

[EMCDDA operating guidelines for the risk assessment of new psychoactive substances](#)

EMCDDA, Lisbon, December 2020

Summary

The purpose of these guidelines is to ensure compliance with the scope and requirements of Regulation (EC) No 1920/2006 (as amended) and Council Framework Decision 2004/757/JHA (as amended) in respect to the risk assessment procedure for and reporting on new psychoactive substances.

To operationalise the technical aspects of the risk assessment, the guidelines are supported by a set of Guidance notes developed by the EMCDDA. The Guidance notes will be adapted as required in order to reflect developments in the field of new psychoactive substances and risk assessment.

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Guidance notes

Main subject:

[NPS](#)

[Team Europe: EIB invests €100 million](#)

to support healthcare infrastructure in Georgia



- **The €100 million loan from the EU bank, guaranteed by the European Union, will support the modernisation of seven major hospitals in Georgia, including those commissioned as COVID hospitals.**
- **The loan also covers the procurement of essential COVID-19-related medical equipment.**
- **The operation is part of the EIB's €6.7 billion COVID-19 emergency response and part of the Team Europe support package to the EU partner countries during the pandemic.**

The European Investment Bank (EIB), the bank of the European Union, will invest €100 million to upgrade and modernise key healthcare infrastructure in Georgia, provide professional training to new medical staff, and finance the procurement of essential medical equipment for the country's healthcare system during the COVID-19 pandemic.

The EIB loan guaranteed by the European Union will enable the Government of Georgia to modernise seven major hospitals across the country: Central Republican Hospital, Children's Infectious Diseases Hospital, Lisi Hospital, Rukhi Hospital, Batumi Republican Hospital, Tbilisi University Clinic and Tbilisi Centre for AIDS and Infectious Diseases. Among these hospitals are those currently commissioned as COVID hospitals, key to the country's ability to contain the spread of coronavirus.

The EIB financing will also cover the procurement of modern medical equipment and vaccines, and the establishment of an effective supply chain to provide comprehensive diagnostic and treatment services for COVID-19 patients.

Teresa Czerwinska, the EIB Vice-President responsible for Georgia, said: "Our investment is designed to help upgrade key hospitals and clinical centres in the country, as well as cover acquisition of medical equipment and on-the-job training for new medical workers. Thus, Georgia will be able to improve the quality of its healthcare system, protect its citizens and medical staff, and have modern resources to tackle the pandemic. I am grateful to the Government of Georgia for the opportunity to help Georgians in these times of need."

Carl Hartzell, EU Ambassador to Georgia, said: "The European Union continues to stand by Georgia's side during this pandemic. Today I am proud to announce another step in our support to Georgia through a favourable loan amounting to €100 million, or GEL 400 million, from the EIB, the EU's bank. This loan is intended to help meet the needs of the healthcare system and assist the men and women that deserve all our support and respect as they carry out their important job. It comes in addition to the GEL 1.5 billion the EU and Team Europe have already mobilised in support of Georgia so far this year. The EU remains committed to working with our international partners, the Government, civil society, and local banks to provide assistance to Georgians where

needed and possible.”

Ivane Machavariani, Minister of Finance of Georgia, said: “The Government of Georgia expresses its gratitude to the EIB for its support in the process of combating the severe health and economic consequences of the COVID-19 pandemic. The second wave of the pandemic called for further urgent measures from our side and we very much appreciate the swift response from our partners. It is of high significance that the EIB is providing €100 million to Georgia to support investments related to COVID-19 specific schemes. This funding is for the concluding phase of the pandemic, which will support Georgia in financing urgent needs for case management, enhancing lab capacity and vaccine supply. The Government of Georgia would like once again to highlight the huge value of the financial support provided by the EIB and is looking forward to continued successful cooperation.”

The operation will enable the Government of Georgia to improve the quality and resilience of the national healthcare system and strengthen the country’s ability to provide an effective response to the ongoing COVID-19 pandemic and save lives, increasing the quality of healthcare for some 3.7 million Georgians. To date, the EIB has invested close to €2 billion to support sustainable social and economic development in Georgia.

Background information

About the EIB:

The European Investment Bank (EIB) is the long-term lending institution of the European Union owned by its Member States. It makes long-term finance available for sound investment in order to contribute towards EU policy goals.

About the EIB and investments in vaccines, treatments and diagnostics for COVID-19:

To date, the EIB has invested €700 million in 20 European meditech and biotech companies working on vaccines, treatments or diagnostics for COVID-19. This includes a €100 million investment in BioNTech, the German company behind the Pfizer/BioNTech vaccine. Against the backdrop of the health crisis, this financing reflects the EIB’s strong mobilisation to support the development of new and effective treatments for COVID-19. For more information, please contact the EIB Press Office.

The EIB in Georgia:

Since the beginning of its operations in Georgia in 2007, the EIB has invested close to €2 billion in 23 projects in infrastructure, the private sector and climate action. The EIB stepped up its support for the country via the 2014 Association Agreement and the Deep and Comprehensive Free Trade Area between Georgia and the European Union, making it the main EIB lending beneficiary per capita in the EU Eastern Neighbourhood.

The EIB finances most projects in Georgia under the EU External Lending Mandate. This provides the EIB with a comprehensive guarantee covered by the

EU budget for projects in the fields of social and economic infrastructure, local private sector development and climate action. For more information on the EIB's activities in Georgia please follow [this link](#).

ESMA Newsletter – N°19

22 December

ESMA ISSUES 2020 REPORT ON ACCEPTED MARKET PRACTICES UNDER MAR

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today published its annual report on the application of accepted market practices (AMPs) in accordance with the Market Abuse Regulation (MAR).

22 December

ESMA UPDATES Q&A ON COSTS AND CHARGES

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today updated its Questions and Answers on the implementation of investor protection topics under the Market in Financial Instruments Directive and Regulation (MiFID II/ MiFIR).

21 December

ESMA UPDATES EMIR Q&AS

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today updated its Questions and Answers on OTC requirements and reporting issues under the European Markets Infrastructure Regulation (EMIR).

21 December

ESMA SEES SIGNIFICANT INCREASE IN EU MARKET ABUSE SANCTIONS TO €88 MILLION IN 2019

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today published its annual report on administrative and criminal sanctions, as well as other administrative measures, issued under the Market Abuse Regulation (MAR) in 2019. The Report shows that National Competent Authorities (NCAs) and other authorities imposed a total of €88 million in fines related to 339 administrative and criminal actions under MAR.

18 December

[ESMA REGISTERS DTCC DATA REPOSITORY \(IRELAND\) PLC AS TRADE REPOSITORY UNDER EMIR AND SFTR](#)

The European Securities and Markets Authority (ESMA), the EU supervisor of trade repositories (TRs), has registered today DTCC Data Repository (Ireland) PLC as a TR under the European Market Infrastructure Regulation (EMIR) and the Securities Financing Transactions Regulation (SFTR), with effect from 23 December 2020.

18 December

[ESMA CONSULTS ON THE IMPACT OF ALGORITHMIC TRADING](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today launched a consultation seeking input from market participants on the impact of requirements under MiFID II/MiFIR regarding algorithmic trading, including high-frequency algorithmic trading.

18 December

[ESMA PUBLISHES CLOUD OUTSOURCING GUIDELINES](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets authority, has today published the final report on its guidelines on outsourcing to cloud service providers (CSPs).

17 December

[ESMA PUBLISHES DRAFT TECHNICAL STANDARDS UNDER EMIR REFIT](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today published a Final Report on technical standards (RTS and ITS) under the EMIR REFIT Regulation. The report covers data reporting to Trade Repositories (TRs), procedures to reconcile and validate the data, access by the relevant authorities to data and registration of the TRs.

17 December

[ESMA RECOMMENDS MORE TIME TO IMPLEMENT A MIX OF SOLUTIONS FOR PSAS TO CLEAR](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has published today a second report on the clearing solutions for Pension Scheme Arrangements (PSAs) under the European Market Infrastructure Regulation (EMIR).

17 December

[ESMA PUBLISHES FINAL GUIDANCE TO ADDRESS LEVERAGE RISK IN THE AIF SECTOR](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today published its final guidance to address leverage

risks in the Alternative Investment Fund (AIF) sector.

17 December

[ESMA RENEWS ITS DECISION REQUIRING NET SHORT POSITION HOLDERS TO REPORT POSITIONS OF 0.1% AND ABOVE](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has renewed its decision to temporarily require the holders of net short positions in shares traded on a European Union (EU) regulated market, to notify the relevant national competent authority (NCA) if the position reaches, exceeds or falls below 0.1% of the issued share capital. The measure applies from 19 December 2020 for a period of three months.

17 December

[ESMA APPOINTS NEW CHAIR OF ITS SUPERVISORY CONVERGENCE STANDING COMMITTEE](#)

The Board of Supervisors of the European Securities and Markets Authority (ESMA) has appointed Mr Jos Heuvelman, who is a Member of Executive Board of the Autoriteit Financiële Markten (AFM) of the Netherlands, to serve as the chair of the Supervisory Convergence Standing Committee (SCSC) and as chair of the Senior Supervisors Forum.

16 December

[ESMA APPOINTS TWO NEW MEMBERS TO ITS MANAGEMENT BOARD](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has appointed two new members to its Management Board to replace outgoing members, whose term has ended, and reappointed one current member. The appointments took place at the Board of Supervisors meeting in Paris today, 16 December.

16 December

[ESMA SUPPORTS IFRS FOUNDATION'S EFFORTS ON INTERNATIONAL STANDARDISATION IN SUSTAINABILITY REPORTING](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has today published its response to the IFRS Foundation's consultation on sustainability reporting. ESMA recommends establishing high-quality international standards while also catering for the needs of jurisdictions that are at different stages in their sustainability efforts.

16 December

[ESMA UPDATES GUIDELINES ON STRESS TESTS FOR MONEY MARKET FUNDS](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, is publishing the 2020 update of guidelines on MMF stress tests under the Money Market Funds Regulation (MMFR). The updates take

account of MMFs recent experience during March 2020, particularly in relation to redemption scenarios.

16 December

[ESMA REMINDS USERS OF SCHEDULED IT OPERATIONS AT THE END OF THE BREXIT TRANSITION PERIOD](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, today publishes a reminder of the operations planned on its databases and systems at the end of the Brexit transition period on 31 December 2020.

16 December

[KROLL BOND RATING AGENCY LLC'S CERTIFICATION STATUS WITHDRAWN](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has withdrawn Kroll Bond Rating Agency LLC's (Kroll LLC) ability to certify its credit ratings for use in the European Union (EU).

14 December

[ESMA is seeking experts in financial innovation for its consultative group](#)

The European Securities and Markets Authority (ESMA), the EU securities markets regulator, is looking for new candidates for the Consultative Working Group (CWG) of the Financial Innovation Standing Committee (FISC).

14 December

[ESMA REPORTS ON ANNUAL MARKET SHARE OF CREDIT RATING AGENCIES](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has published its annual market share calculation for EU registered credit rating agencies (CRAs).

11 December

[ESMA TO RECOGNISE EUROCLEAR UK & IRELAND LIMITED \(EUI\) AFTER BREXIT TRANSITION PERIOD](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has announced that Euroclear UK & Ireland Limited (EUI), the central securities depository (CSD) established in the United Kingdom (UK), will be recognised as a third-country CSD (TC-CSD) after the end of the UK's transition from the European Union (EU) on 31 December 2020.

8 December

[STEVEN MAIJOOR DELIVERS KEYNOTE ABOUT PARADOXES OF SUSTAINABILITY REPORTING](#)

Steven Maijoor, Chair of the European Securities and Markets Authority (ESMA), has delivered a keynote speech at the webinar "A new standard for a

new capitalism: accelerating corporate responsibility through non-financial information” organised by the French Ministry of the Economy, Finance and Recovery

7 December

[ESMA ISSUES LATEST DOUBLE VOLUME CAP DATA](#)

The European Securities and Markets Authority (ESMA), the EU’s securities markets regulator, has updated its public register with the latest set of double volume cap (DVC) data under the Markets in Financial Instruments Directive (MiFID II).

7 December

[ESMA PUBLISHES 2020 ESEF XBRL TAXONOMY FILES AND ESEF CONFORMANCE SUITE](#)

The European Securities and Markets Authority (ESMA), the EU securities markets regulator, has published the 2020 ESEF XBRL taxonomy files and an update to the ESEF Conformance Suite to facilitate implementation of the ESEF Regulation.

7 December

[ESAS HIGHLIGHT THE CHANGE IN THE STATUS OF SIMPLE, TRANSPARENT AND STANDARDISED \(STS\) SECURITISATION TRANSACTIONS AT THE END OF THE UK TRANSITION PERIOD](#)

The Joint Committee of the European Supervisory Authorities (ESAs) – ESMA, EBA and EIOPA – wish to highlight the impact in the change of status of ‘Simple, Transparent and Standardised’ (STS) securitisation transactions after the end of the Transition Period on 31 December 2020.

04 December

[ESMA updates reporting under the Money Market Funds Regulation](#)

The European Securities and Markets Authority (ESMA), the EU’s securities markets regulator, has updated its validation rules regarding the Money Market Fund Regulation (MMFR). This relates to the requirements of Article 37 of MMFR that require MMF managers to submit data to National Competent Authorities, who will then transmit this to ESMA.

26 November

[INC RATING’S CRA REGISTRATION WITHDRAWN](#)

The European Securities and Markets Authority (ESMA), the EU’s securities markets regulator, has withdrawn the credit rating agency (CRA) registration of INC Rating Sp. z o.o.

26 November

[ESMA publishes shortlist of candidates for position of Chair](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has published the shortlist of qualified candidates for the position of Chair, which it has sent to the Council of the European Union (Council) and the European Parliament (Parliament). The Council will appoint the Chair following confirmation by the Parliament.

[ESMA announces 10 Year Anniversary Conference](#)

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, will turn 10 on 1 January 2021 and, as part of our anniversary celebrations, we will host an online conference on 23 March to reflect on the progress the Authority has made as a financial regulator and look to its future.

ESMA starts its second decade as a mature market supervisory authority and a key component of the EU's regulatory framework together with the other European Supervisory Authorities and the European Systemic Risk Board. Over the last 10 years, ESMA has pursued its objectives of protecting investors and ensuring orderly and stable markets by completing the single rulebook for EU financial markets, supervising EU-wide entities directly, conducting risk assessments and promoting supervisory convergence across EU member states.

The anniversary event will look back at how ESMA has evolved into the regulator it is today and examine its future role in the EU's capital markets as their focus shifts towards greater integration and a more sustainable and digital future.

Confirmed participants include:

- Mairead McGuinness, European Commissioner for Financial Stability, Financial Services and the Capital Markets Union;
- Andrea Enria, Chair of the Supervisory Board, European Central Bank;
- Irene Tinagli, Chair of the Committee on Economic and Monetary Affairs, European Parliament;
- Sven Giegold, Member of the European Parliament;
- Anneli Tuominen, Vice Chair of the European Securities and Markets Authority and Director General of the Finnish Financial Supervisory Authority;
- Robert Ophèle, Chairman, Autorité des Marchés Financiers;
- Guillaume Prache, Managing Director, The European Federation of Investors and Financial Services Users;
- Veerle Colaert, Chair of the Securities and Markets Stakeholder Group;
- David Wright, Chair of Eurofi;
- Thomas Book, Member of the Executive Board, Deutsche Börse;
- Alexander Schindler, Member of the Executive Board, Union Investment;

- Niamh Moloney, Professor of Law, London School of Economics; and
- John Rega, Editor, Financial Services Politico.

The event is scheduled to take place between 15:00 and 19:00 (CET) on the afternoon of 23 March. Further details will follow.

EIOPA consults on ORSA in the context of COVID-19

The European Insurance and Occupational Pensions Authority (EIOPA) published today a [consultation on the Supervisory Statement on Own Risk Solvency Assessment \(ORSA\) in the context of COVID-19](#).

The statement promotes convergence by guiding undertakings through common supervisory expectations on the ORSA in the current situation triggered by the pandemic, taking into account that the impact on each individual undertaking can differ depending on its specific risk profile. A proper balance between flexibility and acknowledgment of the ORSA as an undertaking own exercise and clarification of supervisory expectations, in particular in specific circumstances, should be kept.

EIOPA believes that the current situation calls for an ad-hoc/non-regular ORSA in the cases where the pandemic impacts the risk profile of the undertaking materially, in particular in those cases where the performance of the regular ORSA has not allowed the undertaking to assess and to take into account the impact of the pandemic.

Undertakings are expected to take into account the uncertainty in the duration and (macroeconomic) impact of the pandemic in its ORSA and, if relevant for its risk profile, consider multiple scenarios to capture this uncertainty in an appropriate manner. In this case the scenarios are expected to include several degrees of severity for the pandemic's impact on the undertaking's solvency and capital needs taking into account its individual situation.

The stakeholders are invited to provide the views by completing the survey by Monday, 15 March 2021. EIOPA will consider the feedback received, develop impact assessment and publish a final report on the consultation as well as submit the supervisory statement for adoption by its Board of Supervisors.

[Go to the survey](#)