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Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2017/2358 of 21 September 2017 supplementing Directive (EU) 2016/97 of the European Parliament and of the Council with regard to product oversight and governance requirements for insurance undertakings and insurance distributors<sup>(1)</sup> .....** 1
- ★ **Commission Delegated Regulation (EU) 2017/2359 of 21 September 2017 supplementing Directive (EU) 2016/97 of the European Parliament and of the Council with regard to information requirements and conduct of business rules applicable to the distribution of insurance-based investment products<sup>(1)</sup> .....** 8

<sup>(1)</sup> Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.



## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2017/2358

of 21 September 2017

**supplementing Directive (EU) 2016/97 of the European Parliament and of the Council with regard to product oversight and governance requirements for insurance undertakings and insurance distributors**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/97 of the European Parliament and of the Council of 20 January 2016 on insurance distribution <sup>(1)</sup>, and in particular Article 25(2) thereof,

Whereas:

- (1) Directive (EU) 2016/97 empowers the Commission to adopt delegated acts to further specify the product oversight and governance requirements set out in Article 25 of that directive. In the interest of effective customer protection, product oversight and governance rules should apply in a coherent manner to all newly developed insurance products and to significant adaptations of existing insurance products, irrespective of the type of product and of the requirements applicable at the point of sale. The form of a Regulation ensures a coherent framework for all market operators and is the best possible guarantee for a level playing field, equal conditions of competition and an appropriate standard of consumer protection.
- (2) In light of the requirements of Directive (EU) 2016/97, product oversight and governance measures should be chosen and applied in a proportionate and appropriate manner, depending on the complexity of the product and the degree to which publicly available information can be obtained, taking into account the nature of the insurance product and the risk of consumer detriment related to it, the characteristics of the target market and the nature, scale and complexity of the relevant business of the manufacturer or distributor. Proportionality means that those measures should be relatively simple for straightforward and non-complex products that are compatible with the needs and characteristics of the mass retail market, including current non-life insurance products with a limited, easily understandable scope. On the other hand, in the case of more complex products with a higher risk of consumer detriment, including insurance-based investment products not covered by Article 30(3) of Directive (EU) 2016/97, more exacting measures should be required.
- (3) For the purposes of Article 25(1) of Directive (EU) 2016/97, an insurance intermediary should be considered as a manufacturer of an insurance product where it appears from an overall analysis of the intermediary's activity on a case-by-case basis, that the insurance intermediary autonomously decides on the essential features and main elements of an insurance product, including the coverage, costs, risks, target market or compensation or guarantee rights. Activities related to the mere adaptation of existing insurance products, including cases where the intermediary has a choice between different variants of a product, different contractual clauses or options, or may agree with the customer on discounted premiums or fees, should however not be regarded as manufacturing since in such cases the main decisions on the design and development of the product are made by the insurance undertaking and not by the insurance intermediary.

<sup>(1)</sup> OJ L 26, 2.2.2016, p. 19.

- (4) Where an insurance product is designed and developed by an insurance intermediary and an insurance undertaking acting together with both of them having a decision-making role in designing and developing that product, the insurance intermediary and the insurance undertaking should specify in a written agreement their collaboration and respective roles so that competent authorities are able to supervise compliance with the legal requirements.
- (5) The identification of the target market by the manufacturer should be understood as describing a group of customers sharing common characteristics at an abstract and generalised level in order to enable the manufacturer to adapt the features of the product to the needs, characteristics and objectives of that group of customers. It should be distinguished from the individual assessment at the point of sale to determine whether an insurance product meets the demands and needs and, where applicable, whether an insurance-based investment product is suitable or appropriate for the individual customer or potential customer.
- (6) The level of granularity of the target market and the criteria used to define the target market and determine the appropriate distribution strategy should be relevant for the product and should make it possible to assess which customers fall within the target market. For simpler, more common products, the target market should be identified with less detail while for more complicated products or less common products, the target market should be identified with more detail taking into account the increased risk of consumer detriment associated with such products.
- (7) To enhance consumer protection, in particular with regard to insurance-based investment products, manufacturers should have the possibility to identify specific groups of customers for which the insurance product is typically not appropriate.
- (8) As part of the product oversight and governance arrangements, manufacturers should also undertake appropriate testing of insurance products, including, where relevant and in particular for insurance-based investment products, scenario analyses, to ensure that the product meets over its whole lifetime, the identified needs, objectives and characteristics of the target market. This should, in particular, include assessments of the product performance and the risk/reward profile. The requirement to assess the product performance should however not be understood as an interference with the manufacturers' freedom to set premiums or as price control in any form.
- (9) To ensure appropriate information and advice for customers, manufacturers should select insurance distributors that have the necessary knowledge, expertise and competence to understand the features of an insurance product and the identified target market. For the same reason, they should, within the framework of applicable national law governing their relationship with the insurance distributors in question, monitor and examine on a regular basis whether the insurance product is distributed in conformity with the objectives of their product oversight and governance arrangements and take appropriate remedial action where they consider that that is not the case. That should however not prevent insurance distributors from distributing insurance products to customers who do not belong to that target market, provided that the individual assessment at the point of sale justifies the conclusion that those products correspond to the demands and needs of those customers and, where applicable, that insurance-based investment products are suitable or appropriate for the customer.
- (10) To enable insurance distributors to fully understand the products they intend to distribute, so that they can carry out their distribution activities in accordance with the best interest of their costumers, in particular by providing professional advice, manufacturers should provide insurance distributors with all appropriate information on those insurance products, including on the product approval process, the identified target market and the suggested distribution strategy. Conversely, insurance distributors should have arrangements to obtain the required information from the manufacturers in an efficient manner.
- (11) The efficient functioning of product governance obligations requires that insurance distributors regularly inform manufacturers about their experience with the insurance products. Insurance distributors should therefore provide manufacturers with the data needed for the review of the insurance product and check that those products remain in line with the needs, characteristics and objectives of the target market identified by the manufacturer.
- (12) To avert the risk of customer detriment, manufacturers and distributors should take appropriate action when they consider that the product is not or no more aligned with the interests, objectives and characteristics of the identified target market.

- (13) In order to allow competent authorities and insurance professionals to adapt to the new requirements contained in this Regulation, the starting date of application of this Regulation should be aligned with the entry into application of the national measures transposing Directive (EU) 2016/97.
- (14) The European Insurance and Occupational Pensions Authority, established by Regulation (EU) No 1094/2010 of the European Parliament and of the Council <sup>(1)</sup>, has been consulted for technical advice <sup>(2)</sup>,

HAS ADOPTED THIS REGULATION:

#### CHAPTER I

#### GENERAL PROVISIONS

##### *Article 1*

##### **Subject**

This Regulation lays down rules for the maintenance, operation and review of product oversight and governance arrangements for insurance products and for significant adaptations to existing insurance products before those products are brought to the market or distributed to customers ('product approval process'), as well as rules for product distribution arrangements for those insurance products.

##### *Article 2*

##### **Scope**

This Regulation shall apply to insurance undertakings and to insurance intermediaries that manufacture insurance products that are offered for sale to customers ('manufacturers'), as well as to insurance distributors that advise on, or propose, insurance products that they do not manufacture.

##### *Article 3*

#### **Manufacturing insurance products**

1. For the purposes of Article 25(1) of Directive (EU) 2016/97, insurance intermediaries shall be considered manufacturers where an overall analysis of their activity shows that they have a decision-making role in designing and developing an insurance product for the market.
2. A decision-making role shall be assumed, in particular, where insurance intermediaries autonomously determine the essential features and main elements of an insurance product, including its coverage, price, costs, risk, target market and compensation and guarantee rights, which are not substantially modified by the insurance undertaking providing coverage for the insurance product.
3. Personalisation of and adaptation of existing insurance products in the context of insurance distribution activities for individual customers, as well as the design of tailor-made contracts at the request of a single customer, shall not be considered manufacturing.
4. An insurance intermediary and an insurance undertaking that are both manufacturers within the meaning of Article 2 of this Delegated Regulation, shall sign a written agreement which specifies their collaboration to comply with the requirements for manufacturers referred to in Article 25(1) of Directive (EU) 2016/97, the procedures through which they shall agree on the identification of the target market and their respective roles in the product approval process.

<sup>(1)</sup> Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

<sup>(2)</sup> Technical Advice on possible delegated acts concerning the Insurance Distribution Directive, EIOPA-17/048, 1 February 2017, available here: <https://eiopa.europa.eu/Publications/Consultations/EIOPA%20Technical%20Advice%20on%20the%20IDD.pdf>.

## CHAPTER II

**PRODUCT GOVERNANCE REQUIREMENTS FOR MANUFACTURERS***Article 4***Product approval process**

1. Manufacturers shall maintain, operate and review a product approval process for newly developed insurance products and for significant adaptations of existing insurance products. That process shall contain measures and procedures for designing, monitoring, reviewing and distributing insurance products, as well as for corrective action for insurance products that are detrimental to customers. The measures and procedures shall be proportionate to the level of complexity and the risks related to the products as well as the nature, scale and complexity of the relevant business of the manufacturer.
2. The product approval process shall be set out in a written document ('product oversight and governance policy'), which shall be made available to the relevant staff.
3. The product approval process shall:
  - (a) ensure that the design of insurance products meets the following criteria:
    - (i) it takes into account the objectives, interests and characteristics of customers;
    - (ii) it does not adversely affect customers;
    - (iii) it prevents or mitigates customer detriment;
  - (b) support a proper management of conflicts of interest.
4. The manufacturers' body or structure responsible for the manufacturing of insurance products shall do all of the following:
  - (a) endorse and be ultimately responsible for establishing, implementing and reviewing the product approval process;
  - (b) continuously verify internal compliance with that process.
5. Manufacturers designating a third party to design products on their behalf shall remain fully responsible for compliance with the product approval process.
6. Manufacturers shall regularly review their product approval process to ensure that that process is still valid and up to date. They shall amend the product approval process where necessary.

*Article 5***Target market**

1. The product approval process shall for each insurance product identify the target market and the group of compatible customers. The target market shall be identified at a sufficiently granular level, taking into account the characteristics, risk profile, complexity and nature of the insurance product.
2. Manufacturers may, in particular with regard to insurance-based investment products, identify groups of customers for whose needs, characteristics and objectives the insurance product is generally not compatible.
3. Manufacturers shall only design and market insurance products that are compatible with the needs, characteristics and objectives of the customers belonging to the target market. When assessing whether an insurance product is compatible with a target market, manufacturers shall take into account the level of information available to the customers belonging to that target market and their financial literacy.
4. Manufacturers shall ensure that staff involved in designing and manufacturing insurance products has the necessary skills, knowledge and expertise to properly understand the insurance products sold and the interests, objectives and characteristics of the customers belonging to the target market.

*Article 6***Product testing**

1. Manufacturers shall test their insurance products appropriately, including scenario analyses where relevant, before bringing that product to the market or significantly adapting it, or in case the target market has significantly changed. That product testing shall assess whether the insurance product over its lifetime meets the identified needs, objectives and characteristics of the target market. Manufacturers shall test their insurance products in a qualitative manner and, depending on the type and nature of the insurance product and the related risk of detriment to customers, quantitative manner.
2. Manufacturers shall not bring insurance products to the market if the results of the product testing show that the products do not meet the identified needs, objectives and characteristics of the target market.

*Article 7***Product monitoring and review**

1. Manufacturers shall continuously monitor and regularly review insurance products they have brought to the market, to identify events that could materially affect the main features, the risk coverage or the guarantees of those products. They shall assess whether the insurance products remain consistent with the needs, characteristics and objectives of the identified target market and whether those products are distributed to the target market or is reaching customers outside the target market.
2. Manufacturers shall determine the appropriate intervals for the regular review of their insurance products, thereby taking into account the size, scale, contractual duration and complexity of those insurance products, their respective distribution channels, and any relevant external factors such as changes to the applicable legal rules, technological developments, or changes to the market situation.
3. Manufacturers that identify during the lifetime of an insurance product any circumstances related to the insurance product that may adversely affect the customer of that product shall take appropriate action to mitigate the situation and prevent further occurrences of the detrimental event. Manufacturers shall promptly inform concerned insurance distributors and customers about the remedial action taken.

*Article 8***Distribution channels**

1. Manufacturers shall carefully select distribution channels that are appropriate for the target market, thereby taking into account the particular characteristics of the relevant insurance products.
2. Manufacturers shall provide insurance distributors with all appropriate information on the insurance products, the identified target market and the suggested distribution strategy, including information on the main features and characteristics of the insurance products, their risks and costs, including implicit costs, and any circumstances which might cause a conflict of interest to the detriment of the customer. That information shall be clear, complete and up to date.
3. The information referred to in paragraph 2 shall enable the insurance distributors to:
  - (a) understand the insurance products;
  - (b) comprehend the identified target market for the insurance products;
  - (c) identify any customers for whom the insurance product is not compatible with their needs, characteristics and objectives;
  - (d) carry out distribution activities for the relevant insurance products in accordance with the best interests of their customers as prescribed in Article 17(1) of Directive (EU) 2016/97.
4. Manufacturers shall take appropriate steps to monitor that insurance distributors act in accordance with the objectives of the manufacturers' product approval process. They shall in particular verify on a regular basis whether the insurance products are distributed on the identified target market. That monitoring obligation shall not extend to the general regulatory requirements with which insurance distributors have to comply when carrying out insurance distribution activities for individual customers. The monitoring activities shall be reasonable, taking into consideration the characteristics and the legal framework of the respective distribution channels.

5. Manufacturers considering that the distribution of their insurance products is not in accordance with the objectives of their product approval process shall take appropriate remedial action.

#### *Article 9*

### **Documentation**

Relevant actions taken by manufacturers in relation to their product approval process shall be duly documented, kept for audit purposes and made available to the competent authorities upon request.

#### CHAPTER III

### **PRODUCT GOVERNANCE REQUIREMENTS FOR INSURANCE DISTRIBUTORS**

#### *Article 10*

### **Product distribution arrangements**

1. Insurance distributors shall have in place product distribution arrangements containing appropriate measures and procedures to obtain from the manufacturer all appropriate information on the insurance products they intend to offer to their customers and to fully comprehend those insurance products, taking into account the level of complexity and the risks related to the products as well as the nature, scale and complexity of the relevant business of the distributor.

Insurance distributors shall set out the product distribution arrangements in a written document and make it available to their relevant staff.

2. The product distribution arrangements shall:

- (a) aim to prevent and mitigate customer detriment;
- (b) support a proper management of conflicts of interest;
- (c) ensure that the objectives, interests and characteristics of customers are duly taken into account.

3. The product distribution arrangements shall ensure that the insurance distributors obtain from the manufacturer the information to be communicated under Article 8(2).

4. Any specific distribution strategy set up or applied by insurance distributors shall be in accordance with the distribution strategy set up and the target market identified by the manufacturer.

5. The insurance distributors' body or structure responsible for insurance distribution shall endorse and be ultimately responsible for establishing, implementing and reviewing the product distribution arrangements and continuously verify internal compliance with those arrangements.

6. Insurance distributors shall regularly review their product distribution arrangements to ensure that those arrangements are still valid and up to date. They shall amend product distribution arrangements where appropriate. Insurance distributors that have set up or apply a specific distribution strategy shall, where appropriate, amend that strategy in view of the outcome of the review of the product distribution arrangements. When reviewing their product distribution arrangements, insurance distributors shall verify that the insurance products are distributed to the identified target market.

Insurance distributors shall determine the appropriate intervals for the regular review of their product distribution arrangements, thereby taking into account the size, scale and complexity of the different insurance products involved.

To support product reviews carried out by manufacturers, insurance distributors shall upon request provide manufacturers with relevant sales information, including, where appropriate, information on the regular reviews of the product distribution arrangements.

#### *Article 11*

### **Informing the manufacturer**

Insurance distributors becoming aware that an insurance product is not in line with the interests, objectives and characteristics of its identified target market or becoming aware of other product-related circumstances that may adversely affect the customer shall promptly inform the manufacturer and, where appropriate, amend their distribution strategy for that insurance product.



*Article 12***Documentation**

Relevant actions taken by insurance distributors in relation to their product distribution arrangements shall be duly documented, kept for audit purposes and made available to the competent authorities upon request.

## CHAPTER IV

**FINAL PROVISIONS***Article 13***Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 23 February 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 September 2017.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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**COMMISSION DELEGATED REGULATION (EU) 2017/2359****of 21 September 2017****supplementing Directive (EU) 2016/97 of the European Parliament and of the Council with regard to information requirements and conduct of business rules applicable to the distribution of insurance-based investment products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/97 of the European Parliament and of the Council of 20 January 2016 on insurance distribution <sup>(1)</sup>, and in particular Articles 28(4), 29(4) and 30(6) thereof,

Whereas:

- (1) Directive (EU) 2016/97 provides for a set of specific standards aimed at addressing insurance-based investment products, in addition to the conduct of business standards laid down for all insurance products.
- (2) Directive (EU) 2016/97 empowers the Commission to adopt delegated acts to further specify criteria and practical details for the application of that specific set of rules. The relevant empowerments concern the rules on conflicts of interest, on inducements and on the assessment of suitability and appropriateness. To ensure the coherent application of the provisions adopted on the basis of those empowerments and to ensure that market participants and competent authorities as well as investors are provided with a comprehensive understanding and easy access to those provisions, it is desirable to include them in a single legal act. The form of a Regulation ensures a coherent framework for all market operators and is the best possible guarantee for a level playing field, uniform conditions of competition and an appropriate standard of consumer protection.
- (3) The circumstances and situations to be taken into account for the purposes of determining the types of conflicts of interest which may damage the interests of customers or potential customers should cover cases where the insurance intermediary or insurance undertaking is likely to make a financial gain or avoid a financial loss to the detriment to the customer. However, in such situations, it should not be sufficient that the insurance intermediary or insurance undertaking may realise a benefit if this does not result specifically in a detrimental impact for the customer, or that one customer to whom the insurance intermediary or insurance undertaking owes a duty may make a gain or avoid a loss without there being a concomitant detrimental impact to another such customer.
- (4) To avoid unnecessary administrative burdens while ensuring an appropriate level of customer protection, the organisational measures and procedures to manage conflicts of interest should be carefully adapted to the size and activities of the insurance intermediary or insurance undertaking and of the group to which they may belong, and to the risk of damage to the interests of the customer. A non-exhaustive list of possible measures and procedures should be laid down in order to give guidance to insurance intermediaries and insurance undertakings as regards the measures and procedures that should normally be taken into consideration to manage conflicts of interests. Because of the variety of business models the proposed measures and procedures might not be of relevance for all insurance intermediaries and insurance undertakings. They might, in particular, not be appropriate for small insurance intermediaries and their limited scope of business. In such cases, insurance intermediaries or insurance undertakings should be able to adopt alternative measures and procedures that are more suitable to ensure, in their particular situation, that the distribution activities are carried out in accordance with the best interest of the customer.
- (5) While disclosure of specific conflicts of interest is required under Directive (EU) 2016/97, it should be a measure of last resort to be used only where the organisational and administrative arrangements are not sufficient to ensure, with reasonable confidence, that risks of damage to the interests of the customer will be prevented since over-reliance on disclosure may result in a lack of effective protection of the customer's interests. The disclosure of conflicts of interest by an insurance intermediary or an insurance undertaking cannot exempt it from the obligation to maintain and operate the organisational and administrative arrangements which are the most effective means of preventing damage to customers.

<sup>(1)</sup> OJ L 26, 2.2.2016, p. 19.

- (6) To facilitate the practical implementation of the standards set by the Directive, the criteria for the assessment of inducements paid or received by insurance intermediaries and insurance undertakings should be set out in more detail. For this purpose, a non-exhaustive list of criteria deemed relevant for the assessment of a possible detrimental impact on the quality of the service to the customer should be provided as guidance to ensure an appropriate standard of customer protection.
- (7) The suitability assessment set out in Article 30(1) of Directive (EU) 2016/97 and the appropriateness assessment set out in Article 30(2) of that Directive are different in scope with regard to the distribution activities to which they relate, and have different functions and characteristics. It is therefore necessary to clearly specify the standards and requirements to be complied with in obtaining the information required for each of those assessments and in conducting the assessments. It should also be clarified that the assessments of suitability and appropriateness are without prejudice to the obligation, for insurance intermediaries and insurance undertakings, to specify, prior to the conclusion of any insurance contract, on the basis of information obtained from the customer, the demands and needs of that customer.
- (8) The suitability assessment should be performed not only in relation to recommendations to buy an insurance-based investment product, but for all personal recommendations made during the life-time of that product, as such situations may imply advice on financial transactions which should be based on a thorough analysis of the knowledge and experience and the financial situation of the individual customer. The need for a suitability assessment is particularly strong as regards decisions to switch the underlying investment assets or to hold or sell an insurance-based investment product.
- (9) Since the market exposure of insurance-based investment products depends largely on the choice of underlying investment assets, such a product may be unsuitable for the customer or potential customer due to the risks of those assets, the type or characteristics of the product or the frequency of switching of underlying investment assets. It might also be unsuitable where it would result in an unsuitable portfolio of underlying investments.
- (10) Insurance intermediaries and insurance undertakings should remain responsible for performing suitability assessments where advice on insurance-based investment products is provided in whole or in part through an automated or semi-automated system since such systems are providing personal investment recommendations which should be based on a suitability assessment.
- (11) To ensure an appropriate standard of advice with regard to the long-term development of the product, insurance intermediaries or insurance undertakings should include in the suitability statement, and draw customers' attention to, information on whether the recommended insurance-based investment products are likely to require the customer to seek a periodic review of their arrangement.
- (12) As the assessment of appropriateness has, in principle, to be conducted in all cases where insurance-based investment products are sold without advice, insurance intermediaries and insurance undertakings should perform such an assessment in all situations where, in conformity with the applicable rules of national law, the customer requires a sale without advice and where the conditions of Article 30(3) of Directive (EU) 2016/97 are not met. In cases where a suitability assessment cannot be performed because the necessary information about the customer's financial situation and investment objectives cannot be obtained, the customer might agree, in conformity with the applicable rules of national law, to proceed with concluding the contract as a sale without advice. However, in order to ensure that the customer has the necessary knowledge and experience in order to understand the risks involved, an assessment of appropriateness should be required in such situations, unless the conditions of Article 30(3) of Directive (EU) 2016/97 are met.
- (13) For the purposes of point (a)(ii) of Article 30(3) of Directive (EU) 2016/97, criteria should be set for the assessment of whether an insurance-based investment product that does not meet the conditions set out in point (a)(i) of Article 30(3) of Directive (EU) 2016/97 might nevertheless be considered a non-complex product. In that context, the provision of guarantees can play an important role. Where an insurance-based investment product provides a guarantee at maturity that covers at least the total amount paid by the customer, excluding legitimate costs, such guarantee limits significantly the extent to which the customer is exposed to market fluctuations. It may therefore be justified to consider such a product, subject to further conditions, as a non-complex product for the purposes of Article 30(3) of Directive (EU) 2016/97.

- (14) Directive (EU) 2016/97 is aimed at minimum harmonisation and does therefore not preclude Member States from maintaining or introducing more stringent provisions in order to protect customers, provided that such provisions are consistent with Union law. Any provisions adopted by the Commission for the purposes of further specifying the requirements laid down in Directive (EU) 2016/97 should therefore be designed in a way that allows Member States to maintain stricter provisions in their national laws.
- (15) In order to allow competent authorities and insurance professionals to adapt to the new requirements contained in this Regulation, the starting date of application of this Regulation should be aligned with the entry into application of the national measures transposing Directive (EU) 2016/97.
- (16) The European Insurance and Occupational Pensions Authority, established by Regulation (EU) No 1094/2010 of the European Parliament and of the Council <sup>(1)</sup>, has been consulted for technical advice <sup>(2)</sup>,

HAS ADOPTED THIS REGULATION:

#### CHAPTER I

#### SCOPE AND DEFINITIONS

##### *Article 1*

##### **Scope**

This Regulation shall apply to insurance distribution in relation to the sale of insurance-based investment products carried out by insurance intermediaries or insurance undertakings.

##### *Article 2*

##### **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'relevant person' in relation to an insurance intermediary or insurance undertaking, means any of the following:
- (a) a director, partner or equivalent, or manager of the intermediary or undertaking, where applicable;
  - (b) an employee of the insurance intermediary or insurance undertaking, as well as any other natural person whose services are placed at the disposal and under the control of the insurance intermediary or insurance undertaking and who is involved in the distribution of insurance-based investment products;
  - (c) a natural person who is directly involved in the provision of services to the insurance intermediary or insurance undertaking under an outsourcing agreement for the purpose of the distribution by the intermediary or undertaking of insurance-based investment products;
- (2) 'inducement' means any fee, commission, or any non-monetary benefit provided by or to such an intermediary or undertaking in connection with the distribution of an insurance-based investment product, to or by any party except the customer involved in the transaction in question or a person acting on behalf of that customer;
- (3) 'inducement scheme' means a set of rules governing the payment of inducements, including the conditions under which the inducements are paid.

<sup>(1)</sup> Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

<sup>(2)</sup> Technical Advice on possible delegated acts concerning the Insurance Distribution Directive, EIOPA-17/048, 1 February 2017, available here: <https://eiopa.europa.eu/Publications/Consultations/EIOPA%20Technical%20Advice%20on%20the%20IDD.pdf>

## CHAPTER II

**CONFLICTS OF INTEREST AND INDUCEMENTS***Article 3***Identification of conflicts of interest**

1. For the purposes of identifying, in accordance with Article 28 of Directive (EU) 2016/97, the types of conflicts of interest that arise in the course of carrying out any insurance distribution activities related to insurance-based investment products and which entail a risk of damage to the interests of a customer, insurance intermediaries and insurance undertakings shall assess whether they, a relevant person or any person directly or indirectly linked to them by control, have an interest in the outcome of the insurance distribution activities, which meets the following criteria:

- (a) it is distinct from the customer's or potential customer's interest in the outcome of the insurance distribution activities;
- (b) it has the potential to influence the outcome of the distribution activities to the detriment of the customer.

Insurance intermediaries and insurance undertakings shall proceed in the same way for the purposes of identifying conflicts of interest between one customer and another.

2. For the purposes of the assessment pursuant to paragraph 1, insurance intermediaries and insurance undertakings shall take into account, by way of minimum criteria, the following situations:

- (a) the insurance intermediary or insurance undertaking, a relevant person or any person directly or indirectly linked to them by control is likely to make a financial gain, or avoid a financial loss, to the potential detriment of the customer;
- (b) the insurance intermediary or insurance undertaking, a relevant person or any person directly or indirectly linked to them by control has a financial or other incentive to favour the interest of another customer or group of customers over the interest of the customer;
- (c) the insurance intermediary or insurance undertaking, a relevant person or any person directly or indirectly linked by control to an insurance intermediary or an insurance undertaking is substantially involved in the management or development of insurance-based investment products, in particular where such a person has an influence on the pricing of those products or their distribution costs.

*Article 4***Conflicts of interest policy**

1. For the purposes of Article 27 of Directive (EU) 2016/97, insurance intermediaries and insurance undertakings shall be expected to establish, implement and maintain an effective conflicts of interest policy set out in writing and appropriate to their size and organisation and the nature, scale and complexity of their business.

Where the insurance intermediary or insurance undertaking is a member of a group, the policy shall also take into account any circumstances, of which the insurance intermediary or insurance undertaking is or should be aware, which may give rise to a conflict of interest arising as a result of the structure and business activities of other members of the group.

2. The conflicts of interest policy established in accordance with paragraph 1 shall include the following content:

- (a) with reference to the specific insurance distribution activities carried out, the circumstances which constitute or may give rise to a conflict of interest entailing a risk of damage to the interests of one or more customers;
- (b) procedures to be followed and measures to be adopted in order to manage such conflicts and prevent them from damaging the interests of the customer.

*Article 5***Procedures and measures under the conflicts of interest policy**

1. The procedures and measures referred to in Article 4(2)(b) shall be appropriate to the size and activities of the insurance intermediary or insurance undertaking and of the group to which they may belong, and to the risk of damage to the interests of the customer.

The procedures to be followed and measures to be adopted in accordance with Article 4(2)(b) shall include, where appropriate, the following:

- (a) effective procedures to prevent or control the exchange of information between relevant persons engaged in activities involving a risk of conflict of interest where the exchange of that information may damage the interests of one or more customers;
- (b) the separate supervision of relevant persons whose principal functions involve carrying out activities on behalf of, or providing services, to customers whose interests may conflict, or who otherwise represent different interests that may conflict, including those of the insurance intermediary or insurance undertaking;
- (c) the removal of any direct link between payments, including remuneration, to relevant persons engaged in one activity and payments, including remuneration, to different relevant persons principally engaged in another activity, where a conflict of interest may arise in relation to those activities;
- (d) measures to prevent or limit any person from exercising inappropriate influence over the way in which insurance distribution activities are carried out by the insurance intermediary or insurance undertaking or their managers or employees or any person directly or indirectly linked to them by control;
- (e) measures to prevent or control the simultaneous or sequential involvement of a relevant person in separate insurance distribution activities where such involvement may impair the proper management of conflicts of interest;
- (f) a gifts and benefits policy which determines clearly under which conditions gifts and benefits can be accepted or granted and which steps are to be taken when accepting and granting gifts and benefits.

2. Where insurance intermediaries and insurance undertakings can demonstrate that the measures and procedures referred to in paragraph 1 are not appropriate to ensure that the insurance distribution activities are carried out in accordance with the best interest of the customer and are not biased due to conflicting interests of the insurance intermediary, the insurance undertaking or another customer, insurance intermediaries and insurance undertakings shall adopt adequate alternative measures and procedures for that purpose.

#### *Article 6*

#### **Disclosure**

1. Insurance intermediaries and insurance undertakings shall avoid over-reliance on disclosure to ensure that disclosure to customers, pursuant to Article 28(2) of Directive (EU) 2016/97, is a measure of last resort that can be used only where the effective organisational and administrative arrangements established by the insurance intermediary or insurance undertaking to prevent or manage conflicts of interest in accordance with Article 27 of Directive (EU) 2016/97 are not sufficient to ensure, with reasonable confidence, that risks of damage to the interests of the customer will be prevented.

2. For the purposes of a disclosure of conflicts of interest insurance intermediaries and insurance undertakings shall do all of the following:

- (a) provide a specific description of the conflict of interest in question;
- (b) explain the general nature and sources of the conflict of interest;
- (c) explain the risks to the consumer that arise as a result of the conflict of interest and the steps undertaken to mitigate those risks;
- (d) clearly state that the organisational and administrative arrangements established by the insurance intermediary or insurance undertaking to prevent or manage the conflict of interest are not sufficient to ensure, with reasonable confidence, that risks of damage to the interests of the customer will be prevented.

#### *Article 7*

#### **Review and record keeping**

1. For the purposes of Article 27 of Directive (EU) 2016/97, insurance intermediaries and insurance undertakings shall assess and periodically review, on an at least annual basis, the conflicts of interest policy established in accordance with Article 4 and take all appropriate measures to address any deficiencies.

2. Insurance intermediaries and insurance undertakings shall keep and regularly update a record of the situations in which a conflict of interest entailing a risk of damage to the interests of a customer has arisen or, in the case of an ongoing service or activity may arise.

Senior management of the insurance intermediary or insurance undertaking shall receive on a frequent basis, and at least annually, written reports on the situations referred to in the first subparagraph.

#### Article 8

##### **Assessment of inducements and inducement schemes**

1. An inducement or inducement scheme shall be considered to have a detrimental impact on the quality of the relevant service to the customer where it is of such a nature and scale that it provides an incentive to carry out insurance distribution activities in a way that is not in compliance with the obligation to act honestly, fairly and professionally in accordance with the best interests of the customer.

2. For the purposes of assessing whether an inducement or inducement scheme has a detrimental impact on the quality of the relevant service to the customer, insurance intermediaries and insurance undertakings shall perform an overall analysis taking into account all relevant factors which may increase or decrease the risk of detrimental impact on the quality of the relevant service to the customer, and any organisational measures taken by the insurance intermediary or insurance undertaking carrying out distribution activities to prevent the risk of detrimental impact.

They shall, in particular, consider the following criteria:

- (a) whether the inducement or inducement scheme could provide an incentive to the insurance intermediary or insurance undertaking to offer or recommend a particular insurance product or a particular service to the customer despite the fact that the insurance intermediary or insurance undertaking would be able to offer a different insurance product or service which would better meet the customer's needs;
- (b) whether the inducement or inducement scheme is solely or predominantly based on quantitative commercial criteria or whether it takes into account appropriate qualitative criteria, reflecting compliance with applicable regulations, the quality of services provided to customers and customer satisfaction;
- (c) the value of the inducement paid or received in relation to the value of the product and the services provided;
- (d) whether the inducement is entirely or mainly paid at the moment of the conclusion of the insurance contract or extends over the whole term of that contract;
- (e) the existence of an appropriate mechanism for reclaiming the inducement in case the product lapses or is surrendered at an early stage or in case the interests of the customer have been harmed;
- (f) the existence of any form of variable or contingent threshold or any other kind of value accelerator which is unlocked by attaining a target based on volume or value of sales.

#### CHAPTER III

##### **ASSESSMENT OF SUITABILITY AND APPROPRIATENESS**

#### SECTION 1

##### ***Assessment of suitability***

#### Article 9

##### **Information to be obtained for the purposes of the assessment of suitability**

1. For the purposes of providing advice on an insurance-based investment product in accordance with Article 30(1) of Directive (EU) 2016/97, insurance intermediaries or insurance undertakings shall determine the extent of the information to be collected from the customer or potential customer in light of all the features of the advice to be provided to the customer or potential customer.

2. Without prejudice to the fact that, in accordance with Article 20(1) of Directive (EU) 2016/97, any contract proposed shall be consistent with the customer's demands and needs, insurance intermediaries or insurance undertakings shall obtain from customers or potential customers such information as is necessary for them to understand the essential facts about the customer or potential customer and to have a reasonable basis for determining that their personal recommendation to the customer or potential customer satisfies all of the following criteria:

- (a) it meets the customer's or potential customer's investment objectives, including that person's risk tolerance;

- (b) it meets the customer's or potential customer's financial situation, including that person's ability to bear losses;
  - (c) it is such that the customer or potential customer has the necessary knowledge and experience in the investment field relevant to the specific type of product or service.
3. The information regarding the customer's or potential customer's financial situation, including that person's ability to bear losses, shall include, where relevant, information on the source and extent of the customer's or potential customer's regular income, assets, including liquid assets, investments and real property and the regular financial commitments. The level of information gathered shall be appropriate to the specific type of product or service being considered.
4. The information regarding the customer's or potential customer's investment objectives, including that person's risk tolerance, shall include, where relevant, information on the length of time for which the customer or potential customer wishes to hold the investment, that person's preferences regarding risk taking, the risk profile, and the purposes of the investment. The level of information gathered shall be appropriate to the specific type of product or service being considered.
5. Where the insurance intermediary or insurance undertaking does not obtain the information required under Article 30(1) of Directive (EU) 2016/97, the insurance intermediary or insurance undertaking shall not provide advice on insurance-based investment products to the customer or potential customer.
6. When providing advice on an insurance-based investment product in accordance with Article 30(1) of Directive (EU) 2016/97, an insurance intermediary or insurance undertaking shall not make a recommendation where none of the products are suitable for the customer or potential customer.
7. When providing advice that involves switching between underlying investment assets, insurance intermediaries and insurance undertakings shall also collect the necessary information on the customer's existing underlying investment assets and the recommended new investment assets and shall undertake an analysis of the expected costs and benefits of the switch, such that they are reasonably able to demonstrate that the benefits of switching are expected to be greater than the costs.

#### *Article 10*

### **Reliability of information**

Insurance intermediaries and insurance undertakings shall take reasonable steps to ensure that the information collected about customers and potential customers for the purposes of the assessment of suitability is reliable. Such steps shall include, but shall not be limited to, the following:

- (a) ensuring that customers are aware of the importance of providing accurate and up-to-date information;
- (b) ensuring that all tools, such as risk assessment profiling tools or tools to assess a customer's knowledge and experience, employed in the suitability assessment process are fit-for-purpose and are appropriately designed for use with their customers, with any limitations identified and actively mitigated through the suitability assessment process;
- (c) ensuring that questions used in the process are likely to be understood by the customers and to capture an accurate reflection of the customer's objectives and needs and the information necessary to undertake the suitability assessment;
- (d) taking steps, as appropriate, to ensure the consistency of customer information, such as considering whether there are obvious inaccuracies in the information provided by the customer.

#### *Article 11*

### **Communication with customers regarding the assessment of suitability**

Insurance intermediaries and insurance undertakings shall not create any ambiguity or confusion about their responsibilities in the process of assessing the suitability of insurance-based investment products in accordance with Article 30(1) of Directive (EU) 2016/97. Insurance intermediaries and insurance undertakings shall inform customers, clearly and simply, that the reason for assessing suitability is to enable them to act in the customer's best interest.



*Article 12***Automated advice**

The insurance intermediary's or insurance undertaking's responsibility to perform the suitability assessment in accordance with Article 30(1) of Directive (EU) 2016/97 shall not be reduced due to the fact that advice on insurance-based investment products is provided in whole or in part through an automated or semi-automated system.

*Article 13***Group insurance**

With regard to group insurance the insurance intermediary or insurance undertaking shall establish and implement a policy as to who shall be subject to the suitability assessment in case an insurance contract is concluded on behalf of a group of members and each individual member cannot take an individual decision to join. Such a policy shall also contain rules on how that assessment will be done in practice, including from whom information about knowledge and experience, financial situation and investment objectives shall be collected.

The insurance intermediary or insurance undertaking shall record the policy established pursuant to the first paragraph.

*Article 14***Suitability statement**

1. When providing advice on the suitability of an insurance-based investment product in accordance with Article 30(1) of Directive (EU) 2016/97, insurance intermediaries and insurance undertakings shall provide a statement to the customer (suitability statement) that includes the following:

- (a) an outline of the advice given;
- (b) information on how the recommendation provided is suitable for the customer, in particular how it meets:
  - (i) the customer's investment objectives, including that person's risk tolerance;
  - (ii) the customer's financial situation, including that person's ability to bear losses;
  - (iii) the customer's knowledge and experience.

2. Insurance intermediaries and insurance undertakings shall draw customers' attention to, and shall include in the suitability statement, information on whether the recommended insurance-based investment products are likely to require the customer to seek a periodic review of their arrangements.

3. Where an insurance intermediary or insurance undertaking has informed the customer that it will carry out a periodic assessment of suitability, the subsequent statements after the initial service is established may be limited to changes in the services or underlying investment assets, and/or the circumstances of the customer without repeating all the details contained in the first statement.

4. Insurance intermediaries and insurance undertakings providing a periodic assessment of suitability shall review, in accordance with the best interests of their customers, the suitability of the recommended insurance-based investment products at least annually. The frequency of this assessment shall be increased depending on the characteristics of the customer, such as the risk tolerance, and the nature of the recommended insurance-based investment product.

*SECTION 2***Assessment of appropriateness***Article 15***Assessment procedure**

Without prejudice to the fact that, in accordance with Article 20(1) of Directive (EU) 2016/97, any contract proposed shall be consistent with the customer's demands and needs, insurance intermediaries or insurance undertakings shall determine whether the customer has the necessary knowledge and experience in order to understand the risks involved in relation to the service or product proposed or demanded when assessing whether an insurance service or product distributed in accordance with Article 30(2) of Directive (EU) 2016/97 is appropriate for the customer.

*Article 16***Non-complex insurance-based investment products**

An insurance-based investment product shall be considered as non-complex for the purposes of Article 30(3)(a)(ii) of Directive (EU) 2016/97 where it satisfies all of the following criteria:

- (a) it includes a contractually guaranteed minimum maturity value which is at least the amount paid by the customer after deduction of legitimate costs;
- (b) it does not incorporate a clause, condition or trigger that allows the insurance undertaking to materially alter the nature, risk, or pay-out profile of the insurance-based investment product;
- (c) it provides options to surrender or otherwise realise the insurance-based investment product at a value that is available to the customer;
- (d) it does not include any explicit or implicit charges which have the effect that, even though there are technically options to surrender or otherwise realise the insurance-based investment product, doing so may cause unreasonable detriment to the customer because the charges are disproportionate to the cost to the insurance undertaking;
- (e) it does not in any other way incorporate a structure which makes it difficult for the customer to understand the risks involved.

*SECTION 3****Provisions common to the assessment of suitability and appropriateness****Article 17***Information to be obtained from the customer**

1. For the purposes of Article 30(1) and (2) of Directive (EU) 2016/97, the necessary information to be obtained by insurance intermediaries and insurance undertakings with regard to the customer's or potential customer's knowledge and experience in the relevant investment field shall include, where relevant, the following, to the extent appropriate to the nature of the customer, and the nature and type of product or service offered or demanded, including their complexity and the risks involved:

- (a) the types of service, transaction, insurance-based investment product or financial instrument with which the customer or potential customer is familiar;
- (b) the nature, number, value and frequency of the customer's or potential customer's transactions in insurance-based investment products or financial instruments and the period over which they have been carried out;
- (c) the level of education, and profession or relevant former profession of the customer or potential customer.

2. The insurance intermediary or insurance undertaking shall not discourage a customer or potential customer from providing information required for the purposes of Article 30(1) and (2) of Directive (EU) 2016/97.

3. Where information required for the purposes of Article 30(1) or (2) of Directive (EU) 2016/97 has already been obtained pursuant to Article 20 of Directive (EU) 2016/97, insurance intermediaries and insurance undertakings shall not request it anew from the customer.

4. The insurance intermediary or insurance undertaking shall be entitled to rely on the information provided by its customers or potential customers unless it is aware or ought to be aware that the information is manifestly out of date, inaccurate or incomplete.

*Article 18***Periodic report**

1. Without prejudice to Article 185 of Directive 2009/138/EC of the European Parliament and of the Council <sup>(1)</sup>, the insurance intermediary or insurance undertaking shall provide the customer with a periodic report, on a durable medium, of the services provided to and transactions undertaken on behalf of the customer.

<sup>(1)</sup> Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1).

2. The periodic report required under paragraph 1 shall provide a fair and balanced review of the services provided to and transactions undertaken on behalf of that customer during the reporting period and shall include, where relevant, the total costs associated with these services and transactions, and the value of each underlying investment asset.
3. The periodic report required under paragraph 1 shall be provided at least annually.

#### Article 19

##### Retention of records

1. Without prejudice to the application of Regulation (EU) 2016/679 of the European Parliament and of the Council<sup>(1)</sup>, insurance intermediaries and insurance undertakings shall maintain records of the assessment of suitability or appropriateness undertaken in accordance with Article 30(1) and (2) of Directive (EU) 2016/97. The records shall include the information obtained from the customer and any documents agreed with the customer, including documents that set out the rights of the parties and the other terms on which the insurance intermediary or insurance undertaking will provide services to the customer. Such records shall be retained for at least the duration of the relationship between the insurance intermediary or insurance undertaking and the customer.
2. In the case of an assessment of suitability undertaken in accordance with Article 30(1) of Directive (EU) 2016/97, the record shall further include the following:
  - (a) the result of the suitability assessment;
  - (b) the recommendation made to the customer and the statement provided in accordance with Article 14(1) of this Regulation;
  - (c) any changes made by the insurance intermediary or insurance undertaking with regard to the suitability assessment, in particular any change to the customer's risk tolerance;
  - (d) any changes to the underlying investment assets.
3. In the case of an assessment of appropriateness undertaken in accordance with Article 30(2) of Directive (EU) 2016/97, the record shall further include the following:
  - (a) the result of the appropriateness assessment;
  - (b) any warning given to the customer where the insurance-based investment product was assessed as potentially inappropriate for the customer, whether the customer asked to proceed with concluding the contract despite the warning and, where applicable, whether the insurance intermediary or insurance undertaking accepted the customer's request to proceed with concluding the contract;
  - (c) any warning given to the customer where the customer did not provide sufficient information to enable the insurance intermediary or insurance undertaking to assess the appropriateness of the insurance-based investment product, whether the customer asked to proceed with concluding the contract despite the warning and, where applicable, whether the insurance intermediary or insurance undertaking accepted the customer's request to proceed with concluding the contract.
4. The records shall be retained in a medium that allows the storage of information in a way accessible for future reference by the competent authority. The competent authority shall be able to access them readily, to reconstitute each element in a clear and accurate manner and to identify easily any changes, corrections or other amendments, and the contents of the records prior to such modifications.

#### CHAPTER IV

##### FINAL PROVISIONS

#### Article 20

##### Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 23 February 2018.

<sup>(1)</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 September 2017.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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