ESMA consults on disclosure guidelines under the Prospectus Regulation

ESMA is seeking stakeholders' views on the draft Guidelines, whose purpose is to ensure that market participants have a uniform understanding of the relevant disclosure requirements and assist national competent authorities (NCAs) when they assess the completeness, comprehensibility and consistency of information in prospectuses.

Steven Maijoor, Chair, said:

"Prospectuses are an important source of information for investors in their decision-making about whether to invest in an issuer and its securities. Ensuring that prospectuses are comparable both across issuers and borders, is key to a level-playing field for capital raising in Europe.

"ESMA believes that the proposed Guidelines, which clarify the information to be included in prospectuses, will allow issuers to provide information to investors that is complete, comprehensible and consistent across the EU."

The draft Guidelines cover topics, such as:

- historical financial information;
- interim financial information;
- profit forecasts and estimates;
- working capital statements; and
- capitalisation and indebtedness.

The draft Guidelines, to enhance comparability with other financial information, clarify the content of the indebtedness statement. New guidance on working capital statements is provided to clarify how offerings should be considered when determining if an issuer can provide a *clean* working capital statement. Furthermore, ESMA provides specific guidance concerning working capital statements prepared by credit institutions and (re)insurance undertakings.

Next step

The consultation period closes on 4 October 2019. ESMA will use the feedback received to finalise the draft Guidelines.

Consultation on Draft Guidelines on disclosure requirements under the Prospectus Regulation

Responding to this paper

ESMA invites responses to the questions set out throughout this Consultation Paper. Responses are most helpful if they:

- respond to the question stated;
- contain a clear rationale; and
- describe any alternatives ESMA should consider.

ESMA will consider all responses received by **4 October 2019**.

Instructions

In order to facilitate analysis of responses to the Consultation Paper, respondents are requested to follow the below steps when preparing and submitting their response:

- Insert your responses to the questions in the Consultation Paper in the form "ESMA31-62-1333 Response form to CP on Draft Guidelines on disclosure requirements under the PR", available on ESMA's website alongside the present Consultation Paper (www.esma.europa.eu à 'Your input – Open consultations' – 'Consultation on Draft Guidelines on disclosure requirements under the Prospectus Regulation').
- Please do not remove tags of the type <ESMA_QUESTION_CPG_1>. Your response to each question has to be framed by the two tags corresponding to the question.
- If you do not wish to respond to a given question, please do not delete it but simply leave the text "TYPE YOUR TEXT HERE" between the tags.
- When you have drafted your response, name your response form according to the following convention: ESMA_CPG_nameofrespondent_RESPONSEFORM. For example, for a respondent named ABCD, the response form would be entitled ESMA_CPG_ABCD_RESPONSEFORM.
- Upload the form containing your responses, **in Word format**, to ESMA's website (www.esma.europa.eu under the heading 'Your input – Open consultations' à 'Consultation on Draft Guidelines on disclosure requirements under the Prospectus Regulation').

Publication of responses

All contributions received will be published following the close of the consultation, unless you request otherwise. **Please clearly indicate by ticking the appropriate checkbox on the website submission page if you do not wish your contribution to be publicly disclosed.** A standard confidentiality statement in an email message will not be treated as a request for non-

disclosure. A confidential response may be requested from us in accordance with ESMA's rules on access to documents. We may consult you if we receive such a request. Any decision we make not to disclose the response is reviewable by ESMA's Board of Appeal and the European Ombudsman.

Data protection

Information on data protection can be found at www.esma.europa.eu under the heading 'Data protection'.

Who should read this Consultation Paper

This Consultation Paper may be of particular interest to investors, issuers, including issuers already admitted to trading on a regulated market or on a multilateral trading facility, offerors or persons asking for admission to trading on a regulated market as well as to any market participant who is affected by the new Prospectus Regulation.

ESMA updates its Q&As relating to the Prospectus Regulation

Three of these Q&As provide clarification on the following issues in relation to the Prospectus Regulation:

- The application of Article 23(3) of the Prospectus Regulation in relation to issuers that qualify as financial intermediaries.
- Continuing an offer which has initially been made using a base prospectus approved under the Prospectus Directive after the entry into application of the Prospectus Regulation.

Additionally, ESMA is publishing twenty-two Q&As that have been updated in relation to the Prospectus Regulation. These Q&As were originally published in relation to Directive 2003/71/EC (the 'Prospectus Directive').

ESMA has also decided not to update twenty-eight Q&As that were published in relation to the Prospectus Directive. These are Q&As 1, 2, 4, 8, 15, 22, 25, 30, 35, 37, 44, 45, 60, 62, 65, 70, 71, 73, 75, 80, 82, 86, 87, 88, 89, 90, 93, 101. These Q&As will not be carried over in relation to the Prospectus Regulation.

We will continue analysing the existing Q&As published in relation to the Prospectus Directive and will either update and carry them forward in the Q&A document relating to the Prospectus Regulation, or we will not carry them forward as is the case in the paragraph above. In effect, this means that these Q&As will not be published in relation to the Prospectus Regulation. For example, where the Prospectus Regulation sufficiently clarifies an issue

or ESMA considers that the market is already aware of how a particular issue should be addressed then there is no need for further clarification.

ESMA will continue to publish the existing Q&As relating to the Prospectus Directive during the period in which prospectuses that have been approved under the Prospectus Directive may continue to be valid, which is until 21 July 2020. After this period, these Q&As will no longer apply.

The purpose of these Q&As is to promote common supervisory approaches and practices in the application of prospectus supervision. These Q&As are also intended to facilitate market parties by providing guidance as to how national competent authorities will interpret the Prospectus Regulation.

EU-U.S. trade talks: milestone reached in mutual recognition on pharmaceuticals

Today, the European Union and the United States delivered on a significant element of the Joint Statement agreed by Presidents Juncker and Trump in July 2018. The positive transatlantic trade agenda established in the Joint Statement includes a commitment from both sides to reduce barriers and increase trade in a range of sectors, including pharmaceuticals.

The recognition today by the U.S. Food and Drug Administration (FDA) of Slovakia, the last outstanding EU Member State, marks the full implementation of the EU-U.S. Mutual Recognition Agreement (MRA) for inspections of manufacturing sites for human medicines in their respective territories. This can make it faster and less costly for both sides to bring medicines to the market.

Commissioner Vytenis **Andriukaitis**, in charge of Health and Food Safety said: *"The completion of the Mutual Recognition Agreement is not only a step forward in the trade relations between the EU and the U.S., but it will also ensure high quality medicines for the benefit of patients. It means that, on both sides of the Atlantic, the authorities in charge of medicines can now rely on inspections results to replace their own inspections. Today, the U.S. Food and Drug Administration has completed the capability assessments of the 28 EU competent authorities, the result of five years of close transatlantic cooperation".*

This Mutual Recognition Agreement is underpinned by robust evidence that the EU and the U.S. have comparable procedures to carry out good manufacturing practice inspections for human medicines.

Together, Europe and the United States account for more than 80% of global

sales of new medicines. As a result of the full implementation of this agreement, both the industry and public authorities on both sides will be able to free resources that could be used to inspect facilities in other large producing countries.

The pharmaceutical industry is a strategic sector in which EU-U.S. regulatory cooperation is much more advanced than in most other sectors. Since May 2014, teams from the European Commission, EU national competent authorities, the European Medicines Agency (EMA) and the U.S. Food and Drug Administration have been auditing and assessing the respective supervisory systems. The U.S. Food and Drug Administration has now assessed positively all national competent authorities of the EU.

From now on, the batch testing waiver will also start to apply. This means that the qualified persons in the EU pharmaceutical company will be relieved of their task for carrying out the quality controls when carried out already in the United States.

The Mutual Recognition Agreement implementation work will continue with view to expanding the operational scope to veterinary medicines, human vaccines and plasma derived medicinal products.

Background

In 1998, the EU and the U.S. signed a broad Mutual Recognition Agreement, which included a Pharmaceutical Annex providing for anticipated and limited reliance on each other's Good Manufacturing Practices (GMP) inspections.

2017 marked the entry into operation of the agreement between the EU and the U.S. to recognise inspections of manufacturing sites for human medicines conducted in their respective territories. This agreement strengthens reliance upon each other's inspection expertise and resources. Initially it applied between the U.S. Food and Drug Administration and those EU Member States that the U.S. Food and Drug Administration had assessed. This has been gradually extended to all EU countries and now the regulatory authorities in all 28 EU Member States were recognised by the U.S. Food and Drug Administration. Meanwhile, the EU made the same determination about U.S. Food and Drug Administration in June 2017.

ESMA updates the CSDR Q&As

The updated Q&As provide answers to questions regarding practical issues on the implementation of the new CSDR regime. The latest CSDR Q&As clarify aspects regarding the scope of internalised settlement reporting, namely:

• investment firms are not required to report in case they do not execute transfer orders themselves, which they forward in their entirety to a

custodian, irrespective of whether the custodian is established in the EEA or not; and

• trade netting as such does not qualify as internalised settlement.

Q&As are an important tool to promote common supervisory approaches and practices in the application of CSDR. This document is aimed at national competent authorities under the Regulation to ensure that, in their supervisory activities, their actions are converging along the lines of the responses adopted by ESMA. It should also help investors and other market participants by providing clarity on CSDR requirements.

Background

The aim of CSDR is to harmonise certain aspects of the settlement cycle and settlement discipline and to provide a set of common requirements for CSDs operating securities settlement systems across the EU. ESMA will continue to develop Q&As on the CSDR in the coming months and will review and update them where required.