SUBSIDIARY LEGISLATION 403.24

INSURANCE BUSINESS (GENERAL PROVISIONS OF SUPERVISION) REGULATIONS

1st January, 2016*

LEGAL NOTICE 407 of 2015, as amended by Legal Notices 35 of 2017, 194 of 2023 and 281 of 2026.

Citation and scope. *Amended by: L.N. 35 of 2017; L.N. 194 of 2023.*

1. (1) The title of these regulations is the Insurance Business (General Provisions of Supervision) Regulations.

(2) The purpose of these regulations is to implement Articles 28 to 33, 34(4) (in part), 34(6), 36(3), 38(1), 41(5), 52(1), 69, 71(1), 77f(1), 167, 170, 172(3) and (6), 173, 174 176 and 177(1) of the Solvency II Directive and Article 10a(13) and 25a(13) of Directive 2009/103/EC of the European Parliament and of the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability.

Interpretation. *Amended by: L.N. 194 of 2023; L.N. 281 of 2026.*

2. (1) In these regulations, unless the context otherwise requires:

"the Act" is the Insurance Business Act; Cap. 403.

"authorised insurance undertaking" means an undertaking which has received authorisation pursuant to article 7 of the Act to carry on direct general business and, or long term business, and includes an undertaking authorised to carry on direct and reinsurance business;

"authorised reinsurance undertaking" means an undertaking which has received authorisation pursuant to article 7 of the Act to carry on business restricted to reinsurance;

"binding legal instruments" means any directly applicable measures, including, but not limited to, any implementing technical standards, any regulatory technical standards or any similar measures, issued under European Union legislation;

"competent authority" shall have the same meaning assigned to it in the Act; Cap. 403.

"EIOPA" means the European Insurance and Occupational Pensions Authority as established in terms of article 1 of Regulation (EU) No. 1094/2010;

"ESAP" means the European single access point in accordance with the ESAP Regulation;

"ESAP Regulation" means Regulation 2023/2859/EU of the European Parliament and of the Council of 13 December 2023 establishing a European single access point providing centralised

*see regulation 1(3) of these Regulations as originally promulgated.

access to publicly available information of relevance to financial services, capital markets and sustainability, as may be amended from time to time, and includes any implementing measures that have been or may be issued thereunder;

"EU Regulation" means the Commission Delegated Regulation (EU) 2015/35 of 10 October 2014 supplementing Directive 2009/138/EC of the European Parliament and of the Council on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II);

"European insurance undertaking" means an undertaking having its head office in a Member State or an EEA State, other than Malta, pursuing the activity of direct insurance within the meaning of Article 2 of the Solvency II Directive, which has received authorisation in accordance with Article 14 of the Solvency II Directive;

"European regulatory authority" means the supervisory authority or supervisory authorities as defined in Article 13 of the Solvency II Directive, designated by a Member State or EEA State, other than Malta, empowered by law or regulation to supervise insurance or reinsurance undertakings;

"European reinsurance undertaking" means an undertaking having its head office in a Member State or an EEA State, other than Malta, pursuing business restricted to reinsurance within the meaning of Article 2 of the Solvency II Directive which has received authorisation in accordance with article 14 of the Solvency II Directive;

"the Motor Insurance Directive" - means Directive 2009/103/EC relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to insure against such liability, as amended from time to time and includes any delegated acts, any technical standards and any binding legal instruments, guidelines and any other measures that have been or may be issued thereunder;

"parent undertaking" has the same meaning as that assigned to the words “parent company” in article 2 of the Companies Act; Cap. 386.

"Solvency II Directive" means 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) (recast), as amended from time to time, and includes any delegated acts and any technical standards that have been or may be issued thereunder;

"third country" means a country which is not a Member State or EEA State.

(2) Words and expressions used in these regulations which are also used in the Act but which are not defined herein, shall have the same meaning assigned to them as in the Act.

PART I

General Supervisory Powers

Main objective of supervision and supervisory convergence.

3. (1) Without prejudice to article 4(1) of the Act, the competent authority shall, in the exercise of its general duties, duly consider the potential impact of its decisions on the stability of the financial system in the European Union, in particular, in emergency situations, based on the information available at the relevant time:

Provided that, in times of exceptional movements in the financial markets, the competent authority shall take into account the potential pro-cyclical effects of its actions.

(2) In exercising its functions and duties under the Act, the competent authority shall also take into account a European Union dimension.

General principles of supervision.

4. (1) Without prejudice to article 3 of the Act, supervision by the competent authority shall be based on a prospective and risk-based approach. It shall include the verification on a continuous basis of the proper operation of the business of insurance and of the compliance by authorised insurance undertakings and authorised reinsurance undertakings with the Act, regulations and Insurance Rules issued thereunder, and any other delegated acts and any technical standards that have been or may be issued under the Solvency II Directive.

(2) Supervision by the competent authority of authorised insurance undertakings and authorised reinsurance undertakings shall be carried out in a timely and proportionate manner and shall comprise an appropriate combination of off-site and on-site supervision.

(3) The competent authority shall apply the requirements laid down in the Act, regulations and Insurance Rules issued thereunder in a manner which is proportionate to the nature, scale and complexity of the risks inherent in the business of the authorised insurance undertaking and the authorised reinsurance undertaking concerned.

Scope of supervision.

5. (1) The competent authority shall be solely responsible for the financial supervision of an authorised insurance undertaking and an authorised reinsurance undertaking, including the business carried on by that undertaking in a Member State or EEA State, either through establishment or under the freedom to provide services.

(2) For the purposes of sub-regulation (1) "financial supervision" includes verification, with respect to the entire business of the authorised insurance undertaking and authorised reinsurance undertaking, of its state of solvency, of the establishment of technical provisions, of its assets and of the eligible own funds, in accordance with the Act, regulations and Insurance Rules issued thereunder.

(3) Where the authorised insurance undertaking concerned is authorised to cover risks classified in class 18 of Part I of the Third Schedule to the Act, supervision shall extend to the monitoring of the technical resources which the authorised insurance undertaking has at its disposal for the purposes of carrying out the assistance activities it has undertaken to perform.

(4) Where the competent authority receives information -

(*a*) in the case of an authorised insurance undertaking, from the European regulatory authority of the Member State or EEA State, other than Malta, in which the risk is situated or the Member State or EEA State of the commitment; or

(*b*) in the case of an authorised reinsurance undertaking, from the European regulatory authority of the host Member State,

that such European regulatory authority considers that the activities of the authorised insurance undertaking or the authorised reinsurance undertaking might affect the undertaking's financial soundness, the competent authority shall determine whether that undertaking is complying with the prudential principles laid down in the Act, regulations and Insurance Rules issued thereunder.

Transparency and accountability.

6. (1) The competent authority shall carry on its duties in a transparent and accountable manner taking into account the protection of confidential information.

(2) The competent authority shall publish the following information, in accordance with any delegated acts and implementing technical standards adopted by the Commission pursuant to Article 31(4) and (5) of the Solvency II Directive:

(*a*) the texts of laws, regulations, administrative rules and general guidance adopted in Malta in the field of insurance regulation;

(*b*) the general criteria and methods, including the tools to be used in the supervisory review process;

(*c*) without prejudice to the confidentiality provisions contained in the Act, aggregate statistical data on key aspects of the application of the prudential framework in Malta;

(*d*) the manner of exercise of the options provided for in the Solvency II Directive;

(*e*) the objectives of its supervision and its main functions and activities.

(3) The information published in accordance with sub-regulation (1) shall be sufficient to enable a comparison of the supervisory approaches adopted by the different European regulatory authorities, including the competent authority. The information shall be published following a common format and updated regularly. The information referred to in paragraphs (*a*) to (*e*) shall be accessible at a single electronic location.

Prohibition of refusal of reinsurance contracts or retrocession contracts. *Added by: L.N. 35 of 2017.*

6A. Pursuant to Article 32 of the Solvency II Directive, the competent authority shall not refuse -

(*a*) a reinsurance contract concluded by an authorised insurance undertaking whose head office is in Malta with:

(i) an authorised reinsurance or insurance undertaking whose head office is in Malta; or

(ii) a European reinsurance undertaking or a European insurance undertaking; or

(*b*) a retrocession contract concluded by an authorised reinsurance undertaking whose head office is in Malta with:

(i) an authorised reinsurance or insurance undertaking whose head office is in Malta; or

(ii) a European reinsurance undertaking or a European insurance undertaking;

on grounds directly related to the financial soundness of the said undertakings with which the reinsurance contract or the retrocession contract, as applicable, is concluded.

Supervision of branches established in another Member State or EEA State.

7. (1) Where an authorised insurance undertaking or an authorised reinsurance undertaking carries on business of insurance in a Member State or EEA State, other than Malta, through a branch, the competent authority may, after having informed the European regulatory authority concerned, carry out itself or through an intermediary it appoints for that purpose, on-site verification of the information necessary to ensure the financial supervision of that undertaking.

(2) Where the competent authority has informed the European regulatory authority that it intends to carry out an on-site verification in accordance with sub-regulation (1) and where the competent authority is prohibited from exercising its right to carry out that on-site verification, the competent authority may refer the matter to EIOPA and request its assistance in accordance with Article 19 of Regulation (EU) No.1094/2010.

(3) Information obtained by means of an on-site verification referred to in sub-regulation (1) may be disclosed only with the express consent of the competent authority or the European regulatory authority, as applicable.

Supervisory review process.

8. When carrying out the supervisory review process referred to in article 31B of the Act, the competent authority:

(*a*) shall have in place appropriate monitoring tools that enable it to identify deteriorating financial conditions in an authorised insurance undertaking or an authorised reinsurance undertaking and to monitor how that deterioration is remedied;

(*b*) may develop, where appropriate, the necessary quantitative tools under the supervisory review process to assess the ability of an authorised insurance undertaking or an authorised reinsurance undertaking to cope with possible events or future changes in economic conditions that could have unfavourable effects on its overall financial standing.

Supervision of outsourced functions and activities.

9. Without prejudice to article 18I of the Act, the competent authority shall ascertain that an authorised insurance undertaking and an authorised reinsurance undertaking which outsources a function or an insurance or reinsurance activity, takes the necessary steps to ensure that:

(*a*) the service provider undertakes to cooperate with the competent authority in connection with the outsourced function or activity and provide effective access to its business premises in order for the competent authority to be able to exercise those rights of access; and

(*b*) the authorised insurance undertaking and authorised reinsurance undertaking, its auditors and the competent authority have effective access to data related to the outsourced functions or activities.

Verification of system of governance by undertakings.

10. (1) The competent authority shall have appropriate means, methods and powers for verifying the system of governance of authorised insurance undertakings and authorised reinsurance undertakings and for evaluating emerging risks identified by those undertakings which may affect their financial soundness.

(2) The competent authority shall, if the circumstances so warrant, require that the system of governance of an authorised insurance undertaking or an authorised reinsurance undertaking be improved and strengthened to ensure compliance with the requirements set out in article 18I(2) and (3) of the Act.

Designation of the competent authority and obligation of Member States to entrust a body to provide compensation to injured parties. *Added by: L.N. 194 of 2023.*

10A. (1) Pursuant to:

(a) Article 10a(1) and 25a(1) of the Motor Insurance Directive, wherein a body shall be set up or authorised and entrusted with the task of providing compensation in terms of Article 10a and 25a of the Motor Insurance Directive, at least up to the limits of the insurance obligation, for damage to property or personal injuries caused by a vehicle insured by an insurance undertaking, from the moment when the insurance undertaking is subject to winding up proceedings as defined in Article 268(1), point (d) of the Solvency II Directive; and

(b) Article 10a(13)(b) and 25a(13)(b) of the Motor Insurance Directive, whereby an entity shall be designated and empowered to negotiate and conclude an agreement to which the body shall become a party to when it is set up or authorised,

the competent authority is hereby being designated as the entity empowered to negotiate and conclude an agreement by 23 December 2023.

(2) The body to be set up for the purposes of Article 10a(1) and 25a(1) aforesaid shall become a party to such an agreement once such body is set up or authorised.

PART II

Reinsurance

Equivalence in relation to reinsurance undertakings.

11. Reinsurance contracts concluded with a third-country insurance undertakings or a third-country reinsurance undertaking shall be treated in the same manner as reinsurance contracts concluded with an authorised insurance undertaking, an authorised reinsurance undertaking, a European insurance undertaking or a European reinsurance undertaking, where:

(*a*) the solvency regime of the third country has been deemed to be equivalent to that laid down in the Solvency II Directive, in accordance with delegated acts adopted by the Commission pursuant to Article 172(2) of the Solvency II Directive;

(*b*) the solvency regime of the third country has been deemed to be temporarily equivalent to that laid down in the Solvency II Directive, in accordance with delegated acts adopted by the Commission pursuant to Article 172(4) of the said Directive.

Prohibition of pledging of assets.

12. Where the reinsurer is -

(*a*) a third country insurance undertaking or a third country reinsurance undertaking with its head office in a third country whose solvency regime is deemed to be equivalent to that laid down in the Solvency II Directive in accordance with Article 172 of the said Directive;

(*b*) a third country reinsurance undertaking with its head office in a third country whose solvency regime is deemed to be temporarily equivalent in accordance with Article 172(4) of the Solvency II Directive,

in each case, the competent authority shall not retain or introduce for the establishment of technical provisions a system with gross reserving which requires pledging of assets to cover unearned premiums and outstanding claims provisions.

Principle and conditions for conducting reinsurance activity.

13. A third country reinsurance undertaking authorised under article 7 of the Act, carrying on in Malta business restricted to reinsurance, shall not operate under conditions which would result in a more favourable treatment than that granted to an authorised reinsurance undertaking whose head office is in Malta.

Agreements with third countries.

14. The provisions of regulations 11 to 13 shall be without prejudice to any agreements concluded by the Commission with one or more third countries in terms of Article 175 of the Solvency II Directive.

PART III

Third Country Undertakings

Advantages to third country undertakings authorised in more than one Member State or EEA State.

15. (1) A third country insurance undertaking or a third country reinsurance undertaking which is authorised under article 7 of the Act and which has also requested or obtained authorisation from one or more European regulatory authorities, may apply for

approval to the competent authority to benefit from the following advantages, which may be granted only jointly:

(*a*) calculate its Solvency Capital Requirement:

(i) in relation to the entire business which it pursues within Member States or EEA States; and

(ii) taking account only of the operations effected by the branches established within Member States or EEA States;

(*b*) lodge the deposit required under article 11(4) of the Act in only one of those Member States or EEA States in which it has requested or obtained authorisation; and

(*c*) hold the assets required to satisfy the Minimum Capital Requirement in any one of the Member States or EEA States in which it pursues its activities.

(2) The application to be submitted in terms of sub-regulation (1) shall:

(*a*) state the authority of the Member State or EEA State which in future is to supervise the solvency of the entire business of the branches established within the Union, ("solvency supervisor");

(*b*) give reasons for the choice of the authority made by the undertaking; and

(*c*) demonstrate to the competent authority that the said application has also been made to all the European regulatory authorities concerned.

(3) The competent authority shall only approve an application made in terms of sub-regulation (1) where the competent authority and all the European regulatory authorities in which the third country insurance undertaking or third country reinsurance undertaking has requested or obtained authorisation agree that the undertaking should benefit from the approval.

(4) On granting the approval under sub-regulation (3), the competent authority shall require the undertaking to lodge the deposit referred to in sub-regulation (1)(*b*) in the Member State or EEA State of the selected solvency supervisor.

(5) Where the competent authority is the selected solvency supervisor and it approves an application submitted in terms of sub-regulation (1), the advantages applied for shall take effect from the time the competent authority informs all the European regulatory authorities concerned that it will supervise the state of solvency of the entire business of the branches within the European Union.

(6) Where the competent authority is the selected solvency supervisor it shall request any information from the European regulatory authorities concerned, that is necessary for the supervision of the overall solvency of all of the branches established in Member States or EEA States.

(7) Where the competent authority is not the selected solvency

supervisor, the competent authority shall take reasonable steps to provide the European regulatory authority which is the selected solvency supervisor, with any information in relation to the branches of the undertaking in Malta, necessary to supervise the overall solvency of the branches of the undertaking.

(8) The competent authority may vary an approval granted in accordance with sub-regulation (3), where the competent authority and all the European regulatory authorities in which the third country insurance undertaking or third country reinsurance undertaking has requested or obtained authorisation, agree that the undertaking should benefit from the proposed variation.

(9) The competent authority may withdraw an approval granted in accordance with sub-regulation (3) where it considers that there are reasonable grounds for the approval to be withdrawn.

(10) The competent authority shall withdraw an approval granted in accordance with sub-regulation (3), where withdrawal is requested by a European regulatory authority in which the third country insurance undertaking or third country reinsurance undertaking has requested or obtained authorisation.

(11) Before the competent authority withdraws an approval granted in accordance with sub-regulation (3), the competent authority shall:

(*a*) where the approval is withdrawn under sub-regulation (9), request all the European regulatory authorities concerned to withdraw the advantages referred to in Article 167(1) of the Solvency II Directive which have been granted to the undertaking; and

(*b*) take reasonable steps to ensure that the approval is withdrawn at the same time as the European regulatory authorities concerned withdraw those advantages from the undertaking.

Revocation of authorisation of a third country undertaking authorised in more than one Member State or EEA State.

16. (1) Where a third-country insurance undertaking or third country reinsurance undertaking has been granted an approval under regulation 15:

(*a*) the competent authority shall notify the European regulatory authorities where such undertaking operates, where:

(i) the competent authority is the authority responsible for supervising the solvency of the entire business of the branches of the undertaking; and

(ii) it revokes the authorisation granted to that undertaking under article 7 of the Act;

(*b*) the competent authority shall, without prejudice to the powers granted to it under the Act, revoke the authorisation granted to that undertaking under article 7 of the Act, if a European regulatory authority responsible for supervising the solvency of the entire business of the branches of the undertaking:

(i) notifies the competent authority that it has withdrawn the undertaking's authorisation pursuant to Article 162 of the Solvency II Directive; and

(ii) the reason given for the withdrawal is the inadequacy of the undertaking's overall state of solvency as determined by the competent authority and all the European regulatory authorities concerned which agreed to the request, referred to in regulation 15(3).

PART IV

General Provisions

Information to EIOPA.

17. (1) Without prejudice to Article 35 of Regulation (EU) No 1094/2010, the competent authority shall provide the following information to EIOPA on an annual basis:

(*a*) the average capital add-on per undertaking and the distribution of capital add-ons imposed by the competent authority during the previous year, measured as a percentage of the Solvency Capital Requirement, shown separately for:

(i) authorised insurance undertakings and authorised reinsurance undertakings;

(ii) authorised insurance undertakings carrying on long-term business of insurance;

(iii) authorised insurance undertakings carrying on general business of insurance;

(iv) authorised insurance undertakings carrying on general business and long-term business of insurance;

(v) authorised reinsurance undertakings;

(*b*) for each of the disclosures set out in paragraph (*a*), the proportion of capital add-ons imposed under article 31C (1)(*a*), (*b*) and (*c*) of the Act, respectively;

(*c*) the number of authorised insurance undertakings and authorised reinsurance undertakings benefiting from the limitation from regular supervisory reporting and the number of authorised insurance undertakings and authorised reinsurance undertakings benefiting from the exemption of reporting on an item-by-item basis referred to in Insurance Rules issued pursuant to article 32 of the Act, together with their volume of capital requirements, premiums, technical provisions and assets, respectively measured as percentages of the total volume of capital requirements, premiums, technical provisions and assets of authorised insurance undertakings and authorised reinsurance undertakings;

(*d*) the number of groups benefiting from the limitation from regular supervisory reporting and the number of groups benefiting from the exemption of reporting on an item-by-item basis referred to in regulation 39 of the Insurance Business (Supervision of Insurance and Reinsurance Undertakings in a Group) Regulations, together with their volume of capital requirements, premiums, technical provisions and assets, respectively measured as percentages of the total volume of capital requirements, premiums, technical provisions and assets of all the groups. S.L. 403.17

(2) The competent authority shall, on an annual basis and until 1 January 2021, provide the following information to EIOPA on annual basis:

(*a*) the availability of long-term guarantees in insurance products in the Maltese market and the behaviour of authorised insurance undertakings and authorised reinsurance undertakings as long-term investors;

(*b*) the number of authorised insurance undertakings and authorised reinsurance undertakings applying the matching adjustment, the volatility adjustment, the extension of the recovery period in accordance with Article 138(4) of the Solvency II Directive, the duration-based equity risk sub-module and the transitional measures set out in regulations 15 and 16 of the Insurance Business (Solvency II Transitional Provisions) Regulations; S.L. 403.23

(*c*) the impact, at a national level, of the matching adjustment, the volatility adjustment, the symmetric adjustment mechanism to the equity capital charge, the duration-based equity risk sub-module and the transitional measures set out in regulations 15 and 16 of the Insurance Business (Solvency II Transitional Provisions) Regulations, on the financial position of authorised insurance undertakings and authorised reinsurance undertakings, anonymised in respect of each undertaking; S.L. 403.23

(*d*) the effect of the matching adjustment, the volatility adjustment, the symmetric adjustment mechanism to the equity capital charge and the duration-based equity risk sub-module on the investment behaviour of authorised insurance undertakings and authorised reinsurance undertakings and whether any of these measures provide undue capital relief;

(*e*) its assessment of the effect of any extension of the recovery period in accordance with Article 138(4) of the Solvency II Directive on the efforts of authorised insurance and reinsurance undertakings to re-establish the required level of eligible own funds covering the Solvency Capital Requirement or to reduce the risk profile in order to ensure compliance with the Solvency Capital Requirement;

(*f*) where authorised insurance undertakings and authorised reinsurance undertakings apply the transitional measures set out in regulations 15 and 16 of the Insurance Business (Solvency II Transitional Provisions) Regulations, 2015, whether they comply with the phasing-in plans referred to in regulation 17 of the said regulations and the prospects of such undertakings reducing their dependency on these transitional measures, including measures that have been taken or are expected to be taken by the undertakings and the competent authority, taking into account the Maltese regulatory environment.

S.L. 403.23

Information from the competent authority to the Commission and EIOPA.

18. (1) The competent authority shall inform the Commission, EIOPA and the European regulatory authorities concerned of any authorisation issued by the competent authority pursuant to article 7 of the Act, to a direct or indirect subsidiary, one or more of whose parent undertakings are governed by the law of a third country. The information to be provided shall also contain an indication of the structure of the group concerned.

(2) Where a third country insurance undertaking or a third country reinsurance undertaking acquires a holding in an authorised insurance undertaking or an authorised reinsurance undertaking which would result in that authorised undertaking to become a subsidiary of that third country undertaking, the competent authority shall inform the Commission, EIOPA and the European regulatory authorities concerned accordingly.

Accessibility of information on the European single access point. *Added by: L.N. 281 of 2026.*

18A. For the purpose of making the information referred to in article 7(13) and 27(6) of the Act accessible on ESAP, the competent authority shall submit such to the EIOPA, and such information shall be in a data extractable format and accompanied by the following metadata:

(a) all the names of the authorised insurance undertaking or authorised reinsurance undertaking to which the information relates;

(b) the legal entity identifier of the authorised insurance undertaking or authorised reinsurance undertaking, as specified in accordance with point (b) of Article 7(4) of the ESAP Regulation, where available;

(c) the type of information, as classified in accordance with point (c) of Article 7(4) of the ESAP Regulation;

(d) an indication of whether the information contains personal data:

Provided that such obligation shall apply with effect from 10th January 2030.

Third-country treatment of Community insurance and reinsurance undertakings.

19. The competent authority shall inform the Commission and EIOPA of any general difficulties encountered by an authorised insurance undertaking or an authorised reinsurance undertaking when establishing itself and operating in a third country or pursuing activities in a third country.

Insurance Rules.

20. (1) For the better carrying out of these regulations, the competent authority may, from time to time, issue Insurance Rules.

(2) Such Insurance Rules may contain such incidental, supplementary and consequential provisions as appear to the competent authority to be expedient for the purposes of these regulations.