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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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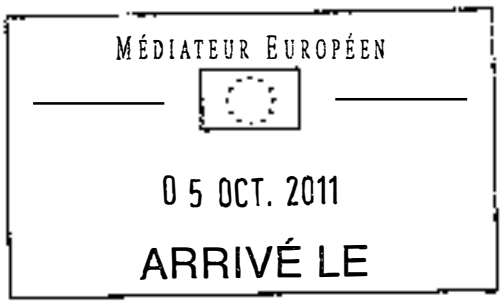

30 September 2011
EMA/705658/2011
Acting Executive Director

Dear Mr Diamandouros

Follow-up to visit to European Medicines Agency 2 May 2011

Thank you for your visit to the Agency on 2 May 2011 and for sharing with us your thoughts and suggestions on how to further promote transparency and enhance communication with the public.

The Agency welcomes your initiative to raise awareness on the value of openness amongst the European agencies and I take this opportunity to reassure you that the Agency is strongly committed to adhere to the transparency principles as most recently enshrined in the Lisbon Treaty.

Further to your visit, you wrote to me on 31 May 2011 and I am pleased to provide you with the following responses to your findings and suggestions. For ease of reference I have followed the numbering of points as set out in your letter.

A. Making information and documents available to the public proactively, as well as responding correctly to requests

(a) Cooperation with national competent authorities on issues of transparency

Since you visited the Agency in May, we have moved forward in fostering cooperation between the European Medicines Agency and the national competent authorities (NCAs) of the Member States by organising additional joint meetings to promote further harmonisation in the way European Medicines Agency and each of the concerned NCA deal with requests for access to documents and information concerning quality, safety and efficacy of medicinal products.

Despite being confronted with different legislation governing freedom of information at national level, which may generate practices of 'forum shopping', we are conscious of our leading role in promoting the adoption of 'gold standards' in the disclosure of relevant information throughout Europe. We consider consistency, together with transparency, a value in the public dissemination of information related to the quality and safety of medicines in Europe. The Agency will work with

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NCAs in order to promote a consistent, transparent and reliable framework to provide information on the quality and safety of medicines to EU citizens.

Particular efforts have been made in order to agree on a common definition of commercial confidential information in the specific context of pharmaceutical research and development. This is particularly challenging as in contrast with other provisions of EU legislation applicable to the authorisation of similar products (e.g. GM food and feed, biocidal products, etc) there are no similar express provisions regarding the confidentiality of documents in the EU legislation on the authorisation of medicinal products, though other provisions make it clear that the provision of information to the public should be without prejudice to the protection of commercially confidential information (cf. Article 13 (3) of Regulation (EC) 726/2004). Therefore, the Agency, together with the NCAs, is involved in striking a careful balance of the different interests at stake when restricting the right of access to documents or information.

Additional discussion is currently ongoing between the European Medicines Agency and NCAs with a view to agree on which parts of the dossier filed by industry to support marketing authorisation applications shall be considered publicly accessible and at which point in time they can be disclosed in consideration of the different steps of the assessment procedure.

(b) Visible engagement with citizens as core business

The Agency has sought to develop interaction with civil society since its creation, leading to a framework of interaction with patients' and consumers' organisations. We regularly organise information days, launch public consultations on documents and policies of major interests, and rely on civil society's feedback to streamline our activities. Work is underway to further strengthen the interaction with these organisations, as well as with individual patient representatives as experts in the Agency's benefit-risk evaluation of medicines. This adds to the Agency's legal obligations in this field, e.g. through the membership of civil society representatives in various scientific forums.

(c) Multilingualism and EMA website

We share your view that the Agency should aim at expanding the amount of information available in all 23 Treaty languages published on our website. This is already the case since 1995 for information addressed to patients and healthcare professionals concerning all approved medicines.

In order to improve our website's accessibility, I have also recently asked my colleagues to explore the feasibility (and related costs) of providing the website homepage or a new welcome page in all the EU languages, together with the navigation and search interfaces. We are also looking at widening the range of documents and static information published in different languages across the entire website, including information on administrative and judicial remedies.

Your comments on multilingualism are timely and come at a moment when the Agency is in the process of implementing Regulation (EU) No 1235/2010 on pharmacovigilance for medicines for human use. As part of this new regulation, the Agency is required to introduce a new European medicines portal targeted specifically at the general public; the issue of multilingualism will clearly be a part of that development process.

For your information, you may be interested to know that a recent web-user survey suggested that about 90% of visitors use our website for professional reasons and of this total over 70% prefer to read in English. Of the survey respondents using the website for personal reasons, over half would

prefer to read in a language *other* than English. It may well be that the new European medicines portal will provide the information that the general public are looking for, and we will need to consider the general public interest when assessing where best to target our efforts and resources.

(d) Consideration of overriding public interest claims

I fully agree with your suggestion that the overriding public interest should be the paramount criterion driving the Agency when taking a decision on disclosure of a document or a piece of information not only when requested but also proactively whenever a general public interest is identified.

We will endeavour to publish on our website an increased amount of information as this not only will mitigate the number of request for access the Agency is likely to receive (with a direct impact on related workload) but as this has to be seen as a vehicle to enhance the Agency's accountability by empowering the public to have faster access to information that may have a significant impact of their health conditions and expectations.

B. Responding to complaints

In line with your proposal, the ability of citizens to complain to the Ombudsman has today been made more visible on our site. A specific link labelled 'complaints' will from today appear in the footer of the website on every page and will highlight the possibility of complaints both to the Agency's Executive Director and the European Ombudsman. This information is currently only in English, but will be made available in other Treaty languages as part of future changes relating to provision of multilingual information.

C. Policies and procedures for dealing with ethical issues

The Agency has been recently confronted with an intense debate concerning the adequacy of existing rules and policies addressing the governance of real and perceived conflicts of interest. This topic has drawn the attention of EU institutions (European Parliament, European Court of Auditors, and European Commission), media and general public. The Agency considers the appropriate management of conflicts of interest an indispensable tool to promote public confidence and trust in the Agency.

(a) EMA rules on conflicts of interest and the OECD recommendations

The Agency's revised policy on handling conflicts of interest came into force today, on 30 September 2011. In revising the previous policy, we have strengthened the robustness of our handling of 'real' conflicts of interests. However, the Agency is also fully aware of the perception which exists amongst its stakeholders as regards the management of conflicts of interests, e.g. throughout the scientific review process. The Agency, therefore, is making additional efforts to further increase its transparency in this field, going beyond the legal requirements, by putting online the declarations of interests of all experts contained in its database (the new database went live on 30 September 2011), and by providing more information on all conflicts of interests declared during a scientific review process and how they have been handled. I trust that you will be pleased to hear about this development, which is in line with your earlier recommendations.

(b) Consultation on revised rules of conflicts of interest

It is acknowledged that so far the consultation on the Agency's current and new policies on conflicts of interests has not been widened by inviting comments in the context of a public consultation. Nevertheless lessons learnt as regards the current Policy as well as proposals for amendment of the current Policy have been discussed with civil society representatives in the context of the established Agency's forums with civil society representatives. The Agency will take your suggestion into account for any future revision of its policy.

(c) EMA and whistleblowers

We have already shared with you our policy on reporting improprieties. As mentioned at our meeting, staff members are reminded of the policy at least on a yearly basis. The policy is also highlighted and explained to staff in relevant training courses, e.g. manager training, so that the correct and fair treatment of any whistleblower is understood.

You raise the issue of whistleblowing by stakeholders and the public. The Agency's practice is to treat all information from third parties extremely seriously, often including it in the information presented to the scientific committees where appropriate. A recent example is a response by the Committee for Medicinal Products for Human Use to a US-based vaccine pressure group published on 23 September 2011.[1]

Your suggestion for publication of information on how to report improprieties or other issues that may raise ethical concerns is therefore supported by the Agency. A policy will be drafted and consulted on with stakeholders. This effort will strive to ensure, in accordance with data protection legislation, the identity of the source of information and that follow up investigations are conducted, where applicable.

We are actively working on a number of transparency and publication initiatives that should in the coming years lead to increasing amounts of information systematically being made public by the Agency, with a consequence of reducing the need for citizens to make recourse to your Office.

Your comments concerning our positive attitude in our approach to dealings with your Office are appreciated and encouraging. While we do strive to ensure that we meet the highest standards of good administrative practice, inevitably there are instances when citizens seek redress. Where this happens we will continue to cooperate with your services in a positive manner working in the best interests of all parties concerned.

The Agency remains at your disposal should you or your services wish to follow-up on any of the issues raised in this letter.

Yours sincerely

Andreas Pott

Acting Executive Director

[1] See http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/09/WC500112851.pdf