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Dr Peter Arlett
European Commission
Brussels, Belgium

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Dear Dr Arlett,

STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGHTENING AND RATIONALISING EU PHARMACOVIGILANCE

General views on the public consultation paper

The National Institute of Pharmacy (the Hungarian national competent authority for human medicinal products) highly appreciates the Commission's efforts reflected in the above paper. We also do emphasise the importance of a robust EU-wide pharmacovigilance system and can not agree more with your statement that „a lack of fast and coherent EU action in response to drug safety alerts may put patient safety at risk".

Thus, revision of the pharmacovigilance legislation is timely.

It should be pointed out, however, that ADRs may only be discussed in connection with the local (member state) therapeutic habits. The nimesulide case has just proven that the ADR profile has been quite different in countries with extensive use and those that apply this product in specific cases exclusively. Without taking it into account, Community-wide mandatory decisions are of questionable value! This concept should also be reflected in the paper (and, perhaps, in the corresponding legislation).

Furthermore, we concentrate to the issues where we, emphasising our general agreement with the proposal, have concerns about the changes indicated.

The new Pharmacovigilance Committee

The draft describes the reorganisation of the Pharmacovigilance Working Party to a formal EMEA Committee. Since this future Committee would still *advise* CHMP on the safety of medicines (possible referrals), it is not clear *what the added value* of the creation of a new EMEA Commit-

tee *would be*? Is it impossible to organise CHMP referrals, based on the present Pharmacovigilance Working Party opinion? The draft says „Pharmacovigilance Working Party informally discusses safety issues but its conclusions are frequently not implemented… across all Member States". This situation will not be changed by the creation a new Pharmacovigilance Committee that has only an advisory role to CHMP, or at least, this is not explained in the draft.

As for other tasks of the new Committee, see below our concerns.

Without any clear added value it is not advisable to raise the number of formal EMEA Committees.

Reporting key safety information (modification of Article 59(1b) of Directive 2001/83/EC, Article 1ba)

We **strongly disagree** with the proposal that ADRs to medicinal products (e.g. which are under intensive monitoring, but also in general) should be reported to the MAH *exclusively* (even putting it into the package leaflet). This way the competent national regulatory authority will be informed about the ADR much later. Until now, in Hungary, reporting to the Hungarian regulatory authority has been requirement if an ADR occurs in our country.

We are not against simplification but if the reports are sent *exclusively to the MAH* (then to EMEA, perhaps within 15 days (!) then to the EudraVigilance data base, etc.), it may happen that the media will know earlier what has happened in Hungary than the regulatory authority!

It applies also to the proposed Article 101a! Reporting to the MAH or the competent authority is not a good solution.

„Work sharing" (see proposed Article 101f 4e-4h of Directive 2001/83/EC)

This proposed provision is *rather a centralised decision making than a work-sharing*! We **strongly disagree with it**! A real work-sharing between the national competent authorities (rather than Pharmacovigilance Committee rapporteurs), organised by either the present Pharmacovigilance WP or the CMDh would be welcome!

European list of medicines under intensive monitoring

The reason for thus intensive monitoring is fully understood. However, making this list public (at a level as reflected by the draft) may, at least in some member states, undermine the reliability of the product listed for a number of patients. (Moreover, it will be used by the competitors to achieve this!) **A more thorough impact analysis would be needed before introducing this measure**!

Less important items are:

Medication errors and adverse drug reactions

We do agree with the proposal that ADRs caused by medication errors should also be reported. However, in addition, we advise to specify also „*off-label use caused ADRs*"!

PSURs for old established products

In theory, we do agree with that where there is no risk, PSURs are less needed. However, care should be taken to specify „old established products". Do not forget that „established product" (e.g. for WEU) means a medicinal product authorised at least 10 years ago in the Community. Ten years are not enough to exclude the possibility of new ADRs, particularly when off-label use or that in higher doses occurs.

> A minor remark to the present draft: „aspirin" is a proprietary name, we should not speak about „hundreds of aspirin products authorised", rather about such „acetylsalicylic acid products".

We sincerely hope that our standpoint helps you to clarify the European attitude to this issue.

Thanking you for the opportunity to express our opinion,
I remain
Yours sincerely

Prof. Tamás L. Paál
Director-General

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