# 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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# Daily News 08 / 08 / 2018

**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)

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# 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.

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# EIOPA publishes monthly technical information for Solvency II Relevant Risk Free Interest Rate Term Structures – end-July 2018

Today, the European Insurance and Occupational Pensions Authority (EIOPA) published technical information on the relevant risk free interest rate term structures (RFR) with reference to the end of July 2018. This RFR information has been calculated on the basis of the Technical Documentation published on 1 February 2018.

All the documents are available here.

**Background**

Technical information relating to risk-free interest rate (RFR) term structures is used for the calculation of the technical provisions for (re)insurance obligations.

In line with the Solvency II Directive, EIOPA publishes technical information relating to RFR term structures on a monthly basis via a dedicated section on EIOPA's Website also containing the provisional release calendar for 2018, the RFR Technical Documentation, the RFR coding and Frequently Asked Questions.

By this publication EIOPA ensures consistent calculation of technical provisions across Europe.

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# Questions and Answers: entry into

# force of the updated Blocking Statute

The EU introduced the Blocking Statute in 1996 (Regulation 96/2271) in response to US extra-territorial sanctions legislation. It aims at countering the effects of US sanctions on EU economic operators engaging in lawful activity with third countries. The Blocking Statute constitutes an important achievement of unified EU action against extra-territorial legislation of third countries.

**How does the Blocking Statute work?**

The Blocking Statute applies with regard to the extra-territorial legislation mentioned in its Annex ("listed extra-territorial legislation").

It forbids EU residents and companies ("operators") from complying with the listed extra-territorial legislation unless they are exceptionally authorised to do so by the Commission; allows EU operators to recover damages arising from such legislation from the persons or entities causing them; and nullifies the effect in the EU of any foreign court rulings based on it.

EU operators should inform the European Commission – within 30 days since they obtain the information – of any events arising from listed extra-territorial legislation that would affect their economic or financial interests.

**Why was the Blocking Statute updated?**

The update was triggered by the US' unilateral decision on 8 May 2018 to re-impose sanctions against Iran (after wind-down periods of 90 and 180 days, i.e. after 6 August 2018 and 4 November 2018) simultaneously with its withdrawal from the Joint Comprehensive Plan of Action (JCPOA) agreed in 2015 between Iran on the one hand, and China, France, Germany, the European Union, Russia, the United Kingdom, and the US, on the other. Some of the re-imposed sanctions have extra-territorial effects and could potentially affect EU operators doing legitimate business with Iran.

**How is the Blocking Statute amended?**

The EU has amended the annex to the Blocking Statute by adding within its scope the list of extra-territorial US sanctions on Iran that the United States is re-imposing.

The amendment is made through a Commission Delegated Regulation, which was adopted by the Commission on 6 June 2018 and to which neither the Council, nor the European Parliament have objected in the 2 months' scrutiny period that was foreseen for this purpose. The Delegated Regulation will be published and enter into force on 7 August.

**What kind of damages can EU operators ask compensation for?**

According to the Blocking Statute, EU operators can recover "any damages,

including legal costs, caused by the application of the laws specified in its Annex or by actions based thereon or resulting therefrom".

**From whom can EU operators claim compensation for those damages?**

According to the Blocking Statute, EU operators can recover damages, namely from "the natural or legal person or any other entity causing the damages or from any person acting on its behalf or intermediary".

**How can EU operators claim compensation?**

The action can be brought before the courts of the Member States and the recovery can take the form of seizure and sale of the assets of the person causing the damage, its representatives or intermediaries. As in any litigation for damages, it will be for the judge to assess the merits of the case, or the causal link.

**Who is responsible for the implementation of the Blocking Statute?**

Implementation of the Blocking Statute, including deciding on effective, proportionate and dissuasive penalties for possible breaches is the competence of Member States. It is also for Member States to enforce those penalties.

**What is the role of the European Commission?**

The European Commission has several roles: it gathers information from EU operators on possible cases of application of the listed extra-territorial legislation; it liaises with national authorities from EU Member states concerning such cases in their jurisdiction; it receives notification from and shares information with Member States on measures taken under the Blocking Statute and other relevant aspects.

The Commission can also, in exceptional cases, authorise an EU operator to fully or partially comply with the listed extra-territorial legislation if non-compliance would seriously jeopardise the interests of the operator or of the European Union. In doing so, the Commission is assisted by a Committee on Extra-Territorial Legislation composed of representatives of Member States.

The Implementing Regulation containing the criteria on the basis of which the Commission will assess such requests for authorisation will also be published on 7 August, following full support by the Committee.

**For More Information**

Press release: Updated Blocking Statute in support of Iran nuclear deal enters into force