the design and development of an insurance product for the market. Ultimately he/she qualifies as *manufacturer de facto* when, both in the creation of a new product and in the modification of an existing product, he/she determines independently the significant elements (e.g. cover, costs, risks, performance and guarantees), with respect to which the insurance undertaking, which assumes the relative risks, has not made substantial changes.
8. The *Technical Advice* does not instead consider the customisation and adaptation of existing insurance products, such as the activity of *design* of so-called "*tailor-made*" contracts at the request of a specific customer, in order to meet the special insurance needs, or the mere possibility of proposing to the customer different lines of products and contractual clauses, options or underlying assets, i.e. premium discounts, as activities eligible for qualifying the intermediary as *manufacturer de facto*.

2. The evolution of Italian regulations

9. The *product governance* of the insurance sector was introduced *ex novo* by the IDD Directive with regard to all insurance products without distinction of class or distribution channel.
10. Without prejudice to the scope and the forecasts of the Directive and its implementing provisions, at national level the POG legislation is in the process of definition. It therefore draws the attention of the operators to the regulatory developments that will define the regulatory framework applicable to them.
11. In any case, for the products of the non-life classes and for life insurance products other than insurance based investment products (so-called IBIPs) the insurance undertakings and

distributors will need to work in such a way as to follow the indications on the preparation for the new regulatory framework as indicated in paragraph 3.

12. With reference to the IBIP products, Legislative Decree no. 129 of 3 August 2017 has provided - in line with the division of competencies in force - the power of Consob (Italian Securities and Exchange Commission) to adopt regulations concerning *product governance* limited to classes III and V. Pending the completion of the legislation on *product governance* within the upcoming transposition of the IDD Directive - which, as said, applies to all products issued by the insurance undertakings, including all investment insurance products - it is necessary that insurance undertakings and distributors prepare themselves adequately for the entry into force of the new legislation, hereby carrying out a thorough *gap analysis* with respect to the European provisions applicable to them.

3. Preparation of the market for the new regulatory framework

13. It is important that, as of now, pending the implementation of the IDD Directive and the related Delegated Acts currently in the course of adoption, the undertakings and intermediaries initiate a path toward the new legislation, in such a way as to arrive prepared for it before the date of its application in national law.
14. The current period and until the transposition of the European legislation, must in fact be used by the manufacturers and distributors to implement a series of preliminary activities necessary for progressively achieving *compliance* with the European POG provisions, which must be fully complied with upon the transposition of the European legislation.
15. In particular, manufacturers will work towards:
- conducting a *gap analysis* of the processes and of the measures in force related both to the *design phase* of the insurance products and to the step of placement of the same, evaluating the distance compared to the total *compliance* with the European reference provisions and scheduling the consequent actions;
 - evaluating whether or not the organisational structure is appropriate in terms of human resources and expertise for the conduct of the new activities required in terms of POG;
 - verifying if its organisational structure is suitable to support the business units involved in the new processes and allowing adequate informational exchanges with the distribution network, privileging the computer channel;
 - defining the procedures for identifying, with a sufficient level of granularity, the various types of customers to which the products will be intended (*target market*) and those for which the product is generally not compatible, where relevant, for the protection of the consumer;
 - defining the procedures for carrying out the monitoring of the products;
 - individuating information on the products supplied to the distributors in order to facilitate the same in the path of preparation with the obligations required by the new regulations;
 - planning adequate procedures for the exchange of information with the sales network finalised at the preparation by the latter of adequate measures for the distribution of the products offered.
16. Analogously, the distributors of insurance products not made by themselves, registered in sections A, B and D of the Single Register of Intermediaries will work towards:

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- evaluating the compliance of the existing information flows to individuate the additional information that is necessary to obtain from the manufacturer in order to adapt to the new guidelines on POG;
 - individuating more efficient information channels to manage communications with the manufacturer as well as with its distribution network in order to ensure their observance of the operating procedures required by the regulations on the POG for the placement of the products.
17. Taking into account that the European regulatory framework is in the process of definition, in the actions to be taken to correspond to the requirements set out in paragraphs 15 and 16, the manufacturers and distributors are invited to refer, respectively, to the indications given in Annexes nos. 1 and 2 in this document. The annexed indications, which recall the European regulatory framework (article 25 of the IDD Directive, consultation of Delegated Acts of the same Directive, the Guidelines and the EIOPA *Technical Advice*), taking account, in application of the principle of proportionality referred to the above-mentioned Directive, of the complexity and risk of the products offered as well as, with particular reference to the distributors, of the corresponding dimension and organisational structure.
18. With reference to the POG safeguards required by Guidelines and by the *Technical Advice* for the distributors, in addition to those designed to achieve adequate information exchange with the manufacturers, shall wait for the definition of the European regulatory framework in order to provide specific indications on possible additional preparatory requirements to be carried out in view of the application of the IDD Directive.

Best regards.

By delegation
of the Joint Directorate