(To be filled out in the EDPS' office)
REGISTER NUMBER: 1334

(To be filled out in the EDPS' office)

NOTIFICATION FOR PRIOR CHECKING

DATE OF SUBMISSION: 30/09/2015

CASE NUMBER: 2015-0820

INSTITUTION: EUROPEAN MEDICINES AGENCY

LEGAL BASIS: ARTICLE 27-5 OF THE REGULATION CE N° 45/2001([1])

INFORMATION TO BE GIVEN[2]

1/ NAME AND ADDRESS OF THE CONTROLLER

Andreas Pott, Deputy Executive Director
European Medicines Agency
30 Churchill Place Canary Wharf
E14 5EU London
United Kingdom

2/ ORGANISATIONAL PARTS OF THE INSTITUTION OR BODY ENTRUSTED WITH THE PROCESSING OF PERSONAL DATA

Anti-Fraud Office

3/ NAME OF THE PROCESSING

Procedure for reporting potential fraud and irregularities

4/ PURPOSE OR PURPOSES OF THE PROCESSING

The purpose of the processing of the personal data is the processing by the Anti-Fraud Office of reported information regarding irregularities and potential fraud cases that are brought to its attention by way of reported information (internal or external whistle-blowing) or that have reached it by other means. This process will allow gathering information on the reported conducts, in order to assess and identify which cases require to be transmitted to OLAF according to Article 8 of Regulation (EU, Euratom) No. 883/2013.

[1] OJ L 8, 12.01.2001.

[2] **Please attach all necessary backup documents**

5/ DESCRIPTION OF THE CATEGORY OR CATEGORIES OF DATA SUBJECTS

The data subjects are the Agency's staff members, interims, trainees, delegates and on-site contractors and every person mentioned in the fraud reporting process. This person can be either a EU national or a non-EU national.

6/ DESCRIPTION OF THE DATA OR CATEGORIES OF DATA
(including, if applicable, special categories of data (Article 10) and/or origin of data)

It is not possible to establish ex ante the categories of data that could be the subject matter of potential fraud or irregularities reported to the EMA.
The personal information processed are contained in the reporting form and may include the name and surname of the person involved in the potential fraud, his/her relation to the alleged fraudster (e.g. family member) as well as data on the nature of the facts potentially constituting fraud.
The data processed may imply also the data of third parties (e.g. if the facts came to the attention of the reporting person through a letter sent by a third person, the Anti-Fraud Office may need to process the data contained in this letter).

7/ INFORMATION TO BE GIVEN TO DATA SUBJECTS

A Data Protection Notice will be part of the reporting template published on the website. (Annex II). A Data Protection Notice will be also published on the section of the EMA's website presenting the activities of the Anti-Fraud Office and making available information about reporting alleged frauds or irregularities.
Information regarding the rights of the data subjects (access, rectifications, etc.) and the procedures to exercise them will also be inserted.
Information is also included regarding within which time limit a reaction can be expected from the Anti-Fraud Office.
The persons reporting the potential case of fraud and the persons involved in the case will be informed and regularly updated about the progress of the proceedings. Please note that the provision of certain information to some data subjects (e.g. the suspected fraudster) may be delayed in order not to jeopardise the proceedings and possible future OLAF investigation in accordance with Article 20 of Regulation (EC) 45/2001.

8/ PROCEDURES TO GRANT RIGHTS OF DATA SUBJECTS
(Rights of access, to rectify, to block, to erase, to object)

In accordance with general data protection notice

9/ AUTOMATED / MANUAL PROCESSING OPERATION

Automated/Manual

10/ STORAGE MEDIA OF DATA

The data will be reported either through the use of electronic communications or through the use of a paper copy of the form for reporting fraud and irregularities. (Annex II). Reports received in paper copies will be also scanned and stored in the secure database.

11/ LEGAL BASIS AND LAWFULNESS OF THE PROCESSING OPERATION

- Article 8 of Regulation (EU, Euratom) No. 883/2013: "The institutions, bodies, offices and agencies shall transmit to the Office [OLAF] without delay any information relating to possible cases of fraud, corruption or any other illegal activity affecting the financial interests of the Union".

- Article 48 of the Financial Regulations applicable to the budget of the European Medicines Agency (document EMA/MB/789566/2013) - based on the Commission Delegated Regulation No 1271/2013 of 30.09.2013 on the framework financial regulation for the bodies referred to in Article 208 of Council Regulation (EU, Euratom) No 966/2012 - in particular its paragraph 2: "In the event of any illegal activity, fraud or corruption which may harm the interests of the Union, the member of staff shall inform the authorities and bodies designated by the applicable legislation. Contracts with external auditors carrying out audits of the financial management of the Agency shall provide for an obligation of the external auditor to inform the authorising officer of any suspected illegal activity, fraud or corruption which may harm the interests of the Union".

- European Medicines Agency's Anti-Fraud Strategy (EMA/591051/2014) and related Action Plan - adopted by the Management Board on the 18th December 2014 -, in particular its Objective No. 2 ('Develop fraud prevention, detection, reporting and handling capacity'). (Annex I)

12/ THE RECIPIENTS OR CATEGORIES OF RECIPIENT TO WHOM THE DATA MIGHT BE DISCLOSED

In accordance with the obligation set out by Reg. (EU, Euratom) No. 883/2013 to inform OLAF without delay, the recipients of the processed data might be OLAF's staff members. Moreover, in the initial phase of internal assessment of the reported information, the data can be communicated to HR or Audit or the relevant Head of Division, and the Executive Director if there is a need to involve OLAF.
The identity of the subjects involved will be treated in confidence.

13/ RETENTION POLICY OF (CATEGORIES OF) PERSONAL DATA

With regards to cases which will not be notified to OLAF and for which no further action is needed, the retention period of data will be 3 years.

With regards to cases which are notified to OLAF, the EMA will align its conservation periods with those of OLAF (15, 8 or 5 years after case closure, as described in Article 13(2) of the OLAF Instructions to Staff on Data Protection for Investigative Activities).

Improper and pointless messages will be deleted immediately.

13 A/ TIME LIMIT TO BLOCK/ERASE ON JUSTIFIED LEGITIMATE REQUEST FROM THE DATA SUBJECTS *(Please, specify the time limits for every category, if applicable)*

In line with general policy on processing of data at the EMA – 15 working days

14/ HISTORICAL, STATISTICAL OR SCIENTIFIC PURPOSES
(*If you store data for longer periods than mentioned above, please specify, if applicable, why the data must be kept under a form which permits identification)*

Only statistical and fully anonymous information concerning the activities (number of cases) of the Anti-Fraud Office will be processed for longer periods.

15/ PROPOSED TRANSFERS OF DATA TO THIRD COUNTRIES OR INTERNATIONAL ORGANISATIONS

N/A

16/ THE PROCESSING OPERATION PRESENTS SPECIFIC RISK WHICH JUSTIFIES PRIOR CHECKING *(Please describe)*

AS FORESEEN IN:

☒ Article 27.2.(a)
(Processing of data relating to health and to suspected offences, offences, criminal convictions or security measures,)

☒ Article 27.2.(b)
(Processing operations intended to evaluate personal aspects relating to the data subject,)

☐ Article 27.2.(c)
(Processing operations allowing linkages not provided for pursuant to national or Community legislation between data processed for different purposes,)

☐ Article 27.2.(d)
(Processing operations for the purpose of excluding individuals from a right, benefit or contract)

☐ Other (general concept in Article 27.1)

17/ COMMENTS

In 2012 the Common Approach on EU decentralised agencies of the European Commission, the Council of EU and European Parliament (Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies, available here: http://europa.eu/agencies/documents/joint_statement_and_common_approach_2012_en.pdf) required a set of anti-fraud measures to be put in place by 2015, with the aim of improving the prevention and detection of fraud within the EU agencies. This has been the trigger for the

adoption of the EMA's Anti-Fraud Strategy, adopted by the Management Board on the 18/12/2014 together with its Action Plan.

In line with Article 1, para. 2 of Regulation (EU, Euratom) No. 883/2013 ("The Office shall contribute to the design and development of methods of preventing and combating fraud, corruption or any other illegal activity affecting the financial interests of the Union"), the European Anti-Fraud Office (OLAF) has developed a "Methodology and guidance for anti-fraud strategies for EU decentralised agencies" (Ref. Ares(2013)3560341, 25.11.2013), which has served as a guidance for the elaboration of the EMA's Anti-Fraud Strategy and Action Plan.

PLACE AND DATE: LONDON, 30/09/2015

DATA PROTECTION OFFICER: ALESSANDRO SPINA

INSTITUTION OR BODY: EUROPEAN MEDICINES AGENCY