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 (¹), 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.

- (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.

- 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 (1), has been consulted for technical advice (2),

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

- 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.
- 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.
- 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.
- 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

⁽¹⁾ 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). 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