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II

*(Information)*INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
AND AGENCIES

EUROPEAN COMMISSION

Guidelines**of 19 March 2015****on principles of Good Distribution Practice of active substances for medicinal products for human use****(Text with EEA relevance)**

(2015/C 95/01)

Introduction

These guidelines are based on the fourth paragraph of Article 47 of Directive 2001/83/EC ⁽¹⁾.

They follow the same principles that underlie the guidelines of EudraLex Volume 4, Part II, Chapter 17, with regard to the distribution of active substances and the Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use ⁽²⁾.

These guidelines provide stand-alone guidance on Good Distribution Practice (GDP) for importers and distributors of active substances for medicinal products for human use. They complement the rules on distribution set out in the guidelines of EudraLex Volume 4, Part II, and apply also to distributors of active substances manufactured by themselves.

Any manufacturing activities in relation to active substances, including re-packaging, re-labelling or dividing up, are subject to Commission Delegated Regulation (EU) No 1252/2014 ⁽³⁾ and EudraLex Volume 4, Part II.

Additional requirements apply to the importation of active substances, as laid down in Article 46b of Directive 2001/83/EC.

Distributors of active substances for medicinal products for human use should follow these guidelines as of 21 September 2015.

CHAPTER 1 — SCOPE

- 1.1. These guidelines apply to distribution of active substances, as defined in Article 1(3a) of Directive 2001/83/EC, for medicinal products for human use. According to that provision, an active substance is any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁽²⁾ OJ C 343, 23.11.2013, p. 1.

⁽³⁾ Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1).

- 1.2. For the purpose of these guidelines, distribution of active substances shall comprise all activities consisting of procuring, importing, holding, supplying or exporting active substances, apart from brokering.
- 1.3. These guidelines do not apply to intermediates of active substances.

CHAPTER 2 — QUALITY SYSTEM

- 2.1. Distributors of active substances should develop and maintain a quality system setting out responsibilities, processes and risk management principles. Examples of the processes and applications of quality risk management can be found in EudraLex Volume 4, Part III: GMP related documents, ICH guideline Q9 on Quality Risk Management (ICH Q9).
- 2.2. The quality system should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities. It should ensure that:
 - (i) active substances are procured, imported, held, supplied or exported in a way that is compliant with the requirements of GDP for active substances;
 - (ii) management responsibilities are clearly specified;
 - (iii) active substances are delivered to the right recipients within a satisfactory time period;
 - (iv) records are made contemporaneously;
 - (v) deviations from established procedures are documented and investigated;
 - (vi) appropriate corrective and preventive actions, commonly known as 'CAPA', are taken to correct deviations and prevent them in line with the principles of quality risk management;
 - (vii) changes that may affect the storage and distribution of active substances are evaluated.
- 2.3. The size, structure and complexity of the distributor's activities should be taken into consideration when developing or modifying the quality system.

CHAPTER 3 — PERSONNEL

- 3.1. The distributor should designate a person at each location where distribution activities are performed who should have defined authority and responsibility for ensuring that a quality system is implemented and maintained. The designated person should fulfil his responsibilities personally. The designated person can delegate duties but not responsibilities.
- 3.2. The responsibilities of all personnel involved in the distribution of active substances should be specified in writing. The personnel should be trained on the requirements of GDP for active substances. They should have the appropriate competence and experience to ensure that active substances are properly handled, stored and distributed.
- 3.3. Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme.
- 3.4. A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

CHAPTER 4 — DOCUMENTATION

- 4.1. Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available or retrievable. All documentation related to compliance of the distributor with these guidelines should be made available on request of competent authorities.
- 4.2. Documentation should be sufficiently comprehensive with respect to the scope of the distributor's activities and in a language understood by personnel. It should be written in clear, unambiguous language and be free from errors.

- 4.3. Any alteration made in the documentation should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.
- 4.4. Each employee should have ready access to all necessary documentation for the tasks executed.

Procedures

- 4.5. Written procedures should describe the distribution activities which affect the quality of the active substances. This could include receipt and checking of deliveries, storage, cleaning and maintenance of the premises (including pest control), recording of the storage conditions, security of stocks on site and of consignments in transit, withdrawal from saleable stock, handling of returned products, recall plans, etc.
- 4.6. Procedures should be approved, signed and dated by the person responsible for the quality system.
- 4.7. Attention should be paid to the use of valid and approved procedures. Documents should be reviewed regularly and kept up to date. Version control should be applied to procedures. After revision of a document a system should exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures should be removed from workstations and archived.

Records

- 4.8. Records should be clear, be made at the time each operation is performed and in such a way that all significant activities or events are traceable. Records should be retained for at least 1 year after the expiry date of the active substance batch to which they relate. For active substances with retest dates, records should be retained for at least 3 years after the batch is completely distributed.
- 4.9. Records should be kept of each purchase and sale, showing the date of purchase or supply, name of the active substance, batch number and quantity received or supplied, and name and address of the supplier and of the original manufacturer, if not the same, or of the shipping agent and/or the consignee. Records should ensure the traceability of the origin and destination of products, so that all the suppliers of, or those supplied with, an active substance can be identified. Records that should be retained and be available include:
 - (i) identity of supplier, original manufacturer, shipping agent and/or consignee;
 - (ii) address of supplier, original manufacturer, shipping agent and/or consignee;
 - (iii) purchase orders;
 - (iv) bills of lading, transportation and distribution records;
 - (v) receipt documents;
 - (vi) name or designation of active substance;
 - (vii) manufacturer's batch number;
 - (viii) certificates of analysis, including those of the original manufacturer;
 - (ix) retest or expiry date.

CHAPTER 5 — PREMISES AND EQUIPMENT

- 5.1. Premises and equipment should be suitable and adequate to ensure proper storage, protection from contamination, e.g. narcotics, highly sensitising materials, materials of high pharmacological activity or toxicity, and distribution of active substances. They should be suitably secure to prevent unauthorised access. Monitoring devices that are necessary to guarantee the quality attributes of the active substance should be calibrated according to an approved schedule against certified traceable standards.

CHAPTER 6 — OPERATIONS**Orders**

- 6.1. Where active substances are procured from a manufacturer, importer or distributor established in the EU, that manufacturer, importer or distributor should be registered according to Article 52a of Directive 2001/83/EC.

Receipt

- 6.2. Areas for receiving active substances should protect deliveries from prevailing weather conditions during unloading. The reception area should be separate from the storage area. Deliveries should be examined at receipt in order to check that:
- (i) containers are not damaged;
 - (ii) all security seals are present with no sign of tampering;
 - (iii) correct labelling, including correlation between the name used by the supplier and the in-house name, if these are different;
 - (iv) necessary information, such as a certificate of analysis, is available; and
 - (v) the active substance and the consignment correspond to the order.
- 6.3. Active substances with broken seals, damaged packaging, or suspected of possible contamination should be quarantined either physically or using an equivalent electronic system and the cause of the issue investigated.
- 6.4. Active substances subject to specific storage measures, e.g. narcotics and products requiring a specific storage temperature or humidity, should be immediately identified and stored in accordance with written instructions and with relevant legislative provisions.
- 6.5. Where the distributor suspects that an active substance procured or imported by him is falsified, he should segregate it either physically or using an equivalent electronic system and inform the national competent authority of the country in which he is registered.
- 6.6. Rejected materials should be identified and controlled and quarantined to prevent their unauthorised use in manufacturing and their further distribution. Records of destruction activities should be readily available.

Storage

- 6.7. Active substances should be stored under the conditions specified by the manufacturer, e.g. controlled temperature and humidity when necessary, and in such a manner to prevent contamination and/or mix up. The storage conditions should be monitored and records maintained. The records should be reviewed regularly by the person responsible for the quality system.
- 6.8. When specific storage conditions are required, the storage area should be qualified and operated within the specified limits.
- 6.9. The storage facilities should be clean and free from litter, dust and pests. Adequate precautions should be taken against spillage or breakage, attack by micro-organisms and cross-contamination.
- 6.10. There should be a system to ensure stock rotation, e.g. 'first expiry (retest date), first out', with regular and frequent checks that the system is operating correctly. Electronic warehouse management systems should be validated.
- 6.11. Active substances beyond their expiry date should be separated, either physically or using an equivalent electronic system, from approved stock and not be supplied.
- 6.12. Where storage or transportation of active substances is contracted out, the distributor should ensure that the contract acceptor knows and follows the appropriate storage and transport conditions. There must be a written contract between the contract giver and contract acceptor, which clearly establishes the duties of each party. The contract acceptor should not subcontract any of the work entrusted to him under the contract without the contract giver's written authorisation.

Deliveries to customers

- 6.13. Supplies within the EU should be made only by distributors of active substances registered according to Article 52a of Directive 2001/83/EC to other distributors, manufacturers or to dispensing pharmacies.
- 6.14. Active substances should be transported in accordance with the conditions specified by the manufacturer and in a manner that does not adversely affect their quality. Product, batch and container identity should be maintained at all times. All original container labels should remain readable.
- 6.15. A system should be in place by which the distribution of each batch of active substance can be readily identified to permit its recall.

Transfer of information

- 6.16. Any information or event that the distributor becomes aware of, which have the potential to cause an interruption to supply, should be notified to relevant customers.
- 6.17. Distributors should transfer all product quality or regulatory information received from an active substance manufacturer to the customer and from the customer to the active substance manufacturer.
- 6.18. The distributor who supplies the active substance to the customer should provide the name and address of the original active substance manufacturer and the batch number(s) supplied. A copy of the original certificate of analysis from the manufacturer should be provided to the customer.
- 6.19. The distributor should also provide the identity of the original active substance manufacturer to competent authorities upon request. The original manufacturer can respond to the competent authority directly or through its authorised agents. (In this context 'authorised' refers to authorised by the manufacturer.)
- 6.20. The specific guidance for certificates of analysis is detailed in Section 11.4 of Part II of Eudralex Volume 4.

CHAPTER 7 — RETURNS, COMPLAINTS AND RECALLS**Returns**

- 7.1. Returned active substances should be identified as such and quarantined pending investigation.
- 7.2. Active substances which have left the care of the distributor, should only be returned to approved stock if all of the following conditions are met:
- (i) the active substance is in the original unopened container(s) with all original security seals present and is in good condition;
 - (ii) it is demonstrated that the active substance has been stored and handled under proper conditions. Written information provided by the customer should be available for this purpose;
 - (iii) the remaining shelf life period is acceptable;
 - (iv) the active substance has been examined and assessed by a person trained and authorised to do so;
 - (v) no loss of information/traceability has occurred.

This assessment should take into account the nature of the active substance, any special storage conditions it requires, and the time elapsed since it was supplied. As necessary and if there is any doubt about the quality of the returned active substance, advice should be sought from the manufacturer.

7.3. Records of returned active substances should be maintained. For each return, documentation should include:

- (i) name and address of the consignee returning the active substances;
- (ii) name or designation of active substance, active substance batch number and quantity returned;
- (iii) reason for return;
- (iv) use or disposal of the returned active substance and records of the assessment performed.

7.4. Only appropriately trained and authorised personnel should release active substances for return to stock. Active substances returned to saleable stock should be placed such that the stock rotation system operates effectively.

Complaints and recalls

7.5. All complaints, whether received orally or in writing, should be recorded and investigated according to a written procedure. In the event of a complaint about the quality of an active substance the distributor should review the complaint with the original active substance manufacturer in order to determine whether any further action, either with other customers who may have received this active substance or with the competent authority, or both, should be initiated. The investigation into the cause for the complaint should be conducted and documented by the appropriate party.

7.6. Complaint records should include:

- (i) name and address of complainant;
- (ii) name, title, where appropriate, and phone number of person submitting the complaint;
- (iii) complaint nature, including name and batch number of the active substance;
- (iv) date the complaint is received;
- (v) action initially taken, including dates and identity of person taking the action;
- (vi) any follow-up action taken;
- (vii) response provided to the originator of complaint, including date response sent;
- (viii) final decision on active substance batch.

7.7. Records of complaints should be retained in order to evaluate trends, product related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action. These should be made available during inspections by competent authorities.

7.8. Where a complaint is referred to the original active substance manufacturer, the record maintained by the distributor should include any response received from the original active substance manufacturer, including date and information provided.

7.9. In the event of a serious or potentially life-threatening situation, local, national, and/or international authorities should be informed and their advice sought.

7.10. There should be a written procedure that defines the circumstances under which a recall of an active substance should be considered.

- 7.11. The recall procedure should designate who should be involved in evaluating the information, how a recall should be initiated, who should be informed about the recall, and how the recalled material should be treated. The designated person (cf. Section 3.1) should be involved in recalls.

CHAPTER 8 — SELF-INSPECTIONS

- 8.1. The distributor should conduct and record self-inspections in order to monitor the implementation of and compliance with these guidelines. Regular self-inspections should be performed in accordance with an approved schedule.
-

ANNEX

Glossary of terms applicable to these guidelines

| Terms | Definition |
|-----------------------------------|---|
| Batch | A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval. |
| Batch number | A unique combination of numbers, letters and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined. |
| Brokering of active substances | All activities in relation to the sale or purchase of active substances that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person. |
| Calibration | The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements. |
| Consignee | The person to whom the shipment is to be delivered whether by land, sea or air. |
| Contamination | The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or active substance during production, sampling, packaging or repackaging, storage or transport. |
| Distribution of active substances | All activities consisting of procuring, importing, holding, supplying or exporting of active substances, apart from brokering. |
| Deviation | Departure from an approved instruction or established standard. |
| Expiry date | The date placed on the container/labels of an active substance designating the time during which the active substance is expected to remain within established shelf life specifications if stored under defined conditions, and after which it should not be used. |
| Falsified active substance | Any active substance with a false representation of: <ul style="list-style-type: none"> a) its identity, including its packaging and labelling, its name or its components as regards any of the ingredients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacture, its country of origin; or c) its history, including the records and documents relating to the distribution channels used. |
| Holding | Storing active substances. |
| Procedure | A documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the distribution of an active substance. |

| Terms | Definition |
|----------------------------|---|
| Procuring | Obtaining, acquiring, purchasing or buying active substances from manufacturers, importers or other distributors. |
| Quality risk management | A systematic process for the assessment, control, communication and review of risks to the quality of an active substance across the product lifecycle. |
| Quality system | The sum of all aspects of a system that implements quality policy and ensures that quality objectives are met (ICH Q9). |
| Quarantine | The status of materials isolated physically or by other effective means pending a decision on the subsequent approval or rejection. |
| Retest date | The date when a material should be re-examined to ensure that it is still suitable for use. |
| Supplying | All activities of providing, selling, donating active substances to distributors, pharmacists, or manufacturers of medicinal products. |
| Signed (signature) | The record of the individual who performed a particular action or review. This record can be initials, full handwritten signature, personal seal, or authenticated and secure electronic signature. |
| Transport (transportation) | Moving active substances between two locations without storing them for unjustified periods of time. |
| Validation | A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria. |

Guidelines
of 19 March 2015
on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for
excipients of medicinal products for human use

(Text with EEA relevance)

(2015/C 95/02)

Introduction

These guidelines are based on the fifth paragraph of Article 47 of Directive 2001/83/EC ⁽¹⁾.

According to the second paragraph of Article 46(f) of Directive 2001/83/EC, the manufacturing authorisation holder is required to ensure that the excipients are suitable for use in medicinal products by ascertaining what the appropriate good manufacturing practice (GMP) is. The appropriate GMP for excipients of medicinal products for human use shall be ascertained on the basis of a formalised risk assessment in accordance with these guidelines. The risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects. The manufacturing authorisation holder shall ensure that the appropriate GMP ascertained is applied. The manufacturing authorisation holder shall document the measures taken.

The excipient risk assessment/risk management procedure should be incorporated in the pharmaceutical quality system of the manufacturing authorisation holder.

Manufacturing authorisation holders should have the risk assessment/management documentation for appropriate GMP for excipients available on site for review by GMP inspectors. Consideration should be given to sharing relevant information from the risk assessment with the excipient manufacturer to facilitate continuous improvement.

A risk assessment as set out in these guidelines should be carried out for excipients for authorised medicinal products for human use by 21 March 2016.

CHAPTER 1 — SCOPE

- 1.1. These guidelines apply to the risk assessment for ascertaining the appropriate GMP for excipients for medicinal products for human use. According to Article 1(3b) of Directive 2001/83/EC, an excipient is any constituent of a medicinal product other than the active substance and the packaging material.
- 1.2. These guidelines do not cover substances added to stabilise active substances that cannot exist on their own.

CHAPTER 2 — DETERMINATION OF APPROPRIATE GMP BASED ON TYPE AND USE OF EXCIPIENT

- 2.1. In EudraLex Volume 4, Guidelines for Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Part III: GMP related documents, ICH guideline Q9 on Quality Risk Management (ICH Q9), principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality, including excipients, can be found.
- 2.2. These quality risk management principles should be used to assess the risks presented to the quality, safety and function of each excipient and to classify the excipient in question, e.g. as low risk, medium risk or high risk. Quality risk management tools such as those listed in EudraLex Volume 4, Part III, ICH Q9 (e.g. hazard analysis and critical control points — HACCP) should be used for this purpose.
- 2.3. For each excipient from each manufacturer used, the manufacturing authorisation holder should identify the risks presented to the quality, safety and function of each excipient from its source — be that animal, mineral, vegetable, synthetic, etc. — through to its incorporation in the finished pharmaceutical dose form. Areas for consideration should include, but are not limited to:

(i) transmissible spongiform encephalopathy;

(ii) potential for viral contamination;

⁽¹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (iii) potential for microbiological or endotoxin/pyrogen contamination;
 - (iv) potential, in general, for any impurity originating from the raw materials, e.g. aflatoxins or pesticides, or generated as part of the process and carried over, e.g. residual solvents and catalysts;
 - (v) sterility assurance for excipients claimed to be sterile;
 - (vi) potential for any impurities carried over from other processes, in absence of dedicated equipment and/or facilities;
 - (vii) environmental control and storage/transportation conditions including cold chain management, if appropriate;
 - (viii) supply chain complexity;
 - (ix) stability of excipient;
 - (x) packaging integrity evidence.
- 2.4. Additionally, with respect to the use and function of each excipient, the manufacturing authorisation holder should consider:
- (i) the pharmaceutical form and use of the medicinal product containing the excipient;
 - (ii) the function of the excipient in the formulation, e.g. lubricant in a tablet product or preservative material in a liquid formulation, etc.;
 - (iii) the proportion of the excipient in the medicinal product composition;
 - (iv) daily patient intake of the excipient;
 - (v) any known quality defects/fraudulent adulterations, both globally and at a local company level related to the excipient;
 - (vi) whether the excipient is a composite;
 - (vii) known or potential impact on the critical quality attributes of the medicinal product;
 - (viii) other factors as identified or known to be relevant to assuring patient safety.
- 2.5. Having established and documented the risk profile of the excipient, the manufacturing authorisation holder should establish and document the elements of EudraLex Volume 4 that he believes are needed to be in place in order to control and maintain the quality of the excipient, e.g. Annex 1 or/and Annex 2; Part II: Basic Requirements for Active Substances used as Starting Materials.
- 2.6. These elements will vary depending on the source, the supply chain and the subsequent use of the excipient, but as a minimum the following high level GMP elements should be considered by the manufacturing authorisation holder:
- (i) establishment and implementation of an effective pharmaceutical quality system;
 - (ii) sufficient competent and appropriately qualified personnel;
 - (iii) defined job descriptions for managerial and supervisory staff responsible for manufacturing and quality activities;
 - (iv) training programmes for all staff involved in manufacturing and quality activities;
 - (v) training programmes related to health, hygiene and clothing as identified as necessary to the intended operations;
 - (vi) provision and maintenance of premises and equipment appropriate to the intended operations;

- (vii) documentation system(s) covering all processes and specifications for the various manufacturing and quality operations;
- (viii) systems for coding and identifying starting materials, intermediates and excipients to allow full traceability;
- (ix) qualification program of suppliers;
- (x) system for quality control of the excipient and a responsible person independent from production to release the batches;
- (xi) retention of records for incoming materials and excipients and retention of samples of excipients for the periods required by EudraLex Volume 4, Part II;
- (xii) systems to ensure that any activity contracted out is subject to a written contract;
- (xiii) maintenance of an effective system whereby complaints are reviewed and excipients may be recalled;
- (xiv) change management and deviation management system;
- (xv) self-inspection program;
- (xvi) environmental control and storage conditions.

CHAPTER 3 — DETERMINATION OF EXCIPIENT MANUFACTURER'S RISK PROFILE

- 3.1. After determination of the appropriate GMP, a gap analysis of the required GMP against the activities and capabilities of the excipient manufacturer should be performed.
- 3.2. Data/evidence to support the gap analysis should be obtained through audit or from information received from the excipient manufacturer.
- 3.3. Certification of quality systems and/or GMP held by the excipient manufacturer and the standards against which these have been granted should be considered as such certification may fulfil the requirements.
- 3.4. Any gaps identified between the required GMP and the activities and capabilities of the excipient manufacturer should be documented. Furthermore, the manufacturing authorisation holder should perform a further risk assessment to determine the risk profile, e.g. low risk, medium risk or high risk, for that excipient manufacturer. EudraLex Volume 4, Part III, ICH Q9 should be used for that purpose. Quality risk management tools such as those listed there — HACCP etc. — should be used for this.
- 3.5. The manufacturing authorisation holder should have a series of strategies ranging from acceptance through control to unacceptable for the different risk profiles and based on these a control strategy, e.g. audit, document retrieval and testing, should be established.

CHAPTER 4 — CONFIRMATION OF APPLICATION OF APPROPRIATE GMP

- 4.1. Once the appropriate GMP for the excipient and the risk profile of the excipient manufacturer have been defined, ongoing risk review should be performed through mechanisms such as:
 - (i) number of defects connected to batches of excipient received;
 - (ii) type/severity of such defects;
 - (iii) monitoring and trend analysis of excipient quality;
 - (iv) loss of relevant quality system and/or GMP certification by excipient manufacturer;
 - (v) observation of trends in drug product quality attributes; this will depend on the nature and role of excipient;
 - (vi) observed organisational, procedural or technical/process changes at the excipient manufacturer;

(vii) audit/re-audit of excipient manufacturer;

(viii) questionnaires.

Based on the outcome of the risk review, the established control strategy should be reviewed and revised if needed.

Non-opposition to a notified concentration
(Case M.7275 — Novartis/GlaxoSmithKline Oncology Business)
(Text with EEA relevance)
(2015/C 95/03)

On 28 January 2015, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation (EC) No. 139/2004 ⁽¹⁾. The full text of the decision is available only in English language and will be made public after it is cleared of any business secrets it may contain. It will be available:

- in the merger section of the Competition website of the Commission (<http://ec.europa.eu/competition/mergers/cases/>). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,
- in electronic form on the EUR-Lex website (<http://eur-lex.europa.eu/homepage.html?locale=en>) under document number 32015M7275. EUR-Lex is the online access to the European law.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1.

Non-opposition to a notified concentration
(Case M.7496 — Panasonic/Ficosa Inversion/Ficosa International)
(Text with EEA relevance)
(2015/C 95/04)

On 17 March 2015, the Commission decided not to oppose the above notified concentration and to declare it compatible with the internal market. This decision is based on Article 6(1)(b) of Council Regulation (EC) No 139/2004 ⁽¹⁾. The full text of the decision is available only in the English language and will be made public after it is cleared of any business secrets it may contain. It will be available:

- in the merger section of the Competition website of the Commission (<http://ec.europa.eu/competition/mergers/cases/>). This website provides various facilities to help locate individual merger decisions, including company, case number, date and sectoral indexes,
- in electronic form on the EUR-Lex website (<http://eur-lex.europa.eu/homepage.html?locale=en>) under document number 32015M7496. EUR-Lex is the online access to European law.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1.

Information related to data on Member States' trusted lists as notified under Commission Decision 2009/767/EC, as amended

(2015/C 95/05)

Pursuant to Article 2(4) of Commission Decision 2009/767/EC ⁽¹⁾, as amended by Commission Decision 2010/425/EU ⁽²⁾ and Commission Implementing Decision 2013/662/EU ⁽³⁾, the European Commission makes available to all Member States, through a secure channel to an authenticated web server, the information notified by Member States under Article 2(3) of the Decision, both in a human readable form and in a signed machine processable form.

The information notified by Member States is available at the following URLs:

— https://ec.europa.eu/information_society/policy/esignature/trusted-list/tl-mp.xml for a signed xml machine processable version,

and

— https://ec.europa.eu/information_society/policy/esignature/trusted-list/tl-hr.pdf for a human readable version.

The authenticity and integrity of the machine processable version of the information is ensured through an electronic signature supported by one of the following digital certificates that can be authenticated through the following digest information:

1. Digest value for the first certificate, valid until 19 December 2018:

— SHA-256 digest (Hex) value: 55 f5 07 de 3a 84 c6 3f 29 f0 46 93 f7 30 ad d1 73 ca df a0 9b 76 ab 07 f5 f9 74 84 12 fd 9a aa

— SHA-1 digest (Hex) value: 31 83 8b b9 5e 4b 76 fc 09 c3 6b ef 8f d2 db 46 d2 ab ab 1a

— SHA-256 digest (Base64) value: VfUH3jqExj8p8EaT9zCt0XPK36CbdqsH9fl0hBL9mqo=

— SHA-1 digest (Base64): MYOLuV5Ldvjw2vvj9LbRtKrqxo=

2. Digest value for the second certificate, valid until 15 September 2018:

— SHA-256 digest (Hex) value: f0 e7 c9 5c 09 a5 f6 79 91 a0 35 3e bb dc e8 20 13 39 49 eb 1f f5 7e 6d 2d f9 62 e8 02 a2 e4 0c

— SHA-1 digest (Hex) value: 80 61 9c af df af 48 db 03 6b 0d 5b 9c 6e 85 32 3a d0 d2 21

— SHA-256 digest (Base64) value: 8OfjXAmI9nmRoDU+u9zoIBM5Sesf9X5tLfli6AKi5Aw=

— SHA-1 digest (Base64): gGGcr9+vSNsDaw1bnG6FMjrQ0iE=

3. Digest value for the third certificate, valid until 16 November 2015:

— SHA-256 digest (Hex) value: 5d 39 e8 f1 16 69 50 e9 97 38 32 ad 26 6f 06 74 2c c4 a9 48 48 69 df 61 ef cb 84 9d b2 fc 60 4a

— SHA-1 digest (Hex) value: a8 4e 18 97 24 1f 85 c5 55 d0 3f 48 f5 a1 95 d6 3c 6a a6 5b

— SHA-256 digest (Base64) value: XTno8RZpUOmXODKtjm8GdCzEqUhIad9h78uEnbL8YEo=

— SHA-1 digest (Base64) value: qE4YlyQfhcVV0D9I9aGV1jxqpls=

⁽¹⁾ Commission Decision 2009/767/EC of 16 October 2009 setting out measures facilitating the use of procedures by electronic means through the 'points of single contact' under Directive 2006/123/EC of the European Parliament and of the Council on services in the internal market (OJ L 274, 20.10.2009, p. 36).

⁽²⁾ Commission Decision 2010/425/EU of 28 July 2010 amending Decision 2009/767/EC as regards the establishment, maintenance and publication of trusted lists of certification service providers supervised/accredited by Member States (OJ L 199, 31.7.2010, p. 30).

⁽³⁾ Commission Implementing Decision 2013/662/EU of 14 October 2013 amending Decision 2009/767/EC as regards the establishment, maintenance and publication of trusted lists of certification service providers supervised/accredited by Member States (OJ L 306, 16.11.2013, p. 21).

The authenticity and integrity of the publication of the human readable version of the 'compiled list' is ensured through a TLS/SSL secured connection supported by a digital certificate, valid until 10 May 2017. The certificate can be authenticated through the following digest information:

- SHA-1 (Hex): b4c0ea6694a5627e8a448bc830483cd38dbd63ec
- SHA-256 (Hex): e2b6c3009afa80bcab2eb5fec5a2c4ae0606aca205ba4ed62f2fb76cc11e08da
- SHA-1 (Base64): tMDqZpSlYn6KRivIMEg80429Y+w=
- SHA-256 (Base64): 4rbDAJr6gLyrLrX+xaLErgYGrKIFuk7WLy+3bMEeCNo=

The authenticity and integrity of the 'compiled' list should be verified by relying parties prior to any use. The Commission accepts no responsibility or liability whatsoever with regard to the content of the pointed national trusted lists which lies exclusively with the Member States.

IV

*(Notices)*NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
AGENCIES

COUNCIL

Notice for the attention of the persons subject to the restrictive measures provided for in Council Decision 2011/172/CFSP and in Council Regulation (EU) No 270/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt

(2015/C 95/06)

The following information is brought to the attention of the persons who are designated in the Annex to Council Decision 2011/172/CFSP ⁽¹⁾, as amended by Council Decision (CFSP) 2015/486 ⁽²⁾, and in Annex I to Council Regulation (EU) No 270/2011 ⁽³⁾ concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt.

The Council of the European Union, after having reviewed the list of persons designated in the above-mentioned Annexes, has determined that the restrictive measures provided for in Decision 2011/172/CFSP and in Regulation (EU) No 270/2011 should continue to apply to those persons.

The attention of the persons concerned is drawn to the possibility of making an application to the competent authorities of the relevant Member State(s) as indicated on the websites in Annex II to Regulation (EU) No 270/2011, in order to obtain an authorisation to use frozen funds for basic needs or specific payments (cf. Article 4 of the Regulation).

The persons concerned may submit a request to the Council before 10 January 2016, together with supporting documentation, that the decision to include them on the above-mentioned list should be reconsidered to the following address:

Council of the European Union
General Secretariat
DG C 1C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

E-mail: sanctions@consilium.europa.eu

Any observations received will be taken into account for the purpose of the Council's next review, in accordance with Article 12 of Regulation (EU) No 270/2011, of the list of designated persons.

⁽¹⁾ OJ L 76, 22.3.2011, p. 63.

⁽²⁾ OJ L 77, 21.3.2015, p. 16.

⁽³⁾ OJ L 76, 22.3.2011, p. 4.

Notice for the attention of the data subjects to whom the restrictive measures provided for in Council Regulation (EU) No 270/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Egypt apply

(2015/C 95/07)

The attention of data subjects is drawn to the following information in accordance with Article 12 of Regulation (EC) No 45/2001 of the European Parliament and of the Council ⁽¹⁾:

The legal basis for this processing operation is Council Regulation (EU) No 270/2011 ⁽²⁾.

The controller of this processing operation is the Council of the European Union represented by the Director-General of DG C (Foreign Affairs, Enlargement, Civil Protection) of the General Secretariat of the Council and the department entrusted with the processing operation is the Unit 1C of DG C that can be contacted at:

Council of the European Union
General Secretariat
DG C 1C
Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË

E-mail: sanctions@consilium.europa.eu

The purpose of the processing operation is the establishment and updating of the list of persons subject to restrictive measures in accordance with Regulation (EU) No 270/2011.

The data subjects are the natural persons who fulfil listing criteria as laid down in that Regulation.

The personal data collected includes data necessary for the correct identification of the person concerned, the Statement of Reasons and any other data related thereto.

The personal data collected may be shared as necessary with the European External Action Service and the Commission.

Without prejudice to restrictions provided for in Article 20(1)(a) and (d) of Regulation (EC) No 45/2001, requests for access, as well as requests for rectification or objection will be answered in accordance with Section 5 of Council Decision 2004/644/EC ⁽³⁾.

Personal data will be retained for five years from the moment the data subject has been removed from the list of persons subject to the asset freeze or the validity of the measure has expired, or for the duration of court proceedings in the event they had been started.

Data subjects may have recourse to the European Data Protection Supervisor in accordance with Regulation (EC) No 45/2001.

⁽¹⁾ OJ L 8, 12.1.2001, p. 1.

⁽²⁾ OJ L 76, 22.3.2011, p. 4.

⁽³⁾ OJ L 296, 21.9.2004, p. 16.

EUROPEAN COMMISSION

Euro exchange rates ⁽¹⁾

20 March 2015

(2015/C 95/08)

1 euro =

| Currency | Exchange rate | Currency | Exchange rate | | |
|----------|-------------------|----------|---------------|-----------------------|-----------|
| USD | US dollar | 1,0776 | CAD | Canadian dollar | 1,3655 |
| JPY | Japanese yen | 130,26 | HKD | Hong Kong dollar | 8,3615 |
| DKK | Danish krone | 7,4516 | NZD | New Zealand dollar | 1,4401 |
| GBP | Pound sterling | 0,72550 | SGD | Singapore dollar | 1,4938 |
| SEK | Swedish krona | 9,3006 | KRW | South Korean won | 1 207,96 |
| CHF | Swiss franc | 1,0552 | ZAR | South African rand | 13,0627 |
| ISK | Iceland króna | | CNY | Chinese yuan renminbi | 6,6864 |
| NOK | Norwegian krone | 8,7125 | HRK | Croatian kuna | 7,6405 |
| BGN | Bulgarian lev | 1,9558 | IDR | Indonesian rupiah | 14 074,33 |
| CZK | Czech koruna | 27,479 | MYR | Malaysian ringgit | 4,0199 |
| HUF | Hungarian forint | 303,86 | PHP | Philippine peso | 48,439 |
| PLN | Polish zloty | 4,1272 | RUB | Russian rouble | 64,9276 |
| RON | Romanian leu | 4,4327 | THB | Thai baht | 35,227 |
| TRY | Turkish lira | 2,7882 | BRL | Brazilian real | 3,5220 |
| AUD | Australian dollar | 1,3988 | MXN | Mexican peso | 16,2650 |
| | | | INR | Indian rupee | 67,1690 |

⁽¹⁾ Source: reference exchange rate published by the ECB.

COMMISSION DECISION
of 20 March 2015
appointing two Commission representatives and two alternates to the Management Board of the
European Medicines Agency
(2015/C 95/09)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ⁽¹⁾, and in particular Article 65(3) thereof,

Whereas:

- (1) In 2010, Commission Decision of 14 December 2010 appointing two Commission representatives and two alternates to the Management Board of the European Medicines Agency ⁽²⁾ appointed two Commission representatives and two alternates to the Management Board of the European Medicine Agency (hereinafter 'the Agency').
- (2) Due to changes in the organisation chart of the Commission, it is necessary to adopt a new decision, replacing Commission Decision of 14 December 2010 and appointing two Commission representatives and two alternates to the Management Board of the European Medicines Agency,

HAS DECIDED AS FOLLOWS:

Article 1

The representatives of the Commission to the Management Board of the European Medicines Agency shall be the persons occupying the following positions and exercising the following functions:

- (1) from the Directorate-General for Health and Food Safety:
 - (a) as member, the Director-General of the Directorate-General for Health and Food Safety;
 - (b) as alternate, the Director heading the Directorate which is responsible for medicinal products, within the remit of responsibilities assigned to the Directorate-General for Health and Food Safety;
- (2) from the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs:
 - (a) as member, the Director heading the Directorate which is responsible for medicinal products, within the remit of responsibilities assigned to the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs;
 - (b) as alternate, the Head of Unit heading the Unit which is responsible for medicinal products, within the remit of responsibilities assigned to the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.

Article 2

This Decision shall apply to the persons occupying, including on a temporary basis, the positions referred to in Article 1 at the date of adoption of this Decision, or to any successor of those persons in those positions.

Article 3

The Director-Generals of the Directorate-General for Health and Food Safety and the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs shall inform the Chair of the Management Board and the Executive Director of the Agency of the names of the persons occupying the positions referred to in Article 1, and any changes thereof.

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

⁽²⁾ OJ C 340, 15.12.2010, p. 17.

Article 4

Commission Decision of 14 December 2010 appointing two Commission representatives and two alternates to the Management Board of the European Medicines Agency is repealed.

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 March 2015.

For the Commission

Vytėnis ANDRIUKAITIS

Member of the Commission

EUROPEAN INVESTMENT FUND

STATUTES OF THE EUROPEAN INVESTMENT FUND

approved 14 June 1994 and amended 19 June 2000, 30 November 2007, 8 March 2012 and 27 May 2014 by the General Meeting

(2015/C 95/10)

Article 1

Establishment

A European Investment Fund, hereinafter called the 'Fund', is hereby established with legal personality and financial autonomy.

Article 2

Task and Activities

1. The task of the Fund shall be to contribute to the pursuit of the objectives of the European Union.

The Fund shall pursue this task through activities consisting of:

- the provision of guarantees as well as of other comparable instruments for loans and other financial obligations in whatever form is legally permissible,
- the acquisition, holding, managing and disposal of participations in any enterprise subject to the conditions laid down in paragraph 2(i) of Article 12 of these Statutes.

2. In addition, the Fund may engage in other activities connected with or resulting from the tasks set out in this Article. The activities of the Fund may include borrowing operations.

3. The activities of the Fund shall be based on sound banking principles or other sound commercial principles and practices as applicable. Without prejudice to the provisions of Article 28, the said activities shall be pursued in close cooperation between the Fund and its founder members or between the Fund and its actual members at the relevant time, as the case may be.

Article 3

Seat

The seat of the Fund shall be in Luxembourg.

Article 4

Members

1. The founder members of the Fund shall be:

- the European Union, hereinafter called the 'Union', represented by the European Commission, hereinafter called the 'Commission',
- the European Investment Bank, hereinafter called the 'Bank',
- the financial institutions, the list of which is annexed to these Statutes (Annex I), hereinafter called the 'Financial Institutions'.

2. On the terms and conditions defined by the Board of Directors acting on a decision taken by the General Meeting, other legal entities from the financial sector whose business objectives support the tasks of the Fund may become members of the Fund.

*Article 5***Capital**

1. The authorised capital of the Fund shall be four billion five hundred million Euro, divided into 4 500 shares each with a nominal value of one million Euro, open to subscription by the members of the Fund in accordance with Article 6 of these Statutes.
2. The authorised capital may be increased by decision of the General Meeting acting with a majority of 85 % of the votes cast.
3. In the event of an increase in capital and subject to the conditions laid down by the General Meeting, each member shall have the option to subscribe to a fraction of the increase corresponding to the ratio which existed between the shares subscribed to by that member and the capital of the Fund before the increase.
4. The members of the Fund shall be liable for the obligations of the Fund only up to the amount of their share of the capital subscribed and not paid in.

*Article 6***Subscription of Shares**

1. The founder members of the Fund shall subscribe to the number of shares set out in Annex II to these Statutes at par value.
2. Subsequent subscription of shares shall take place on the terms laid down by the General Meeting; the price of such shares may not be less than par.

*Article 7***Shares**

1. The shares in the initial subscribed capital shall be paid in as to 20 % in four equal annual instalments.
2. In the event of a capital increase, the arrangements for payment shall be decided by the General Meeting.
3. The General Meeting, acting on a proposal from the Board of Directors, may require payment of the subscribed but not paid in capital to the extent required for the Fund to meet its liabilities towards its creditors. Such payment shall be effected within 90 days from the decision of the General Meeting.
4. Payments shall be made in Euro.
5. Except with the prior written agreement of the Board of Directors, shares may not be pledged or encumbered in any way.
6. Without prejudice to paragraph 4 of Article 5 of these Statutes, no member shall by reason of its membership incur any liability for the obligations of the Fund.
7. Any resources not required by the Fund for the pursuit of its activities under Article 2 may be invested on the financial markets. In managing these investments, the Fund shall not engage in any currency arbitrage not directly required to carry out its operations or to fulfil commitments entered into.
8. Members of the Fund may dispose of their shares by transferring them either to another member or to a third party pursuant to Article 4, paragraph 2 of these Statutes. Should a member wish to dispose of its shares, it shall offer them to the Bank or, with the latter's consent, to any other member of the Fund or to a third party satisfying the criteria of Article 4, paragraph 2 of these Statutes.

*Article 8***Rights attaching to Shares**

On the terms laid down in Articles 27 and 33 of these Statutes, each share shall confer rights in respect of ownership of the assets of the Fund, the sharing of net profit and, where appropriate, the proceeds of liquidation pro rata to the number of existing shares.

*Article 9***Management and Administration of the Fund**

The Fund shall be managed and administered by the following three authorities:

- the General Meeting,
- the Board of Directors,
- the Chief Executive.

*Article 10***General Meeting**

1. A General Meeting of members of the Fund shall be held at least once a year when convened by the Chairman of the Board of Directors. General Meetings shall be held either at the seat of the Fund or at another location specified in the notice convening such meetings.
2. General Meetings may also be convened at the request of one of the members of the Fund and following a decision of the Board of Directors. A General Meeting shall be convened if members whose shares represent 13 % or more of the subscribed capital so request, specifying the subject that is the cause of such request.
3. Decisions of the General Meeting may be taken by written procedure subject to the conditions and in accordance with the rules laid down in the Rules of Procedure.

*Article 11***Participation — Representation — Quorum — Majority**

1. All members of the Fund shall be entitled to attend General Meetings.
2. The Union shall be represented by one of the members of the Commission, or by another duly authorised individual.
3. The Bank shall be represented by its President or by a Vice-President, or by another duly authorised individual.
4. The Financial Institutions shall be represented by one individual for each Financial Institution.
5. Each member of the Fund shall have a number of votes equal to the number of shares subscribed by it.
6. The members may vote by written, including electronic, correspondence or be represented by another member.
7. The quorum required for the holding of General Meetings shall be constituted when members present or represented hold not less than 50 per cent of the subscribed capital.
8. Save as otherwise provided in these Statutes, decisions of the General Meeting shall be adopted by the majority of the votes cast.

*Article 12***Powers of the General Meeting**

1. The members of the Fund shall exercise their rights through the General Meeting.
2. The General Meeting shall:
 - (i) Take any decision authorising the Fund to conduct the operations provided for in the second indent of paragraph 1 of Article 2 of these Statutes.
 - (ii) Approve the Rules of Procedure of the Fund.
 - (iii) Decide on the admission of new members.
 - (iv) Approve the annual report submitted by the Board of Directors.
 - (v) Approve the annual balance sheet and profit and loss account.
 - (vi) Determine the appropriation and distribution of the net income of the Fund.
 - (vii) Appoint the members of the Audit Board of the Fund.

- (viii) Exercise the powers laid down in Article 34 of these Statutes for adopting any amendments of these Statutes.
 - (ix) Decide on the increase of the authorised capital of the Fund, and any calls for non-paid-in subscribed capital.
 - (x) Subject to the conditions laid down in Article 26 of these Statutes, decide on the increase of the ceiling on the commitments of the Fund.
 - (xi) Take decisions to suspend or expel members.
 - (xii) Take decisions concerning the permanent termination of the operations of the Fund and distribution of its assets.
 - (xiii) Appoint the members of the Board of Directors and any alternates to these members from the individuals designated pursuant to Article 15, paragraphs 1 and 3 of these Statutes.
 - (xiv) Compulsorily retire a member of the Board of Directors if that member is no longer able to fulfil his duties or is guilty of serious misconduct.
 - (xv) Exercise all powers conferred upon it by any other provision of these Statutes.
3. The operating procedures of the General Meeting shall be laid down in the Rules of Procedure.

Article 13

Chairmanship of the General Meeting

General Meetings shall be chaired by the representative of the member with the highest number of shares in the Fund.

Article 14

Minutes — Extracts

The proceedings of the General Meeting shall be minuted. The minutes shall be drawn up by the secretariat of the Fund and copies or extracts thereof shall be certified and issued to the members.

Article 15

Board of Directors

1. The Board of Directors shall consist of seven members appointed by the General Meeting and designated by the members of the Fund in accordance with the procedure laid down in the Rules of Procedure. The General Meeting may vary the number of members on the Board of Directors.
2. In carrying out their duties the members of the Board of Directors shall act independently and serve the best interests of the Fund. They shall be accountable only to the General Meeting. Each member of the Board of Directors may be assisted by an alternate who, in his/her absence, shall act in his/her name, attend the meetings of the Board of Directors, and be vested with the same powers as those of the member he/she is replacing.
3. The members of the Board of Directors and any alternates shall be designated in accordance with arrangements laid down in the Rules of Procedure. The Rules of Procedure may provide that a designated member shall be empowered to act as a Board member in advance of the decision on appointment by the Annual General Meeting. The rules applicable to Board members shall also apply to any such designated member.
4. Members of the Board of Directors shall be appointed for a term of two years, which shall be renewable.
5. If the annual report submitted to the General Meeting by the Board of Directors is not approved, the Board of Directors shall resign.
6. The operating procedures of the Board of Directors shall be laid down in the Rules of Procedure.

Article 16

Powers of the Board of Directors

1. In addition to the powers conferred upon it by the other provisions of these Statutes, the Board of Directors shall:
 - (i) Decide on all operations of the Fund. It may delegate the power to decide in whole or in part, as it deems appropriate.
 - (ii) Adopt guidelines and directives for the operations and the management of the Fund.

- (iii) Draw up proposals for submission to the General Meeting.
- (iv) Fix the general conditions for participations.
- (v) Set return criteria for the Fund's operations.
- (vi) Determine the objectives and the limits of the borrowing operations referred to in Article 2, paragraph 2 of these Statutes.
- (vii) On the basis of proposals made by the members of the Fund in accordance with the procedure laid down in the Rules of Procedure, appoint the Chief Executive and his/her deputy, if any. It shall also have the power to dismiss the Chief Executive and his/her deputy, if any.
- (viii) Supervise the Chief Executive and his/her deputy and ensure that the Fund is managed in accordance with the provisions of these Statutes and with the guidelines and directives laid down by the Board of Directors.
- (ix) Submit the annual accounts and the annual report on the activities of the Fund to the General Meeting.
- (x) Convene General Meetings of the Fund.
- (xi) Without prejudice to the powers of the General Meeting, take decisions on any other matters falling outside the competence of the Chief Executive.

Article 17

Chairmanship of the Board of Directors

1. The Board of Directors shall be chaired by one of its members designated in accordance with the provisions laid down in the Rules of Procedure.
2. If the Chairman is unable to attend, the Board of Directors shall be chaired by another member of the Board of Directors designated in accordance with the provisions in the Rules of Procedure.

Article 18

Board of Directors — Meetings — Quorum

1. The Board of Directors shall meet as often as required by the interests of the Fund and at least once a calendar quarter. Meetings shall be convened by the Chairman and agendas shall be drawn up in accordance with the Rules of Procedure. The Chairman shall convene a meeting of the Board of Directors if a Board member submits a reasoned request to this effect. Board meetings shall be held either at the seat of the Fund or at any other location selected by the Chairman.
2. Decisions of the Board of Directors may be taken by written procedure subject to the conditions and in accordance with the rules laid down in the Rules of Procedure.
3. The proceedings of the Board of Directors shall be valid only if not less than half of the Board members are present.
4. Decisions of the Board of Directors shall be adopted by majority vote, save in respect of any proposal referred to in paragraph 2 of Article 23, which shall be adopted by unanimous vote.

Article 19

Minutes

The proceedings of the Board of Directors shall be minuted. The minutes shall be drawn up by the secretariat of the Fund and copies or extracts thereof shall be certified and issued to the members.

Article 20

Chief Executive

1. The Fund shall be managed by a Chief Executive. He/She shall act independently and serve the best interests of the Fund and shall be accountable only to the Board of Directors in carrying out his/her duties.
2. The Chief Executive shall be appointed for a term of up to 5 years and shall be eligible for reappointment.
3. The Chief Executive may be assisted by a deputy who, in his/her absence, shall replace the Chief Executive and be vested with the same powers.

4. The procedures for making proposals for the appointment of the Chief Executive and any deputy shall be laid down in the Rules of Procedure.

Article 21

Powers of the Chief Executive

1. The Chief Executive shall be responsible for the day-to-day management of the Fund in accordance with the provisions of these Statutes and the guidelines and directives adopted by the Board of Directors.
2. The Chief Executive shall in particular:
 - Act in line with the guidelines and directives adopted by the Board of Directors in accordance with Article 16 of these Statutes.
 - Submit the annual report of the Fund to the Board of Directors.
 - Establish under his/her responsibility the annual accounts of the Fund within three months following the end of each financial year and submit them to the Board of Directors.
 - Provide the Board of Directors with such additional reports and documents as are laid down in the Rules of Procedure or as the Board of Directors may request.
3. The Chief Executive shall represent the Fund in its relations with third parties and in judicial proceedings.
4. Documents concerning the Fund and all commitments entered into on its behalf shall be signed by the Chief Executive or by a representative duly authorised by the Chief Executive.
5. The employees of the Fund shall be under the authority of the Chief Executive and shall be engaged and discharged by him/her.

Article 22

Audit

1. The accounts of the Fund shall be audited annually by an Audit Board consisting of three auditors appointed by the General Meeting. The General Meeting may decide to increase the number of auditors to a maximum of five. Nominations shall be made in accordance with the terms laid down in the Rules of Procedure.
2. The members of the Audit Board shall act in accordance with the customary standards of their profession. The Audit Board shall confirm that the balance sheet and profit and loss account of the Fund give a true and fair view of the financial position of the Fund in respect of its assets and liabilities, and of the results of its operations for the financial year under review.

Article 23

Geographical Scope

1. The Fund may conduct its activities in the territory of the Member States of the Union, in candidate and potential candidate countries to the Union, and in the European Free Trade Association (EFTA) countries.
2. By way of derogation to the foregoing paragraph, the General Meeting may, on proposal from the Board of Directors and in connection with any task entrusted to the Fund by third parties in accordance with Article 28 of these Statutes, decide that the Fund may conduct activities in connection with such entrusted task outside the territories set out in paragraph 1 of this Article.

Article 24

Remuneration of the Fund

The level of remuneration or other income sought by the Fund in connection with its activities pursuant to these Statutes shall be determined in such a way so as to reflect the risks incurred, to cover the operating expenses, to establish reserves commensurate with the said risks and to generate an appropriate return on its resources.

*Article 25***Limits on the Operations of the Fund**

With respect to the provision of guarantees, the limits on the commitments of the Fund shall be laid down by the Board of Directors in accordance with Article 16 of these Statutes.

The corresponding limits on the commitments of the Fund when acquiring participations in enterprises shall be laid down in the relevant decisions referred to in paragraph 2(i) of Article 12 of these Statutes.

*Article 26***Ceiling on the overall Commitments of the Fund**

The overall commitments of the Fund, excluding commitments made by the Fund on behalf of third parties, may not exceed:

- for guarantee operations: three times the amount of subscribed capital; this ceiling may be raised by decision of the General Meeting up to a maximum of five times the subscribed capital. If the reserves of the Fund are equal to or exceed 7,5 % of the amount of subscribed capital, this ceiling may be raised by decisions of the General Meeting up to a maximum of eight times the subscribed capital,
- for participations: the amount decided by the General Meeting pursuant to Article 12 of these Statutes.

*Article 27***Appropriation and Distribution of Net Income**

1. The General Meeting shall determine at least annually what part of the net income of the Fund shall be appropriated to reserves or to other purposes, or be distributed to the members of the Fund.

Prior to any distribution to the members of the Fund, an amount at least equal to 20 % of the net income shall be appropriated each year to reserves. Appropriation to reserves shall cease once reserves reach 10 % of subscribed capital and shall be reintroduced if the reserves fall below 10 % of subscribed capital.

2. Distributions to the members of the Fund shall be made in proportion to the number of shares held by each member.

*Article 28***Cooperation with Third Parties**

1. The Fund may accept the tasks of administering special resources entrusted to it by third parties, provided that they are compatible with its task, that they are entered in separate accounts and that they are adequately remunerated.

2. The Fund may within the terms of these Statutes cooperate with all international organisations exercising their activity in areas similar to its own.

3. The Fund may conclude agreements with such organisations as well as with national organisations and banking partners in the Member States of the Union or third countries with a view to pursuing its objectives or achieving its tasks.

*Article 29***Suspension or Expulsion of Members**

1. If a member of the Fund fails to fulfil any of its obligations hereunder, it may be suspended by decision of the General Meeting.

2. While under suspension, the member shall remain bound by its obligations as a member of the Fund; it may not however exercise any of the rights provided for in these Statutes.

3. If, after a period of six months following the decision taken by the General Meeting to suspend a member, the latter has not fulfilled its obligations having given rise to this decision, the General Meeting may declare such member expelled.

*Article 30***Settlement of Accounts with Members expelled from the Fund**

1. Termination of membership shall entail partial settlement of accounts with the member in question.
2. The shares of an expelled member shall be disposed of in accordance with the provision of Article 7, paragraph 8 of these Statutes. If the shares are not acquired by the Bank or by another member of the Fund, the General Meeting may authorise the sale thereof to entities satisfying the criteria of Article 4, paragraph 2 of these Statutes.

In the event of the shares not being repurchased by the other members or by entities satisfying the criteria of Article 4, paragraph 2 they shall be repurchased by the Fund.

3. Subject to paragraph 2 above, the Fund shall repurchase the shares of an expelled member at the lower of nominal value or book value calculated on the date on which membership of the Fund is terminated.

Notwithstanding expulsion from the Fund, the expelled member shall remain bound by its direct obligations and by its contingent liabilities to the Fund so long as any part of the guarantees or equity participations contracted prior to termination of membership is outstanding. It shall not however be bound by the obligations arising out of guarantees and equity participations entered into thereafter by the Fund and shall not share in either the income or the expenses of the Fund.

4. Payment for shares repurchased by the Fund from the expelled member shall be made on the following terms and conditions:

- no payment shall be made prior to expiry of a period of six months as from the date of termination of membership. Payment shall be limited to the amount by which the repurchase price exceeds the sum of liabilities towards the Fund on the part of the former member arising out of the operations of the Fund,
- if losses are sustained by the Fund on any guarantees or equity participations of the Fund which were outstanding on the date of termination of membership and the amount of such losses exceeds the amount of the provisions against losses on the date of termination of membership, such former member shall repay, upon demand from the Fund, the amount by which the repurchase price of its shares would have been reduced if the losses had been taken into account when the repurchase price was determined. In addition, the former member shall remain bound to respond to any call for non-paid-in subscriptions to the extent that it would have been required to respond if the impairment of capital of the Fund had occurred and the call been made at the time the repurchase price of its shares was determined.

*Article 31***Termination of Operations**

1. The Board of Directors may, if circumstances so require, temporarily suspend the operations of the Fund. It shall refer this decision to the General Meeting for further consideration. The General Meeting, acting with a qualified majority of 85 % of the votes cast, may decide to terminate permanently the operations of the Fund, which shall then cease all its activities apart from those relating to liquidation of the Fund.
2. Permanent cessation of the operations of the Fund shall entail its liquidation. The General Meeting shall appoint the liquidators who shall undertake the operations required by the liquidation.

*Article 32***Liability of the Members of the Fund**

1. In the event of permanent cessation of the operations of the Fund, outstanding claims on the Fund shall be settled by means of the following resources in the order given below:
 - assets of the Fund,
 - sums owed to the Fund in respect of capital subscribed but not paid in.

2. The Board of Directors shall take appropriate measures to ensure apportionment between the holders of direct claims and the holders of contingent claims pro rata according to their respective legal rights.

Article 33

Distribution of Assets

1. In the event of cessation of the activities of the Fund, the assets shall not be distributed among its members on account of their subscription to the capital of the Fund until:

- all liabilities to creditors of the Fund have been fully discharged,
- the General Meeting has decided to make a distribution of assets.

2. The assets shall be distributed between the members of the Fund in proportion to each member's contribution to the capital of the Fund.

3. The Board of Directors shall lay down procedures for this distribution.

Article 34

Amendments

1. These Statutes can be amended by decision of the General Meeting on proposal by the Board of Directors. Any changes to Articles 2 and 3 of these Statutes shall require a majority of 85 % of the votes cast.

2. Unless the General Meeting decides otherwise, approved amendments shall take effect three months following the date on which these amendments have been notified to the members of the Fund.

Article 35

Law and Jurisdiction

1. Disputes between the Fund on the one hand, and the beneficiaries of its operations on the other, whether Financial Institutions in their capacity as beneficiaries or other beneficiaries, shall be decided by the competent national courts.

2. To this end, the Fund shall have an address for service in each Member State of the Union. It may, however, in any contract, specify a particular address for service or provide for arbitration.

3. As provided for and within the limits laid down in the Treaty on the Functioning of the European Union ⁽¹⁾ (Article 28(5) of the Statute of the Bank), disputes concerning measures adopted by the organs of the Fund shall be subject to the jurisdiction of the Court of Justice of the European Union.

Article 36

Privileges and Immunities

The Protocol on the Privileges and Immunities of the European Union shall also apply to the Fund, to the members of its organs and to its staff on the terms and conditions laid down in the Treaty on the functioning of the European Union ⁽¹⁾ (Article 28(4) of the Statute of the Bank).

Article 37

Entry into Force

The present Statutes shall enter into force on the date to be determined by the General Meeting.

⁽¹⁾ Formerly known as the Treaty establishing the European Community.

ANNEX I

Financial Institutions — Founder Members of the Fund

(Article 4, paragraph 1 of the Statutes)

Annexes I and II and information about the current shareholding of the European Investment Fund are available on the website: www.eif.org

ANNEX II

Initial Subscriptions of Shares in the Authorised Capital

(Article 6, paragraph 1 of the Statutes)

Annexes I and II and information about the current shareholding of the European Investment Fund are available on the website: www.eif.org

V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION
POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case M.7526 — G.L. Swarovski/Bilfinger/ProfiCare)

Candidate case for simplified procedure

(Text with EEA relevance)

(2015/C 95/11)

1. On 16 March 2015, the Commission received a notification of a proposed concentration pursuant to Article 4 and following a referral pursuant to Article 4(5) of Council Regulation (EC) No 139/2004 ⁽¹⁾ by which CareInvest GmbH, indirectly controlled by Gernot Langes Swarovski (G.L. Swarovski, Austria) and Bilfinger Ahr Healthcare and Services GmbH, belonging to the group Bilfinger SE ('Bilfinger', Germany) acquire within the meaning of Article 3(1)(b) and Article 3(4) of the Merger Regulation joint control over ProfiCare GbR (Germany) by way of purchase of shares in a newly created company constituting a joint venture.

2. The business activities of the undertakings concerned are:

- for G.L. Swarovski: the sale and worldwide distribution of goods, including disposable tableware and service packaging, packaging materials, hygiene products, tabletop, household aid, decorative items and accessories as well as paper articles; consultancy in biological agriculture, hotel construction and operation of ski lifts,
- for Bilfinger: the provision of catering, cleaning and other services such as facility management and patient services, to hospitals or nursing care facilities; development, maintenance and operation of plants and buildings for the industry, the energy sector and real estate,
- for ProfiCare: distribution of single use medical and care products of all kind to hospitals, nursing care facilities and private individuals.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under the Council Regulation (EC) No 139/2004 ⁽²⁾ it should be noted that this case is a candidate for treatment under the procedure set out in this Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax (+32 22964301), by e-mail to COMP-MERGER-REGISTRY@ec.europa.eu or by post, under reference number M.7526 — G.L. Swarovski/Bilfinger/ProfiCare, to the following address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

⁽²⁾ OJ C 366, 14.12.2013, p. 5.

OTHER ACTS

EUROPEAN COMMISSION

Notice for the attention of Angga Dimas Pershada, Bambang Sukirno, Wiji Joko Santoso and Hilal Ahmar Society Indonesia (HASI) who were added to the list referred to in Articles 2, 3 and 7 of Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network, by virtue of Commission Regulation (EU) 2015/480

(2015/C 95/12)

1. Common Position 2002/402/CFSP⁽¹⁾ calls upon the Union to freeze the funds and economic resources of the members of the Al-Qaida organisation and other individuals, groups, undertakings and entities associated with them, as referred to in the list drawn up pursuant to UNSCR 1267(1999) and 1333(2000) to be updated regularly by the UN Committee established pursuant to UNSCR 1267(1999).

The list drawn up by this UN Committee comprises:

- Al Qaida,
- natural or legal persons, entities, bodies and groups associated with Al Qaida, and
- legal persons, entities and bodies owned or controlled by, or otherwise supporting, any of these associated persons, entities, bodies and groups.

Acts or activities indicating that an individual, group, undertaking, or entity is 'associated with' Al-Qaida include:

- (a) participating in the financing, planning, facilitating, preparing, or perpetrating of acts or activities by, in conjunction with, under the name of, on behalf of, or in support of Al Qaida, or any cell, affiliate, splinter group or derivative thereof;
- (b) supplying, selling or transferring arms and related materiel to any of them;
- (c) recruiting for any of them; or
- (d) otherwise supporting acts or activities of any of them.

2. The UN Security Council approved on 13 March 2015 the addition of Angga Dimas Pershada, Bambang Sukirno, Wiji Joko Santoso and Hilal Ahmar Society Indonesia (HASI) to the Al-Qaida Sanctions Committee's list.

They may submit at any time a request to the UN Ombudsperson, together with any supporting documentation, for the decision to include them in the UN list referred to above, to be reconsidered. Such request should be sent to the following address:

United Nations — Office of the Ombudsperson
Room TB-08041D
New York, NY 10017
UNITED STATES OF AMERICA

Tel. +1 2129632671
Fax +1 2129631300/3778
E-mail: ombudsperson@un.org

See for more information at <http://www.un.org/sc/committees/1267/delisting.shtml>

⁽¹⁾ OJ L 139, 29.5.2002, p. 4.

3. Further to the UN decision referred to in paragraph 2, the Commission has adopted Regulation (EU) 2015/480 ⁽¹⁾, which amends Annex I to Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network ⁽²⁾. The amendment, made pursuant to Article 7(1)(a) and Article 7a(1) of Regulation (EC) No 881/2002, adds Angga Dimas Pershada, Bambang Sukirno, Wiji Joko Santoso and Hilal Ahmar Society Indonesia (HASI) to the list in Annex I to that Regulation ('Annex I').

The following measures of Regulation (EC) No 881/2002 apply to the individuals and entities included in Annex I:

- (1) the freezing of all funds and economic resources belonging to the individuals and entities concerned, or owned or held by them, and the prohibition (on everyone) on making funds and economic resources available to any of the individuals and entities concerned or for their benefit, whether directly or indirectly (Articles 2 and 2a); and
- (2) the prohibition on granting, selling, supplying or transferring technical advice, assistance or training related to military activities to any of the individuals and entities concerned, whether directly or indirectly (Article 3).

4. Article 7a of Regulation (EC) No 881/2002 provides for a review process where observations on the grounds for listing are submitted by those listed. Individuals and entities added to Annex I by Regulation (EU) 2015/480 may make a request for the grounds for their listing to the Commission. This request should be sent to:

European Commission
'Restrictive measures'
Rue de la Loi/Wetstraat 200
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

5. The attention of the individuals and entities concerned is also drawn to the possibility of challenging Regulation (EU) 2015/480 before the General Court of the European Union, in accordance with the conditions laid down in the fourth and sixth paragraphs of Article 263 of the Treaty on the Functioning of the European Union.

6. For good order, the attention of the individuals and entities included in Annex I is drawn to the possibility of making an application to the competent authorities in the relevant Member State(s), as listed in Annex II to Regulation (EC) No 881/2002, in order to obtain an authorisation to use frozen funds and economic resources for essential needs or specific payments in accordance with Article 2a of that Regulation.

⁽¹⁾ OJ L 77, 21.3.2015, p. 1.

⁽²⁾ OJ L 139, 29.5.2002, p. 9.

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