ESMA updates the ESEF Reporting Manual

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, published today an update of its Reporting Manual on the European Single Electronic Format (ESEF). The update expands existing guidance and reflects relevant developments in the technical specifications.

The ESEF Reporting Manual is aimed at all market participants involved in the implementation of the requirements set out in the ESEF Delegated Regulation, and in particular in the first-time preparation of IFRS consolidated financial statements in Inline XBRL.

Background

The ESEF Reporting Manual is intended to provide guidance on issues commonly encountered when generating Inline XBRL instance documents in compliance with the ESEF Delegated Regulation. It was originally published by ESMA in December 2017 and updated in July 2019. ESMA will continue to monitor markets developments and gather feedback from stakeholders. Where relevant and/or necessary, ESMA will provide further guidance to the public.

EU Framework meets Commissioner Dalli to discuss future EU Disability Strategy

The Framework consists of the EU Agency for Fundamental Rights, European Parliament, European Ombudsman and the European Disability Forum.

FRA called on the Commission to develop, in close cooperation with EU Member States, a human-rights based Strategy aimed at removal of physical and legal barriers for all rights-holders with clear indicators and a robust accountability framework.

Presentation of the Fundamental Rights

Report 2020 and the Fundamental Rights Survey to Member States

FRA's Fundamental Rights Report 2020 reflects on the developments and shortfalls of human rights protection in the EU in 2019.

Its focus section highlights how the EU's Fundamental Rights Charter has gained visibility and sparked a new fundamental rights culture at EU level.

FRA will also present key results from the Fundamental Rights Survey, based on the report 'What do fundamental rights mean for people in the EU?' which was launched online on 24-25 June.

New AMR Action Fund steps in to save collapsing antibiotic pipeline with pharmaceutical industry investment of US$1 billion

Partnership aims to bring 2 to 4 new antibiotics to patients by the end of the decade and facilitate needed long-term policy solutions

Today, more than 20 leading biopharmaceutical companies announced the launch

of the AMR Action Fund, a ground-breaking partnership that aims to bring 2-4 new antibiotics to patients by 2030. These treatments are urgently needed to address the rapid rise of antibiotic-resistant infections – also called antimicrobial resistance, or AMR. The companies have raised so far nearly US$1 billion new funding to support clinical research of innovative new antibiotics that are addressing the most resistant bacteria and life-threatening infections. Through the AMR Action Fund, pharmaceutical companies will join forces with philanthropies, development banks, and multilateral organizations to strengthen and accelerate antibiotic development. The Fund will focus on urgent public health needs. It will provide much needed financial resources, as well as important technical support to help biotech companies bring novel antibiotics to patients.

The AMR Action Fund, an initiative of the international body representing the R&D pharmaceutical industry (International Federation of Pharmaceutical Manufacturers & Associations, IFPMA), was announced at simultaneous virtual launch events in Berlin, Germany, and Washington, D.C., USA, with a third event in Tokyo, Japan taking place on July 10.

AMR is a looming global crisis that has the potential to dwarf COVID-19 in terms of deaths and economic costs. While tragically the death toll of COVID-19 continues to rise, each year 700,000 people are dying from AMR. In some of the most alarming scenarios, it is estimated that by 2050 AMR could claim as many as 10 million lives per year.

"Unlike COVID-19, AMR is a predictable and preventable crisis. We must act together to rebuild the pipeline and ensure that the most promising and innovative antibiotics make it from the lab to patients," said **Thomas Cueni, Director General of the IFPMA**, one of the organizers of the new fund. He adds: *"The AMR Action Fund is one of the largest and most ambitious collaborative initiatives ever undertaken by the pharmaceutical industry to respond to a global public health threat".*

The world urgently needs new antibiotics, but there are few in the pipeline because of a paradox: despite the huge societal costs of AMR, there is currently no viable market for new antibiotics. New antibiotics are used sparingly to preserve effectiveness, so in recent years, a number of antibiotic-focused biotechs have declared bankruptcy or exited this space due to the lack of commercial sustainability, resulting in the loss of valuable expertise and resources. The consequence is a huge public health need for new antibiotics, but a lack of funding available for antibiotic R&D, particularly the later stages of clinical research. This creates a "valley of death" between discovery and patient access.

"With the AMR Action Fund, the pharmaceutical industry is investing nearly US$1 billion to sustain an antibiotic pipeline that is on the verge of collapse, a potentially devastating situation that could affect millions of people around the world," said **David Ricks, Chairman and CEO of Eli Lilly and Company and President of IFPMA**. *"The AMR Action Fund will support innovative antibiotic candidates through the most challenging later stages of drug development, ultimately providing governments time to make the necessary policy reforms to enable a sustainable antibiotic pipeline."*

While the AMR Action Fund is an important step in addressing the challenge of AMR, policymakers across the globe must enact market-based reforms, including reimbursement reform and new pull incentives, to revitalize the antibiotics market and drive sustainable investments in antibiotic R&D. Until then, the biopharmaceutical industry is taking action now to support the current pipeline of antibiotics.

With this investment from leading biopharmaceutical companies, the AMR Action Fund will be the largest collective venture ever created to address AMR. The AMR Action Fund will:

- **Invest in smaller biotech companies focused on developing innovative antibacterial treatments that address the highest priority public health needs**, make a significant difference in clinical practice, and save lives.
- **Provide technical support to portfolio companies, giving them access to the deep expertise and resources of large biopharmaceutical companies**, to strengthen antibiotic development, and support access and appropriate use of antibiotics.
- **Bring together a broad alliance of industry and non-industry stakeholders**, including philanthropies, development banks, and multilateral organizations, and help encourage governments to create market conditions that enable sustainable investment in the antibiotic pipeline.

The AMR Action Fund expects to invest more than US$1 billion with the support of future partners into a portfolio of companies to address the funding gap for the financing of antibiotic development. The Fund is expected to be operational during the fourth quarter of 2020.

For more details on the AMR Action fund, visit www.AMRactionfund.com.

Messages of support for the AMR Action Fund

"AMR is a slow tsunami that threatens to undo a century of medical progress. I very much welcome this new engagement of the private sector in the development of urgently-needed antibacterial treatments. WHO looks forward to working with the AMR Action Fund to accelerate research to address this public health crisis." **Dr Tedros Adhanom Ghebreyesus, Director General World Health Organization**

"New antibiotics are needed to address growing resistance. EIB is actively addressing identified market failures with innovative financial instruments, antimicrobial resistance is clearly one. We welcome the opportunity to join forces with public and private actors, such as the pharmaceutical industry, philanthropic funders, multilateral development banks, and the World Health Organization to tackle this threat. The initiative is aligned with the EIB's core objectives in health and we are proud to be part of the origination group of the new AMR Action Fund." **Werner Hoyer, President, EIB**

Read President Hoyer's speech

Biopharmaceutical companies and foundations supporting the AMR Action Fund

Almirall, Amgen, Bayer, Boehringer Ingelheim, Chugai, Daiichi Sankyo, Eisai, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, LEO Pharma, Lundbeck, Menarini, Merck, MSD, Novartis, Novo Nordisk, Novo Nordisk Foundation, Pfizer, Roche, Shionogi, Takeda, Teva, UCB

About AMR Action Fund

The AMR Action Fund is an initiative from over 20 leading biopharmaceutical companies that have pledged to invest nearly US$1 billion, with the aim to bring 2-4 new antibiotics to market by 2030. The AMR Action Fund will invest in small companies developing innovative antibacterial treatments. It will forge partnerships with institutions and philanthropic organizations, development banks, and multilateral organizations to strengthen and accelerate antibiotic development. It will also work with governments to ensure there is a sustainable pipeline of new antibiotics to fight superbugs.

The concept of the AMR Action Fund was developed by the IFPMA and the Biopharmaceutical CEOs Roundtable (BCR), and biopharmaceutical companies and foundation, in collaboration with the World Health Organization (WHO), The European Investment Bank (EIB), and the Wellcome Trust.

ESMA highlights further aspects to consider in the finalisation of the framework for third-country CCPs

The European Securities and Markets Authority (ESMA), the EU's securities markets regulator, has published a letter that has just been sent to the European Commission (EC) as a contribution to the EC consultation on the delegated acts on tiering, comparable compliance and fees related to third-country central counterparties (TC-CCPs) under the revised European Market Infrastructure Regulation (EMIR 2.2).

ESMA appreciates that the EC duly considered in the development of these Delegated Acts the technical advice provided by ESMA on 11 November 2019. ESMA is also mindful of both the political considerations and the objectives for the targeted and important changes that have been introduced.

These Delegated Acts will be instrumental in further specifying the scope and range of measures available for the EU in ensuring an effective and proportionate regulatory and supervisory framework with regards to TC-CCPs. Leveraging on the multiple discussions with competent authorities and on the varied input received from stakeholders throughout the development of ESMA's

technical advice, ESMA believes it is useful to raise a few key aspects about the draft Delegated Acts that are presented in the letter, in particular with respect to the assessment of comparable compliance.

ESMA would welcome the EC considerations for the points raised when finalising the Delegated Acts in order to improve the soundness of the framework for TC-CCPs and all affected stakeholders.