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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)

(OJ L 341, 20.12.2017, p. 1)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Delegated Regulation (EU) 2018/541 of 20 December 2017	L 90	59	6.4.2018

**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)**

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.

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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.

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.

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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;

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- (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;

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(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.

▼ B*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*.

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It shall apply from the date from which Member States are to apply the measures referred to in the first subparagraph of Article 42(1) of Directive (EU) 2016/97.

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