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Response to the European Commission consultation on the introduction of fees to be charged by the EMA for pharmacovigilance

Madam, Sir,

Our organisation realises the major change in the regulation of medicines introduced by the new pharmacovigilance legislation. These changes are welcome; they correspond to a public health need and are in the interests of the patients and consumers.

It will be only a success if adequate resources are invested in these activities, both at the European and National level.

Our main concerns are about the resources allocated for the civil society organisations to play its role in pharmacovigilance, firstly to fairly compensate volunteers (the involvement in PRAC activities would represent 77 to 88 days a year and this can hardly be done on a mere volunteer basis without a fair system to compensate of days of work lost), secondly to support their organisations involved in pharmacovigilance at large.

Support to volunteers

In particular, the impact assessment of Pharmacovigilance legislation failed to identify the need to better support the Pharmacovigilance Risk Assessment Committee: the objectives were to contain the costs;

hence the number of PRAC members was reduced. However, and this is constant in all European Commission impact assessments, a discussion on how to best involve the civil society in these activities was totally omitted. In particular there was no discussion on how to support PRAC members representing patients, consumers or healthcare professionals, or their respective organisations. Patients or consumers can be seriously involved with quality work, only if supported by a well-structured network of such organisations, able to identify and train their members willing to become experts, preventing potential conflicts of interests, communicating both-ways, providing assistance to those who become sick or worsen during their mandate, or proposing help to those who need to leave home many days a year and still need someone to look after their children. And all this has a cost. Unfortunately, but this is real life, there is a limit to what volunteers can do, particularly when their involvement requires more and more professionalization.

Since the creation of the Patients' and Consumers' Working Party at the EMA in 2007, this concern has been brought to the attention of the EMA Management Board. The EMA Management Board took our demand into consideration, together with the needs of other external experts who are not always supported by a national authority, and started a dialogue with the European Commission. Other scientific committees also had similar requests, e.g. the Committee for Orphan Medicinal Products where members receive no fee at all for the work accomplished not only during the 2 or 3 days of meetings but also for the 2 days minimum of preparation and one day of follow up, without considering the many workshops or conferences one need to attend so to play fully its role..

However, since this dialogue has started, we regret to see no progress. We trust that the European Commission allocates appropriate resources and can guide the EMA on how to implement the text as well as the spirit of the EU Regulations. When DG Health and Consumers Protection initiated the financial instrument "Operating Grants", we asked whether the DG could consider financial support to patients/consumers organisations participating in EMA activities as provided by the European legislation, and DG Health replied this had to be discussed with DG Enterprise who was responsible for the EMA. DG Enterprise responded DG Health was responsible for project and operating grants, DG Enterprise had no such financial instruments itself. Now that DG Health and Consumers Protection has both the responsibility of EMA and the financial instruments such as the Operating Grant , we see no reason to differ a reflexion how to best support patients/consumers organisations in all activities decided by the European legislator but without proper reflexion on how to support this:

1. REGULATION EC 726/2004 establishing EMA
   - *Article 26: The Agency may request that the MAH arrange for specific pharmacovigilance data to be collected from targeted groups of patients*
   - *Article 65 - The Management Board: Two representatives of patients' organisations shall be appointed by Council in consultation with EP*

   - *Article 78: The committees and any working parties and scientific advisory groups shall establish contacts, with parties concerned with the use of medicinal products, in particular patient organisations*
2. REGULATION EC 141/2000 on orphan medicinal products
   - *Article 4 – COMP: Three members nominated by the Commission to represent patients' organisations*
3. REGULATION EC 1901/2006 on medicinal products for paediatric use
   - *Article 4 - Paediatric committee: Three members and three alternates appointed by the Commission in order to represent patient associations*
4. REGULATION EC 1394/2007 on advanced therapy medicinal products
   - *Article 14 - Package leaflet: The package leaflet shall reflect the results of consultations with target patient groups*
   - *Article 21 - Composition of the Committee for Advanced Therapies: The Committee for Advanced Therapies shall be composed of … two members and two alternates to represent patients associations*
5. REGULATION (EU) No 1235/2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004
   - *Article 61a: The Pharmacovigilance Risk Assessment Committee shall be composed of the following: one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.*

By decision of the EMA Management Board (EMEA/MB/753771/2009) on 10 December 2009, the proposals aimed at more structured involvement of patients/consumers in the various activities of the Agency was adopted. The proposals included revising the framework of interaction between the Agency and patients' and consumers' organisations, and providing financial support by doubling the daily allowance in well-defined cases.

This certainly represents a significant effort giving the increasing number of patients and consumers involved in EMA activities, however this represents a maximum of 208 €. We estimate a fair compensation of 450-600 € per meeting day at the agency (but in fact compensating for 3 worked days, thus representing 150 to 200€/day of work) would be reasonable, both for members who are volunteers or paid staff (for the later, a certain number of days can be deduced from their salary, equivalent to the number of days involved in EMA activities to respect the legal limit of annual days of work). This fair compensation could follow the following rules:

- No distinction between different statuses of individuals (retired, active, self-employed, compensated, volunteer, paid staff): one rule that applies to all
- A distinction would apply according to the type of involvement
    - Activity that requires intensive preparatory work, or post-meeting work: financial compensation, amount around 450 € - 600 € per meeting day (e.g. scientific committee,

SAG meeting, some working parties), actually compensating for 3 worked days, thus representing 150 to 200€/day of work;
    - Activity that does not require intensive preparatory work or homework: daily allowance as it is, with possibility of double allowance for volunteers not employed by their organisation (e.g. participation to workshops or conferences)
- The chair and co-chair of each meeting would decide whether participants fall into the category of intensive or non-intensive preparatory work according to the number of documents to be read for the meeting
- In cases the amount of 450 € or more would be over the ceiling accepted for a daily allowance by the tax system of the participant, it would be declared as a revenue and be eligible for tax payment; it would be the responsibility of the recipient to declare accordingly.

Support to organisations

The proposal for fees for pharmacovigilance does not rectify this omission: we think it should be an opportunity to propose some compensation for the work in the PRAC.

The Pharmacovigilance Directive 2010/84/EU, Article 102, states:

> *The Member States shall:*
> *(a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the national competent authority; for these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate;*
>
> *and (d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary.*

The pharmacovigilance fees could pay for the expenses related to all appropriate measures that Member States are invited to adopt. If there is no new funding to achieve this, it is not likely that innovative and efficient measures are adopted, as very little public money will be available in the current economic context.

The pharmacovigilance fees could be redistributed to National Competent Authorities who could then give grants to patients'/consumers' organisations participating in their activities on pharmacovigilance.

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

EURORDIS disagrees with the new pharmacovigilance service fee as currently proposed. What is foreseen is to cover general activities related to the new pharmacovigilance tasks of the agency, including

operation of the specific IT tools, literature monitoring and monitoring the effectiveness of public measures. The following is omitted:

- support to PRAC members, in particular external experts, as financial compensation of their participation in PRAC activities
- Member States are encouraged to adopt all appropriate measures to encourage patients and healthcare professionals to report suspected adverse drug reactions and to inform the public. For Centrally Authorised Products, and also for non-Centrally Authorised Products, pharmacovigilance fees could cover the costs of such measures for the additional work it will represent for National Competent Authorities (NCAs) and/or to organisations such as patients' organisations or healthcare professionals' organisations.

Alternative: we propose 1250 € to cover these costs, to be partially redistributed to NCAs, or to increase the current annual fee proportionally to the estimated new costs.

Consultation item n°10: What other aspects would you like to rise? Do you have additional comments?

Not all guidelines for the implementation of the pharmacovigilance legislation have been adopted yet. More is to come, for example guidelines on Public Participation in Pharmacovigilance. Some measures proposed in these guidelines will have a cost, and these costs need to be covered by the fees. Else, it is unlikely that the public will benefit from the adequate information and support to participate in pharmacovigilance.

Public hearings are not funded yet while EURORDIS believes public hearings are an essential instrument to add quality to the debate, and enhance the trust by both national decision makers and EU citizens into their European system: the pharmacovigilance fees should cover their costs and this is not mentioned in the proposal.

Other suggestions

Support to patients / consumers who volunteer to be members of the scientific committees at the European Medicines Agency is needed, and beyond the EMA, other EU agencies or official advisory committees also appoint representatives of the civil society, and the same difficulties always occur.

To level up the involvement of civil society, we propose the European Commission to explore the possibility to adopt a European decision for EU citizens called to become member of a body created by European legislation, – advisory or otherwise – instituted by legal or regulatory provision by a European authority. As an example, we translated four articles of the French Code du Travail that introduces

financial compensation to both the patients/consumers when they are volunteers and employees, and to their employers:

Article L3142-S1
"When a salaried employee, who is a member of an association governed by the 1st July 1901 law on the contract of association (…) is appointed as representative of that association to be on a body – advisory or otherwise – instituted by legal or regulatory provision by a state or regional authority, the employer must grant him or her the necessary time to participate in meetings of that body."

Article L3142-S2
"The salaried employee benefiting from leave of representation who is subject as a result to a reduction in pay receives from the state or regional authority an allowance compensating, wholly or partially, if need arise, on a lump sum basis, the reduction in pay.

The employer can decide to maintain pay wholly or partially, above and beyond the compensatory allowance.

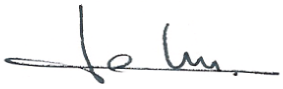
Article L3142-S3
"The period of leave of representation must not exceed nine days in a year. It may be divided into half days. The period of leave of representation is calculated on the basis of the effective working period used to determine holiday pay entitlement and other rights due to the interested party under the terms of his or her contact. It may not be attributed to annual leave entitlement."

Article L3142-S4
"Authorisation of leave may only be refused by the employer in the event that the employer considers, after advice from the works council (comité d'entreprise) or from the elected staff representatives, that this absence would have prejudicial effects on the output and smooth functioning of the business.

Refusal which is not justified is rendered null and void. Refusal can be directly contested at the labour court (prud'hommes) which gives a ruling based on the terms in force under law."

This provision would not apply to patients/consumers who are self-employed, and for whom further thinking is needed.

Best regards



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Please contact François Houÿez, Director of Health Policy, for any question regarding this letter (francois.houyez@eurordis.org).