EIOPA joins the Sustainable Insurance Forum

The European Insurance and Occupational Pensions Authority (EIOPA) recently became a member of the Sustainable Insurance Forum (SIF), a network of insurance supervisors and regulators from around the world working together on sustainability challenges facing the insurance sector.

The SIF, together with the International Association of Insurance Supervisors (IAIS), called on the insurance sector to enhance awareness and intensify climate risk scrutiny in a new issues paper on climate change risks published on 31 July 2018. It underlines physical, transition as well as liability risk related to climate change as key for the insurance sector. Furthermore, analyses of extreme weather events point to a growing trend of damages, both for insured and uninsured goods, leading to a significant protection gap. EIOPA particularly welcomes the case studies regarding supervisory practices, being of high value for all supervisors around the globe.

EIOPA will consider transition and physical risk alike and provide input from a European perspective on taxonomy, fiduciary duty, governance, Own Risk and Solvency Assessment as well as disclosure in EIOPA's Sustainable Action Plan planned to be released in autumn this year.

Background

The International Association of Insurance Supervisors (IAIS) is a voluntary membership organization of insurance supervisors and regulators from more than 200 jurisdictions with a mission to promote effective and globally consistent supervision of the insurance industry to develop and maintain fair, safe and stable insurance markets for the benefit and protection of policyholders and contribute to global financial stability.

The Sustainable Insurance Forum (SIF) is a global network of insurance supervisors and regulators working together to strengthen responses to sustainability challenges facing the insurance sector. Launched in December 2016, the SIF provides a platform for international collaboration among supervisors, facilitating knowledge sharing, dialogue, and uptake of policy innovations. The SIF is convened by UN Environment, which serves as its Secretariat.

ESMA issues clarifications on the

clearing obligation and trading obligation for pension scheme arrangements

The European Securities and Markets Authority (ESMA) has issued today an updated statement on the clearing obligation and trading obligation for pension scheme arrangements (PSAs), with the objective to avoid, to the extent possible, disruption to certain PSAs who may face potential challenges clearing their OTC derivative contracts and trading them on trading venues on 17 August 2018, when the current, and final, exemption from the clearing obligation under EMIR expires.

EMIR introduced a temporary exemption for PSAs from the clearing obligation to allow time for a suitable technical solution for the transfer of non-cash collateral as variation margins to be developed by CCPs. With the two possible extensions already granted, there is no possibility to further extend this temporary exemption under EMIR. However, a further extension of the temporary exemption is part of the Refit negotiations. Furthermore, MiFIR exempts financial counterparties exempted from the clearing obligation under EMIR from the trading obligation for derivatives.

The updated statement clarifies that also for the purpose of the trading obligation, ESMA expects competent authorities to not prioritise their supervisory actions towards entities that are expected to be exempted again in a relatively short period of time, and to generally apply their risk-based supervisory powers in their day-to-day enforcement of applicable legislation in a proportionate manner. Nevertheless, ESMA would encourage PSAs to trade on trading venues.

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Victims of the earthquake in the Indonesian island of Lombok receive EU support

The European Commission is closely following through the EU Civil Protection Mechanism the impact of the strong earthquakes that struck the Indonesian island of Lombok in late July and in early August that displaced thousands of people. The EU's emergency Copernicus Satellite mapping system has been activated to help the Indonesian civil protection authorities and the first maps have already been delivered. The Commission is also allocating a first emergency assistance of €150 000 to provide to the most affected communities. The aid will directly benefit 4 000 people in the worst hit districts of East

Lombok and North Lombok. This initial EU funding supports the Indonesian Red Cross Society in delivering life-saving support to the most vulnerable through the distribution of emergency shelter material and relief items, such as tarpaulins, blankets, mattresses, family kits and hygiene parcels. The assistance also ensures access to clean water, good hygiene services, basic health care, as well as psychological support to the affected families. To contribute to the restoration of livelihoods, targeted individuals will also receive unconditional cash grants to help them to recover and increase their resilience to future shocks. In addition, the EU Delegation in Jakarta formed a consular protection group which organised an EU/Schengen Consular Desk at the airport in Lombok. The group is formed by representatives of the EU Delegation and embassies of ES, FR, IE, IT, NL, SE and UK. The group so far assisted around 1 000 European citizens with information, availability of flights, assistance in booking flights and access to waiting lists, assistance to injured people. *(For more information: Carlos Martin Ruiz De Gordejuela – Tel.: +32 229 65322; Daniel Puglisi – Tel.: +32 229 69140)*

Concentrations : la Commission européenne autorise l'acquisition de Sisaho International, de sa filiale Siaci Saint Honoré et des filiales de cette dernière, par Watling Street Capital Partners

La Commission européenne a approuvé, en vertu du règlement européen sur les concentrations, l'acquisition du contrôle exclusif de Sisaho International SAS, de sa filiale Siaci Saint Honoré SAS et des filiales de cette dernière, toutes ensemble "Siaci", basées en France, par Watling Street Capital Partners LLP, basée au Royaume-Uni. Siaci est actif dans le courtage en assurances couvrant les deux grandes catégories de risques, à savoir les assurances de personnes et les assurances de dommages. Watling Street réunit un ensemble de sociétés de gestion de fonds d'investissement dont les sociétés composant le portefeuille ont majoritairement leur siège social en Europe de l'Ouest. Par l'intermédiaire de la société Funecap Topco SAS dont Watling Street envisage d'acquérir le contrôle, cette dernière sera active dans le courtage en assurance prévoyance obsèques. La Commission a conclu que l'opération envisagée ne soulèverait pas de problème de concurrence, compte tenu des chevauchements horizontaux limités et l'absence de relations verticales entre les entreprises. L'opération a été examinée dans la cadre de la procédure simplifiée du contrôle des concentrations. De plus amples informations sont disponibles sur le site internet concurrence de la Commission, dans le registre public des affaires sous le numéro d'affaire M.9022. *(Pour plus d'informations: Ricardo Cardoso – Tel.: +32 229 80100; Giulia Astuti – +32 229 55344)*

ANNOUNCEMENTS

Federica Mogherini discussed enhanced bilateral and multilateral cooperation between the EU and New Zealand in Wellington

On 7 August, Federica **Mogherini** was in New Zealand for the first visit by an EU High-Representative for Foreign Affairs and Security Policy/Vice-President of the European Commission to the country. While in Wellington, she met with Prime Minister Jacinda Ardern. They discussed the excellent EU-New Zealand bilateral relations under the Partnership Agreement and explored ways of

increasing cooperation between the two even further, including on global challenges such as climate change and terrorism, protection and strengthening of the rules-based international order, and working for peace, security and sustainable development in their respective neighbourhoods and beyond. Together they committed to swift progress on the recently-launched negotiations for a comprehensive and ambitious EU-New Zealand Free Trade Agreement and reiterated their united position in favour of global free trade. The High Representative also met her counterparts Foreign Minister Winston Peters – a joint press release was issued after their meeting – and Defence Minister Ron Mark. They discussed priorities such as the joint commitment to continued implementation of the Iran nuclear deal and support for the diplomatic efforts aimed at full denuclearisation of the Korean peninsula. They also committed to increase cooperation on security in the Pacific region, including on the peaceful and sustainable use of the Pacific Ocean. For more information on EU-New Zealand cooperation visit the website of the EU Delegation to New Zealand. (*For more information: Maja Kocijančič – Tel.: +32 229 86570; Lauranne Devillé – Tel.: +32 229 80833; Judith Hebekeuser: +32 22952656)*

Upcoming events of the European Commission (ex-Top News)

Zambia: European support to help unlock Great North Road's potential for Zambians

- **European support for T2 to eliminate bottlenecks and improve road safety in Zambia on the stretch between Mpika and Nakonde (372km)**
- **EUR 110 million loan to Ministry of Finance will support upgrading of Great North Road, leveraging the Zambian economy and the expansion of intra-Africa trade**

The European Investment Bank (EIB) has signed a EUR 110 million (ZMK 1.27 billion) concessional loan with the Zambian Ministry of Finance in support of the Great North Road (T2), to be followed shortly by the signature of an EU grant of EUR 72.45m that will complement EIB financing.

Support for a regional project

The overall project, co-financed by the government and AfDB, will upgrade and widen some 372 kilometres of road between Mpika and Nakonde, making for both faster and safer travelling. It also includes the rehabilitation of about 50km of feeder roads and complementary initiatives in the area, as well as technical assistance. The T2 Upgrade is a key national project with a strong regional dimension, connecting Zambia to neighbouring Tanzania and Zimbabwe. It is also part of several important international transport routes including

the continental Trans-Africa Highway from Cape Town to Cairo. The reconstruction of the T2 will thus boost continental integration and help transform Zambia from a land-locked to a land-linked country. The EIB and EU package will finance the 162km stretch from Mpika to Chinsali.

Technical improvements

Apart from creating better conditions for transport and communication, the project will contribute to provide economic and social opportunities, including better accessibility to markets, employment and additional investments both at national and regional levels. By unlocking and diversifying the country's economic potential, the road upgrade is expected to promote inclusive growth and reduce poverty.

Safety measures will be introduced to reduce the risk of accidents for both road users and local communities. The design has taken into account that women use the road for more diverse needs and destinations (such as health centres and educational facilities). Finally, adaptation measures are considered to make the road more resilient to climate change, in particular with respect to the high risk of wild fire and flooding. Works contracts will be tendered according to international competitive bidding process.

Saving time, life and the environment

EIB Vice-President **Ambroise Fayolle**, responsible for operations in Sub-Saharan Africa, commented: "The upgrade of the Great North Road will be invaluable for Zambia and the wider region. Enhanced road transport should lead to time-saving and cost-reduction, making Zambia and other countries along the North-South corridor more productive and rendering their economies more competitive, which will ultimately have an effect on poverty alleviation. This underlines the Bank's longstanding support to regional transport corridors on the African continent that enable economic and social development which in turn supports the UN's Sustainable Development Goals."

The Ambassador of the European Union to Zambia, H.E. **Alessandro Mariani**, indicated that: "The T2 upgrade fully supports the joint Africa-EU cooperation strategy. The objective is to reduce poverty, which can be attained facilitating regional trade and economic integration through the improvement of key transport infrastructures such as regional transport corridors. Through an additional EUR 72.45m grant (870 million Zambian Kwacha) to be signed in the coming months, the European Union will complement the concessional loan of the EIB (the EU Bank) thus providing an excellent financial solution for the full benefit of Zambia. This new opportunity to blend financial resources (sizeable grant + concessional loan) – already made by the EU in Zambia in the road, water and energy sectors – is very important in the Zambian context."

RDA Director and CEO, **Elias Mwape** said: "The Bank has provided substantial non-financial added value in terms of project preparation since 2015. Thanks to its early involvement and the mobilisation of technical assistance, the EIB helped RDA design a bankable and sustainable project – especially with respect to structuring, road safety, climate resilience, technical solutions

and social standards – incorporating lessons learnt from GER Rehabilitation and EU's best practice. During implementation, the EIB will provide further technical assistance to the RDA through a Project Implementation Consultant and audits to support the implementation of the project."

EIB has a longstanding relationship with Zambia, first lending to a project in the country in 1978, and this will be the second intervention for the benefit of strategic transport corridors after the signature in 2011 of the Bank's EUR 80 million loan for the Great East Road Rehabilitation. In total, the EIB has provided EUR 474 million in financing in Zambia in the past seven years, in a wide range of public infrastructure (transport, water, sanitation, energy), as well as in private sector through local banks and microfinance institutions to support SMEs and micro-entrepreneurs.

Esmya: new measures to minimise risk of rare but serious liver injury

08/08/2018

Esmya: new measures to minimise risk of rare but serious liver injury

EMA concludes review of medicine for uterine fibroids

On 31 May 2018, the European Medicines Agency (EMA) recommended that several measures be put in place to minimise the risk of rare but serious liver injury with Esmya (ulipristal acetate). Certain women may start treatment with Esmya once the new measures are implemented.

The measures include: contraindication in women with known liver problems; liver tests before, during and after stopping treatment; a card for patients to inform them about the need for liver monitoring and to contact their doctor should they develop symptoms of liver injury. In addition, use of the medicine for more than one treatment course has been restricted to women who are not eligible for surgery.

Esmya is used to treat moderate to severe symptoms of uterine fibroids (benign tumours of the womb). The medicine has been shown to be effective at reducing bleeding and anaemia associated with the condition, as well as the size of the fibroids.
The review of Esmya was carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) following reports of serious liver injury, including liver failure leading to transplantation. The PRAC concluded that Esmya may have contributed to the development of some cases of serious liver injury.[1]

The PRAC therefore recommended that use of the medicine should be restricted. It also recommended that studies should be performed to determine the effects of Esmya on the liver and whether the new measures are effective in minimising the risks.

The PRAC's recommendations were endorsed by EMA's Committee for Medicinal Products for Human Use (CHMP) and sent to the European Commission for a final legal decision. A letter was sent to doctors to inform them of the new conditions of use.

Information for patients

- The medicine Esmya, used to treat uterine fibroids, has been reviewed because cases of serious liver problems have occurred in women taking the medicine, including four cases that resulted in liver transplantation.
- Esmya will not be prescribed to you if you have liver problems.
- A liver test will be performed before you start treatment and if the test is abnormal, treatment with Esmya will not be started.
- You will also have liver tests during treatment and after treatment has stopped.
- If no liver problems are detected, a single course of Esmya can be used in women who are about to have surgery for their fibroids; Esmya can be used for more than one course only in women who cannot have surgery.
- A card will be included in the package of the medicine with information on the risk of liver injury and the need for liver monitoring.
  • You should stop treatment and contact your doctor immediately if you develop symptoms of liver injury (such as tiredness, yellowing of the skin, darkening of the urine, nausea and vomiting).
- If you have any questions or concern about your treatment, speak to your doctor or pharmacist.

Information for healthcare professionals

- Four cases of serious liver injury leading to hepatic transplantation and additional cases of hepatic injury have been reported in patients treated with Esmya (ulipristal acetate). Although uncertainties around causality remain, the following measures to minimise a possible risk for liver injury have been introduced:
  - Contraindication in patients with underlying liver disorders.
  - Restricted indication in the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age: Esmya should only be used in women who are not eligible for surgical treatment. (Esmya continues to be indicated for one course (lasting up to 3 months) of pre-operative treatment for moderate to severe symptoms of uterine fibroids in adult women of reproductive age.)
  - Liver function tests to be performed before starting each treatment course, monthly during the first 2 treatment courses, and thereafter as clinically indicated. Liver testing also to be performed again 2-4 weeks after stopping treatment.
  - Esmya should not be started if levels of alanine transaminase (ALT)

    - or aspartate aminotransferase (AST) are more than 2 times the upper limit of normal (ULN).
    - Treatment should be stopped in patients with ALT or AST levels more than 3 times ULN.
- Healthcare professionals should advise their patients about the signs and symptoms of liver injury and the action to take should they occur. In case of signs or symptoms suggestive of such injury, treatment should be stopped. Patients should be investigated immediately including liver function testing.
- Healthcare professionals prescribing Esmya in the EU have been sent a letter with further details.

More about the medicine

Esmya was authorised in the EU in 2012 for the treatment of moderate to severe symptoms of uterine fibroids, which are benign (non-cancerous) tumours of the womb, in women who have not reached the menopause.
The active substance in Esmya, ulipristal acetate, works by attaching to the targets on cells (receptors) that the hormone progesterone normally attaches to, preventing progesterone from having its effect. Since progesterone may promote the growth of fibroids, by preventing the effects of progesterone ulipristal acetate reduces the size of the fibroids.

Ulipristal acetate is also the active substance of a single-dose medicine authorised for emergency contraception, ellaOne. No cases of serious liver injury have been reported with ellaOne and there are no concerns with this medicine at this time.

More about the procedure

The review of Esmya was initiated at the request of European Commission on 30 November 2017, under Article 20 of Regulation (EC) No 726/2004.

The review was carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines.

While the review was ongoing, the PRAC had issued temporary recommendations that no new patients should start treatment.

The PRAC issued its final recommendations on 17 May 2018, replacing the temporary measures. The PRAC’s final recommendations were sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted an opinion.

The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 26/07/2018.