Note on the consultation 46(d) by the Data Protection Officer (DPO) of the European Medicines Agency (EMA) on the role of the Agency in the processing of personal data for the clinical study in the frame of the research project PROTECT (case 2010-0818)

In response to the request for consultation from the DPO of the EMA, and on the basis of available information, we are providing herewith elements of guidance on how to ensure that the activities carried out by the EMA in the context of the clinical study for the research project PROTECT are in compliance with Regulation (EC) No 45/2001 ("the Regulation").

1. Description of the clinical study undertaken in the frame of PROTECT

1.1. PROTECT: a European research project carried out by a public/private partnership

The EMA is taking part in a European-wide research project entitled "*Phar macoepidemiological Research on Outcomes of Therapeutics in a European ConsorTium*", Grant Agreement Number 115004 (hereinafter "PROTECT"). The project is divided into several work packages; Work Package 4 (WP4) provides for the elaboration of a clinical study ("the Study"), which is the subject of this consultation.

PROTECT is carried out by a consortium funded by the IMI-Joint Undertaking[1], whose members include the EMA as well as academic and research institutions, national regulatory authorities responsible for public health, patient organisations, private partners and the pharmaceutical industry. The 29 members of the consortium have entered into an agreement governing their collaboration and setting out their roles and responsibilities. The EMA is acting as coordinator of the consortium; it contributes to the project by providing advice on technical and scientific issues.

The decision making in relation to the overall management of the project is the responsibility of a Steering Committee that is composed of 16 consortium members, the EMA representative being one of them. The Steering Committee adopts the work programme of the work packages in PROTECT and decides on technical roadmaps. Normally it adopts decisions on a higher level than the implementation of practical issues related with the conduct of the research activities which are within the remit of the single work package. The WP4, in the frame of which the Study is carried, is composed of 12 members of the consortium; those include the EMA.

[1] The IMI-Joint Undertaking was established by Council Regulation 73/2008.

1.2. The purpose of the Study: evaluating a novel method of data collection

The WP4 provides for the elaboration of a study for purpose of determining how to improve the collection of information on medication use and other risk factors during pregnancy. According to the description of WP4, this study is carried out to pilot the methodology for potential use in future rigorous studies evaluating drug safety in pregnancy and assess its suitability as a novel method of data collection in populations where existing methods are sub-optimal or subject to bias.

1.3. The point of departure for the Study: the collection of personal data

The completion of WP4 involves carrying out a field study based on interviews made with voluntary participants recruited at the site of different universities in the following European countries: Denmark, the Netherlands, Poland and the UK. The data will be collected directly from pregnant women on a periodic basis at least once a month, through the Internet or on telephone.

The data collected will include information about lifestyle (including alcohol consumption, smoking and the use of adverse drugs), medical history and what medicines the person takes. In Denmark and the UK, it will be possible to match the information collected about medication to that obtained from health records or pharmacy dispensing data. Linkage is possible through unique patient identifiers.

The data processing was entrusted by the consortium to Outcome Europe Ltd. (hereafter "Outcome"), a company incorporated in the UK which is also part of the consortium, on the basis of protocols and other documents adopted by the consortium.

According to the DPO of the EMA, members of the consortium will only receive from Outcome aggregated and fully anonymised scientific data. Members of the consortium including the EMA will have no further or direct access to the database managed by Outcome. The DPO also indicated that the EMA will not be substantially in a position to enable data subjects to make use of the rights under Articles 11 and 12 of the Regulation.

2. Legal issues raised in respect of the activities undertaken by the EMA in the elaboration of data within the Study for the research project PROTECT

A question has been raised as to whether the Agency could be considered as a "joint controller" together with all other participants of the consortium and whether the processing of personal data for the Study in WP4 would fall under the scope of the Regulation. If so, the EMA would prepare a prior check notification to the EDPS pursuant to Article 27(2)(a) of the Regulation.

In this respect, the EMA indicated that the agreement entered into between the members of the consortium does not contain any specific clause regarding the processing of personal data and their respective obligations *vis à vis* such data processing. Clause 4.6 of the agreement only provides that *"The Participants shall perform their obligations and exercise their rights [...] in accordance with all applicable laws and regulations*".

The EDPS was therefore consulted by the EMA on the scope of its obligations under the Regulation with respect to the activities it carries out for the elaboration of data for the Study within the WP4 of PROTECT.

The EDPS underlines that the legal assessment conducted below is limited to the role of the EMA in respect of the Study carried out in WP4 of PROTECT, considering the nature of the Study which deals with sensitive medical information. Therefore, this assessment does not apply to other activities of the consortium.

2.1. Allocation of responsibilities

As a starting point, it must be ascertained whether the EMA is a controller of the data processing performed for the Study in order to determine whether Regulation (EC) No 45/2001 is applicable to the activities it undertakes in relation to the Study.

The approach taken should be pragmatic and practical rather than theoretic and dogmatic. In this perspective, useful guidance can be found in the Article 29 Data Protection Working Party Opinion 1/2010[2] on the concepts of "controller" and "processor". According to the opinion, the concept of controller is "intended to allocate responsibilities where the factual influence is, and thus based on a factual rather than a formal analysis"[3].

According to the DPO of the EMA, it is the Steering Committee who decides on the purposes and means of the data processing activity necessary for the development of the Study; the EMA is part of this Steering Committee. The EDPS believes that **the notion of controller of the processing of personal data carried out for the Study shall be considered with regard to the consortium as a whole, for the following reasons**:

First, the fact that the members of the consortium have delegated the decision making to the Steering Committee does not mean that they do not remain responsible for these decisions. As part of the consortium, all members have agreed to share all responsibilities by virtue of the agreement they have entered into for purpose of conducting the research project PROTECT. Furthermore, all consortium members have an interest in the result of the Study, which is one of the elements of the research project PROTECT; the consortium was created for the specific purpose of carrying out the research project PROTECT and its very existence will terminate at the end of the project. It appears that the Steering Committee acts without specific autonomy and that it only takes decision on behalf of the consortium. As a consequence, it seems that these are the members of the consortium who decide with respect to the Study and not the specific persons taking part in the Steering Committee. Consequently, it can be considered that all the members of the consortium co-decide in respect of the conduct of the Study.

As member of the consortium, the EMA shall be considered as a (one of the) controller(s) of the personal data processing undertaken for the Study. The EDPS cannot draw conclusions as concerns the responsibilities of the other members of the

[2] Article 29 Data Protection Working Party Opinion 1/2010 on the concepts of "controller" and "processor", adopted on 16 February 2010.
[3] See page 9.

consortium -and, eventually, of the consortium as a whole- and the degree in which they are controlling each or jointly the processing, as we do not have sufficient factual elements to conduct such assessment.

The fact that the EMA will not be in a position to enable data subjects to exercise their rights directly does not alter this conclusion in this case, since it is for the controller(s) to define the modalities of the exercise of the rights by data subjects - in this case this will be done through another controller, Outcome. The EDPS further notes that the information notice distributed to participants in the Study is done on behalf of an EU-wide research project; thus it is the project as a whole that is made visible to the data subjects and not a single actor.

As concerns the role and responsibilities of Outcome, although it was entrusted by the consortium the performance of the personal data processing, it cannot be considered as acting simply as a processor since it is also taking part in the decision making process as a member of the consortium and in the Steering Committee. **Outcome must therefore be considered as a principal controller of the processing amongst other controllers** since it should be the only member of the consortium that is actually processing personal data.

Recommendation: Responsibilities should be clearly set out in writing

Given the number of controllers, it is most important to ensure that the responsibility for data processing is clearly defined and can be applied effectively. The EDPS therefore recommends that the controllers define in writing the responsibilities incumbent on each of them as concerns data protection.

Considering that the EMA is one of the controllers, the agreement should specifically require that the processing of personal data for the Study is also carried out in accordance with Regulation (EC) No 45/2001 (the "Regulation"), which contains similar data protection principles as those established in Directive 95/46/EC. The agreement should lay down the respective responsibilities of the controllers; it may distinguish between several levels of responsibility taking into account the involvement of controllers with personal data.

In this perspective, Outcome -as the only controller that should be collecting and processing personal data- should bear specific responsibilities with respect to the proper handling of personal data. In particular, Outcome should be required to comply with applicable data protection laws for the collection and processing of personal data[4].

As one of the controllers, and to ensure that it satisfies its obligations under the Regulation, the EMA should notably require that Outcome:

- provides data subjects with appropriate notice at the moment of collection (in order to satisfy Articles 11 and 12 of the Regulation);

[4] Amongst those obligations, Outcome should notify the data processing it carries out to the competent data protection authority, in accordance with Directive 95/46/EC and applicable data protection law.

- obtains data subjects express informed consent to the processing of their medical data (Article 10 of the Regulation) and, where applicable, to their data matching (Article 5(d) of the Regulation);
- only processes the data for the specified, explicit and legitimate purpose of the Study (Article 4(1)(b) of the Regulation);
- keeps personal data confidential, does not disclose them to unauthorised recipients, and adequately secures them at all times of the processing - considering that a higher level of security is required as concerns medical data (Articles 21 and 22 of the Regulation);
- enables data subjects to effectively exercise their rights (Articles 13 to 18 of the Regulation);
- destroys personal data at the end of the agreed retention period (in order to satisfy Article 4(1)(e) of the Regulation);
- fully anonymises the data before transferring them to other participants in the Study (see further section 2.2. below);
- shall be primarily responsible for carrying out the said tasks and shall be liable to pay damages to the EMA in case of failure to comply with any of these obligations. The EDPS however underlines that as one of the controllers, the EMA will remain liable in case of damage or misprocessing.

As concerns the general responsibility of the EMA as a controller, it appears that it would remain responsible -jointly or solely as the case may be- for at least the following aspects of the personal data processing:

- lawfulness of the processing (Article 5 of the Regulation);
- definition of the purposes of the processing and of the types of personal data to be collected (Articles 4(1)(b) and (c) of the Regulation);
- lawfulness of the data matching: it should be assessed whether (i) the data matching is necessary and proportionate to the purpose of the processing (Article 4(1)(c) of the Regulation), (ii) the further processing of the data is not incompatible with the original purpose of collection (Article 4(1)(b) of the Regulation), and (iii) there is a valid legal basis for the processing, in this case consent (Article 5(d) of the Regulation);
- setting up appropriate retention periods for the storage of personal data by Outcome (Article 4(1)(e) of the Regulation);
- deciding who may be recipients of personal data, in compliance with Articles 7 and 8 of the Regulation, as well as determining how data subjects may exercise their rights in accordance with Articles 13 to 18 of the Regulation;
- if applicable, notifying the data processing to the competent data protection authority pursuant to Article 27 of the Regulation.

2.2. The obligations of the EMA in respect of its own activities in the elaboration of data for the Study

The EMA claims that it only receives from Outcome aggregated and fully anonymised scientific data. When considering anonymity from a data protection point of view, account should also be taken of the interpretation of the Article 29 Working

Party in its opinion on the concept of personal data[5]. In its view, based on Directive 95/46/EC, "a*nonymised data would therefore be anonymous data that previously referred to an identifiable person, but where that identification is no longer possible."*[6] As pointed out by the Article 29 Working Party, there are cases where *"despite the fact that the information may be presented as aggregated data, the original sample is not sufficiently large and other pieces of information may enable the identification of individuals"*[7].

Furthermore, in accordance with recital 8 of the Regulation, in order to determine whether a person is identifiable *"account should be taken of all the means likely to be reasonably used either by the controller or by any other person to identify the said person*". In this case, it must be particularly taken into account that one of the controllers, Outcome, has means to identify the person to whom the information relates. Therefore, the data processed in the context of the Study will remain identifiable, through Outcome.

For data to be truly anonymised, controllers should ensure that Outcome cannot re-identify data subjects once the data have been transferred to the members of the consortium for purpose of the Study. In this case, re-identification of data subjects after the data have been passed on to the members of the consortium should be excluded since there is no therapeutical aspect involved, the research project aiming at assessing a methodology for the collection of data. To this end, controllers, and in particular the EMA, should require Outcome to put in place appropriate legal, technical and organisational measures to prevent Study data from being related to an identified or identifiable individual. This would notably require Outcome to apply strict personal data retention periods in order to have personal data deleted before data are communicated to members of the consortium.

However, even if the EMA were not itself processing data relating to identified or identifiable individuals, this would not alter the conclusion that the EMA is one of the controllers of the initial personal data processing taking place in the context of the Study. As described in section 2.1. above, as a controller who, together with others, determines the purposes and means of the processing, the EMA bears certain responsibilities under the Regulation in respect of the personal data processing that will be carried out for the Study.

Amongst others, as controller, the EMA is required pursuant to Article 27 of the Regulation to submit to the EDPS a notification of processing operations that present specific risks to the rights and freedoms of data subjects. Article 27(2(a) specifies that data relating to health fall within this category. Since the data processing carried out by the EMA for the Study relates to health data, it is therefore subject to prior checking.

In view of the above, the EDPS therefore concludes that the processing operations carried out by the EMA for the Study qualify for prior checking under Article 27(2)(a) of the Regulation.

[5] See Opinion 4/2007 of the Article 29 Data Protection Working Party on the concept of personal data, adopted on 20 June 2007.
[6] See Opinion 4/2007, page 21.
[7] See footnote 6.

The EDPS therefore invites the EMA to notify the personal data processing undertaken for the Study to the EDPS for prior checking without delay, taking into account all the recommendations made herein.

Done at Brussels, on 21 March 2011

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