Preparatory Guidelines on product oversight and governance arrangements by insurance undertakings and insurance distributors
1. Introduction

1.1. According to Article 9(2) and Article 16 of Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (hereinafter “EIOPA Regulation”)¹, EIOPA is issuing Preparatory Guidelines addressed to competent authorities on how to proceed in the preparatory period leading up to the transposition of Directive (EU) 2016/97 of the European Parliament and of the Council of 20 January 2016 on insurance distribution (hereinafter “IDD”)² and the application of the delegated acts envisaged thereunder. The Preparatory Guidelines were issued for the purpose of establishing consistent, efficient and effective supervisory practices with regard to product oversight and governance arrangements as outlined in Article 25 of the IDD and to bridge the time until those provisions in the IDD are fully applicable.

1.2. Product oversight and governance arrangements play a key role in customer protection in ensuring that insurance products meet the needs of the target market and thereby mitigating mis-selling. They are an essential element of the new regulatory requirements under the IDD. Because of their relevance in terms of customer protection, it is of utmost importance that the new requirements are properly implemented from the outset and applied as early as possible. This justifies the issuance of preparatory Guidelines to ensure that competent authorities follow a consistent and convergent approach with respect to the preparation of implementation of the IDD.

1.3. The Preparatory Guidelines do not only aim to support competent authorities when implementing the IDD, but also aim to achieve cross-sectoral consistency. As the European Markets Supervisory Authority (ESMA)³ and the European Banking Authority (EBA)⁴ have already issued guidance on product oversight and governance arrangements, the Guidelines seek to ensure a level playing field in financial markets and prevent regulatory arbitrage.

1.4. Due to their nature as preparatory Guidelines, it is not the intention of the Guidelines to necessitate enforcement action by competent authorities if they become aware of practices which are not fully in line with the Guidelines, but that competent authorities discuss with market participants possible ways for appropriate remedial action. Therefore, the objective of these preparatory Guidelines is to support and to provide guidance to competent authorities in their preparatory steps leading to a consistent implementation of the

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organisational requirements on product oversight and governance arrangements of the IDD at an early stage. This allows competent authorities to take into account EIOPA’s expectation already at the implementation phase mitigating the risk of different approaches on national level and the need for further alignment for the sake of consistency and a level playing field among Member States at a later point of time.

1.5. Moreover, EIOPA will review the preparatory Guidelines once the delegated acts under the IDD have been adopted to assess to which extent a revision of the Guidelines is necessary.

1.6. According to the Joint Position of the European Supervisory Authorities on Manufacturers’ Product Oversight & Governance Processes⁵, the Guidelines take into account Recital 16 and Articles 40 and 41(1) of 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 (hereinafter “Solvency II”)⁶ that provide for the following:

- “The main objective of insurance and reinsurance regulation and supervision is the adequate protection of policyholders and beneficiaries...”⁷,
- “Member States shall ensure that the supervisory authorities are provided with the necessary means, and have the relevant expertise, capacity, and mandate to achieve the main objective of supervision, namely the protection of policy holders and beneficiaries”⁸.
- “Member States shall ensure that the administrative, management or supervisory body of the insurance or reinsurance undertaking has the ultimate responsibility for the compliance, by the undertaking concerned, with the laws, regulations and administrative provisions adopted pursuant to this Directive”⁹,
- “Member States shall require all insurance and reinsurance undertakings to have in place an effective system of governance which provides for sound and prudent management of the business”¹⁰.

1.7. The Preparatory Guidelines take also into account the provisions on product oversight and governance arrangements of the IDD as laid down in Article 25 thereof, stating the following:

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⁷ Recital 16 of Solvency II
⁸ Article 27 of Solvency II
⁹ Article 40 of Solvency II
¹⁰ Article 41(1) first para of Solvency II
• “Insurance undertakings, as well as intermediaries which manufacture any insurance product for sale to customers, shall maintain, operate and review a process for the approval of each insurance product, or significant adaptations of an existing insurance product, before it is marketed or distributed to customers.”

• “The product approval process shall be proportionate and appropriate to the nature of the insurance product.”

• “The product approval process shall specify an identified target market of customers for each product and ensure that all relevant risks to such identified target market are assessed, the intended distribution strategy is consistent with the identified target market and take reasonable steps to ensure that the insurance product is distributed to the identified target market.”

• “The insurance undertaking shall understand and regularly review the insurance products it offers or markets, taking into account any event that could materially affect the potential risk to the identified target market, to assess at least whether the product remains consistent with the needs of the identified target market and whether the intended distribution strategy remains appropriate.”

• “Insurance undertakings, as well as intermediaries which manufacture insurance products, shall make available to any distributor all appropriate information on the insurance product and the product approval process, including the identified target market of the insurance product.”

• “Where an insurance distributor advises on or proposes insurance products which it does not manufacture, it shall have in place adequate arrangements to obtain the information referred to in the fifth subparagraph and to understand the characteristics and identified target market of each insurance product.”

1.8. The product oversight and governance arrangements should be primarily considered as an implementation of the fundamental objective of insurance supervision, namely the protection of policyholders and beneficiaries as stated in Solvency II.

1.9. Due to their purpose and objectives the organisational arrangements as outlined in the Guidelines have a substantial link to the system of governance under the Solvency II framework, requiring firms to have a sound and prudent management of the business under a risk based approach including an appropriate risk management system. Organisational arrangements which aim to ensure a correct design of the insurance products fall within the system of governance of the insurance undertaking. The Guidelines introduce very explicit
processes and measures with regard to the design, development and monitoring of new insurance products.

1.10. In this context, the IDD will provide for a detailed regulation which takes into account the specific profiles of transparency and protection of the customer with regard to both the design of the product and its distribution. On this basis, the product oversight and governance arrangements have their foundation in Solvency II as well as in the IDD, the latter specifying the requirements from a customer protection point of view and adding requirements for distributors, which are not in the scope of the Solvency II framework.

1.11. These Guidelines are addressed to competent authorities. Notwithstanding the explicit references to insurance undertakings and insurance distributors, this document is not to be read as imposing any direct requirements upon those financial institutions. Financial institutions are expected to comply with the supervisory or regulatory framework applied by their competent authority.

1.12. The arrangements outlined in these Guidelines refer to internal processes, functions and strategies for designing and bringing products to the market, monitoring and reviewing them over their life cycle. The arrangements differ depending on whether the regulated entities are acting as manufacturer and/or distributors of insurance products and refer to steps such as:

(i) identifying a target market for which the product is considered appropriate;

(ii) identifying market segments for which the product is not considered appropriate;

(iii) carrying out product analysis to assess the expected product performance in different stressed scenarios;

(iv) carrying out product reviews to check if the product performance may lead to customer detriment and, in case this occurs, take actions to change its characteristics and mitigate the detriment;

(v) identifying the relevant distribution channels taking into account the characteristics of the target market and of the product;

(vi) verifying that distribution channels act in compliance with the manufacturer’s product oversight and governance arrangements.

1.13. The administrative, management or supervisory body of the insurance undertaking is responsible for the establishment and subsequent reviews of the product oversight and governance arrangements. However, implementing product oversight and governance arrangements should not be understood as introducing a new key function for insurance undertakings. Moreover, these arrangements are not necessarily linked with the risk management, internal audit, actuarial or compliance functions of insurance undertakings, as prescribed by Solvency II.

1.14. Product oversight and governance arrangements are complementary to point of sale disclosure rules (where applicable) which require to proactively disclose a
description of the main characteristics of the product, its risks and the total price of the product to be paid by the customer, including all related fees, charges and expenses.

1.15. Product oversight and governance arrangements need to 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 regulated entity.

1.16. The Guidelines cover arrangements that generally apply to all insurance undertakings and all insurance distributors, including any natural or legal person pursing the activity of insurance distribution, independent from the question whether these activities are pursued as a principal professional activity or on an ancillary basis, by an independent broker or by a tied agent, provided that they fall within the scope of the IDD. However, competent authorities should take a proportionate and risk-based approach when applying these Guidelines. These Guidelines do not apply to services or products that are explicitly exempted from the scope of the IDD, such as certain activities on an ancillary basis as defined in Article 1(3) or to insurance products which consists of the insurance of large risks as stated in Article 25(4) thereof.

1.17. Competent authorities shall make every effort to comply with these Guidelines with regard to products which are newly designed or substantially modified. Competent authorities may wish to consider requiring, as of the date of entry into force of national measures implementing these Guidelines, compliance with, at least Guideline 8 (Product monitoring) and Guideline 9 (Remedial action) of Chapter I for products still being distributed or brought to the market prior to that date.

1.18. In applying these Guidelines, competent authorities also need to give due consideration, where relevant, to EIOPA’s Guidelines on the System of Governance under Solvency II\textsuperscript{11}, EIOPA’s Guidelines on Complaints-Handling by Insurance Undertakings\textsuperscript{12} as well as EIOPA’s Guidelines on Complaints-Handling by Insurance Intermediaries\textsuperscript{13}.

1.19. For the purpose of these Guidelines, the following definitions have been developed:

- **Manufacturer** means an insurance undertaking and an insurance intermediary that manufacture insurance products for the sale to customers.

- **Target market** means the group(s) of customers for whom the manufacturer is designing the product.

\textsuperscript{11} Available at \url{https://eiopa.europa.eu/GuidelinesSII/EIOPA_Guidelines_on_System_of_Governance_EN.pdf#search=system%20of%20governance%20Guidelines}

\textsuperscript{12} Available at \url{https://eiopa.europa.eu/publications/eiopa-Guidelines/index.html}.

\textsuperscript{13} Available at \url{https://eiopa.europa.eu/publications/eiopa-Guidelines/Guidelines-on-complaints-handling-by-insurance-intermediaries}
• *Distribution strategy* means a strategy which addresses the question on how insurance products are distributed to the customers, in particular whether the product should be sold only where advice is given.

• *Products* means the classes of non-life insurance and life insurance listed in Annex I and Annex II of Solvency II.

1.20. If not defined in these Guidelines, the terms have the meaning defined in the legal acts referred to in the introduction.
Chapter 1 - Preparatory Guidelines for insurance undertakings and insurance intermediaries which manufacture insurance products for sale to customers

Guideline 1 - Establishment of product oversight and governance arrangements

1.21. The manufacturer should establish and implement product oversight and governance arrangements that set out appropriate measures and procedures aimed at designing, monitoring, reviewing and distributing products for customers, as well as taking action in respect of products that may lead to detriment to customers (product oversight and governance arrangements).

1.22. The product oversight and governance arrangements need to 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 regulated entity.

1.23. The manufacturer should set out the product oversight and governance arrangements in a written document (product oversight and governance policy) and make it available to its relevant staff.

Guideline 2 – Objectives of the product oversight and governance arrangements

1.24. The product oversight and governance arrangements should aim to prevent and mitigate customer detriment, support a proper management of conflicts of interests and should ensure that the objectives, interests and characteristics of customers are duly taken into account.

Guideline 3 – Role of management

1.25. The manufacturer’s administrative, management or supervisory body or equivalent structure responsible for the manufacturing of insurance products should endorse and be ultimately responsible for the establishment, implementation, subsequent reviews and continued internal compliance with the product oversight and governance arrangements.

Guideline 4 - Review of product governance and oversight arrangements

1.26. The manufacturer should regularly review the product oversight and governance arrangements to ensure that they are still valid and up to date and the manufacturer should amend them where appropriate.
Guideline 5 – Target market

1.27. The manufacturer should include in its product oversight and governance arrangements suitable steps in order to identify the relevant target market of a product.

1.28. The manufacturer should only design and bring to the market products with features and through identified distribution channels which are aligned with the interests, objectives and characteristics of the target market.

1.29. When deciding whether a product is aligned with the interests, objectives and characteristics or not of a particular target market, the manufacturer should consider the level of information available to the target market and the degree of financial capability and literacy of the target market.

1.30. The manufacturer should also identify groups of customers for whom the product is considered likely not to be aligned with their interests, objectives and characteristics.

Guideline 6 – Skills, knowledge and expertise of personnel involved in designing products

1.31. The manufacturer should ensure that relevant personnel involved in designing products possess the necessary skills, knowledge and expertise in order to properly understand the product’s main features and characteristics as well as the interests, objectives and characteristics of the target market.

Guideline 7 - Product testing

1.32. Before a product is brought to the market, or if the target market is changed, or changes to an existing product are introduced, the manufacturer should conduct appropriate testing of the product including, if relevant, scenario analyses. The product testing should assess if the product is in line with the objectives for the target market over the lifetime of the product.

1.33. The manufacturer should not bring a product to the market if the results of the product testing show that the product is not aligned with the interests, objectives and characteristics of the target market.

1.34. The manufacturer should carry out product testing in a qualitative and, where appropriate, in a quantifiable manner depending on the type and nature of the product and the related risk of detriment to customer.
**Guideline 8 - Product monitoring**

1.35. Once the product is distributed, the manufacturer should monitor on an on-going basis that the product continues to be aligned with the interests, objectives and characteristics of the target market.

**Guideline 9 - Remedial action**

1.36. Should the manufacturer identify, during the lifetime of a product, circumstances which are related to the product and give rise to the risk of customer detriment, the manufacturer should take appropriate action to mitigate the situation and prevent the re-occurrence of detriment.

1.37. If relevant, the manufacturer should notify any relevant remedial action promptly to the distributors involved and to the customers.

**Guideline 10 - Distribution channels**

1.38. The manufacturer should select distribution channels that are appropriate for the target market considering the particular characteristics of the product.

1.39. The manufacturer should select distributors with appropriate care.

1.40. The manufacturer should provide information, including the details of the products to distributors, of an adequate standard, which is clear, precise and up-to-date.

1.41. The information given to distributors should be sufficient to enable them to:

   - understand and place the product properly on the target market;
   - identify the target market for which the product is designed and also to identify the group of customers for whom the product is considered likely not to meet their interests, objectives and characteristics.

1.42. The manufacturer should take all reasonable steps to monitor that distribution channels act in compliance with the objectives of the manufacturer’s product oversight and governance arrangements.

1.43. The manufacturer should examine, on a regular basis, whether the product is distributed to customers belonging to the relevant target market.

1.44. When the manufacturer considers that the distribution channel does not meet the objectives of the manufacturer’s product oversight and governance arrangements, the manufacturer should take remedial actions towards the distribution channel.
Guideline 11 - Outsourcing of the product design

1.45. The manufacturer should retain full responsibility for compliance with product oversight and governance arrangements as described in these Guidelines when it designates a third party to design products on their behalf.

Guideline 12 - Documentation of product governance and oversight arrangements

1.46. Relevant actions taken by the manufacturer in relation to the product oversight and governance arrangements should be duly documented, kept for audit purposes and made available to the competent authorities upon request.

Chapter 2 - Preparatory Guidelines for insurance distributors which distribute insurance products which they do not manufacture

Guideline 13 - Establishment of product distribution arrangements

1.47. The distributor should establish and implement product distribution arrangements that set out appropriate measures and procedures for considering the range of products and services the distributor intends to offer to its customers, for reviewing the product distribution arrangements and for obtaining all necessary information on the product(s) from the manufacturer(s).

1.48. The product distribution arrangements need to 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 regulated entity.

1.49. The distributor should set out the product distribution arrangements in a written document and make it available to its relevant staff.

Guideline 14 - Objectives of the product distribution arrangements

1.50. The product distribution arrangements should aim to prevent and mitigate customer detriment, support a proper management of conflicts of interests and should ensure that the objectives, interests and characteristics of customers are duly taken into account.

Guideline 15 – Role of management

1.51. The distributor’s administrative, management or supervisory body or equivalent structure responsible for the insurance distribution should endorse and be ultimately responsible for the establishment, implementation, subsequent
reviews and continued internal compliance with the product distribution arrangements.

**Guideline 16 – Obtaining all necessary information on the target market from the manufacturer**

1.52. The product distribution arrangements should aim to ensure that the distributor obtains all necessary information from the manufacturer on the insurance product, the product approval process, the target market in order to understand the customers for which the product is designed for as well as the group(s) of customers for which the product is not designed for.

**Guideline 17 – Obtaining all other necessary information on the product from the manufacturer**

1.53. The product distribution arrangements should aim to ensure that the distributor obtains all other necessary information on the product from the manufacturer in order to fulfil its regulatory obligations towards the customers. This includes information on the main characteristics of the products, its risks and costs as well as circumstances which may cause a conflict of interests at the detriment of the customer.

**Guideline 18 – Distribution strategy**

1.54. Where the distributor sets up or follows a distribution strategy it should not contradict the distribution strategy and the target market identified by the manufacturer of the insurance product.

**Guideline 19 – Regular review of product distribution arrangements**

1.55. The distributor shall regularly review the product distribution arrangements to ensure that they are still valid and up to date and should amend them where appropriate, in particular the distribution strategy, if any.

**Guideline 20 – Provision of sale information to the manufacturer**

1.56. The distributor should inform the manufacturer without undue delay if he becomes aware that the product is not aligned with the interests, objectives and characteristics of the target market or if he becomes aware of other product related circumstances increasing the risk of customer detriment.
Guideline 21 – Documentation

1.57. Relevant actions taken by the distributor in relation to the product distribution arrangements should be duly documented, kept for audit purposes and made available to the competent authorities on request.

Compliance and Reporting Rules

1.58. This document contains Guidelines issued under Article 16 of the EIOPA Regulation. In accordance with Article 16(3) of the EIOPA Regulation, competent authorities and financial institutions shall make every effort to comply with Guidelines and recommendations.

1.59. Competent authorities that comply or intend to comply with these Guidelines should incorporate them into their regulatory or supervisory framework in an appropriate manner.

1.60. Competent authorities shall confirm to EIOPA whether they comply or intend to comply with these Guidelines, with reasons for non-compliance, within two months after the issuance of the translated versions.

1.61. In the absence of a response by this deadline, competent authorities will be considered as non-compliant to the reporting and reported as such.

Final Provision on Reviews

1.62. The present Guidelines shall be subject to a review by EIOPA after the adoption of the delegated acts referred to in Article 25(2) of the IDD.