The European Agency for the Evaluation of Medicinal Products
Directorate

London, Friday 9 June 2000
Doc. Ref: EMEA/D/16906/00

Outcome of public consultation on new EMEA transparency initiatives

A consultation exercise was launched in February 2000 to gather comments on two new transparency initiatives proposed by the EMEA (EMEA/D/6135/00). Comments were invited on the following:

- Publication of a *Summary of opinion* for all CPMP and CVMP opinions on the granting of a marketing authorisation. These would be published on the day of adoption of the opinion and be made available for positive and negative opinions.

- The development of an EMEA post-marketing communication strategy.

Contributions were received from the following:

- AESGP
- EFPIA
- European AIDS Treatment Group
- European Consumers' Organisation (BEUC)
- FEDESA
- HAI Europe
- International Society of Drug Bulletins
- Pharmaceutical Group of the European Union

Copies of these contributions are attached.

The EMEA Management Board considered the contributions received at its meeting of 7 June 2000 and decided the following with effect from July 2000:

1. Summaries of opinion (both positive and negative) will be published 15 days after the adoption of CPMP opinions, once the right of appeal has expired and the opinion has become final. Opinions that are appealed will therefore not be published until they are final.

2. All applicant companies will similarly be requested not to communicate before 'day 15'. This will be monitored by the EMEA in liaison with EFPIA during a period of 6 months.

3. The template annexes I and II were adopted, with some technical amendments to take into account comments from interested parties.

4. Separate discussions will be held with FEDESA to clarify their position. Pending the outcome of these discussions, the '60-day' publication policy will continue to apply to all CVMP opinions. Template annexes III and IV of the original consultation paper will therefore not be used at this time.

5. A workshop will be convened in autumn 2000 with interested parties to consider a strategy for post-marketing communication.

6. The Management Board will finalise its position at its meeting on 20 December 2000.

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Annex I
Template to be used for a final positive or negative CPMP opinion

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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for <*name of the product*>

International Non-proprietary Name (INN): <*name of the active substance*>

On <*date of the adoption of the opinion*> the Committee for Proprietary Medicinal Products (CPMP) adopted a <*positive/negative*> opinion <*to/not to*> recommend the granting of a marketing authorisation for the medicinal product <*name of the product*> intended for <*treatment of /prophylaxis against/diagnosis of*> <*disease*>. The applicant for this medicinal product is <*name of the company*>.

The active substance of <*name of the product*> is a <*therapeutic class – cfr. ATC system and brief description of mode of action*>.

(For a positive opinion)

- The benefits with <*name of product*> relate to its <*brief statement on the character of the main clinical benefits in terms of the approved indication(s)*> and its most significant side effects relate to <*brief statement on the character of the main safety concerns*>.

The approved indication is for <*the indication as worded in the CPMP approved SPC*>. <*It is proposed that <name of the product> is prescribed by physicians experienced in the treatment of <disease>*>. Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for <*name of the product*> and therefore recommends the granting of the marketing authorisation <*under exceptional circumstances***>.

(For a negative opinion)

The grounds for the negative opinion relate to the following points*:*

- <*Brief statements on the major grounds for refusal of the marketing authorisation)*>.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is an unfavourable benefit to risk balance for <*name of the product*> and therefore cannot recommend the granting of the marketing authorisation.

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* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.

Annex II

Template to be used for an amended CPMP opinion further to new information* or to a request from the European Commission in the framework of the Standing Committee procedure

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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION**
for <*name of the product*>

International Non-proprietary Name (INN): <*name of the active substance*>

On <*date of the adoption of the opinion*> the Committee for Proprietary Medicinal Products (CPMP), having considered new information, adopted a <*positive/negative*> opinion <*to/not to*> recommend the granting of a marketing authorisation for the medicinal product <*name of the product*> intended for <*treatment of /prophylaxis against/diagnosis of*> <*disease*>. <*Brief statement on the background with dates*>. The Applicant for this medicinal product is<name of the company>.

The active substance of <*name of the product*> is a <*therapeutic class –cfr. ATC system and brief description of mode of action*>.

(For a positive opinion)

- The benefits with <*name of product*> relate to its <*brief statement on the character of the main clinical benefits in terms of the recommended indication(s)*> and its most significant side effects relate to <*brief statement on the character of the main safety concerns*>.

The approved indication is for <*the indication as worded in the CPMP approved SPC*>. <*It is proposed that <name of the product> is prescribed by physicians experienced in the treatment of <disease>*>. Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for <*name of the product*> and therefore recommends the granting of the Marketing Authorisation <*under exceptional circumstances****>.

(For a negative opinion)

The grounds for the negative opinion relate to the following points*:*

- <*Brief statements on the major grounds for refusal of the Marketing Authorisation: (indicate as per category in the annex of the List of Questions template)*>.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is an unfavourable benefit to risk balance for <*name of the product*> and therefore cannot recommend the granting of the Marketing Authorisation.

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* See *Conduct of Pharmacovigilance for Centrally Authorised Products*, CPMP/183/97, page 7.

** Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

*** Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.

EUROPEAN FEDERATION OF
PHARMACEUTICAL INDUSTRIES
AND ASSOCIATIONS

FÉDÉRATION EUROPÉENNE
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Ref: BA.mcf/51.280

17 May, 2000

Professor André BROEKMANS
Chairman EMEA Management Board
7 Westferry Circus
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U.K.

Dear Professor Broekmans,

It was a pleasure to meet with you last week with Fernand Sauer and I am looking forward to further meetings with you together with EFPIA's President.

We appreciated in particular the discussion on the transparency issue on 10 May. As promised, I am now forwarding the EFPIA revised position so that it can be put forward at the Management Board in June.

Also I can confirm that assuming the Management Board accepts the proposal we would envisage a review of the way this has worked after six months. We are aware that the operation of this revised requires commitment of principle by EFPIA members.

With kind regards,
Yours sincerely,

Brian AGER
Director General

cc : Fernand Sauer
Jorge Gallardo

Telefax
Fax-N°:
Aan/To/A:
Van/From/De:
Datum/Date: 18/5/00 N° Pag.: 4
Post-it Notes 7693

European Federation of Pharmaceutical Industries and Associations

Fédération Européenne d'Associations et d' Industries Pharmaceutiques

EFPIA POSITION ON THE

PUBLIC CONSULTATION ON NEW EMEA TRANSPARENCY INITIATIVES (DOC. REF. EMEA/D/6135/00)

GENERAL COMMENTS

EFPIA considers that the establishment of a sound, appropriate and well-balanced system for regulatory communication and transparency is extremely important for the pharmaceutical sector. In particular, EFPIA appreciates the efforts made by EMEA to improve the transparency of its procedures and of its related scientific committees.

The EMEA document on new transparency initiatives which went out for public consultation (Doc. Ref. EMEA/D/6135/00), whilst referred to as derived from an "EFPIA proposal", relates in fact only to one specific part of the actual EFPIA proposals: the suggestion that a summary of the CPMP opinion would be published after adoption by the committee.

EFPIA's main objective with its original proposals was to improve Regulatory Transparency from an overall perspective, with a view to meeting the expectations of the key customers (health professionals, patients, regulators, industry, etc.), and also to developing a sound and appropriate post-marketing communication system. We were somewhat disappointed that these essential elements of our proposals for a comprehensive communication policy were not reflected in the above EMEA document. However, we now understand that it is foreseen to have a discussion on Post-marketing/Pharmacovigilance Communication, as part of the re-organised joint meetings between EMEA/CPMP and Interested Parties, which we welcome of course. It is essential that representatives from patient groups be also invited to participate in the latter discussions, in addition to doctors, pharmacists, consumers and industry.

EFPIA welcomes EMEA's decision to adapt its current communication policy with respect to CPMP opinions (i.e. the release of the opinion 60 days after adoption by the CPMP, including the full summary of product characteristics (SmPC) in the case of positive opinions). The issue of the detailed SmPC on day 270 was considered of limited value to the promotion of public health and of little interest to the main key customers (health professionals, patients and the general public), since its content may change during the Commission decision-making process and the product cannot be made available until that process is completed.

EFPIA is however concerned that an automatic publication of summaries of opinions (positive or negative) on the day of adoption by CPMP (i.e. day 210) would become the norm in all instances. While this may on the whole be acceptable in the case of a positive opinion, it is clearly problematical for a negative and the company reasonably needs time to consider its position. Considering that from both legal and practical viewpoints it is possible to appeal either a negative or a positive opinion, we propose that as a general rule, summaries of CPMP opinions be published only after completion of the appeal procedure, if one is undertaken, or not sooner than 15 days after the adoption if an appeal is not lodged.

Specific circumstances may justify the issue of a public statement by the company earlier than 15 days after adoption of an opinion. This should of course be done in close consultation/co-operation with the EMEA.

Finally, we would like to stress that it is essential that the content of the summary of the CPMP opinion is agreed with the applicant prior to its publication. In this respect, we would appreciate a confirmation, in the EMEA document, of our understanding that the applicant company will be asked to fill-in the proposed draft template initially.

SPECIFIC COMMENTS

EMEA explanatory note

The second paragraph of the EMEA document refers to the proposal made by EFPIA that EMEA should publish a summary of the opinion, whether positive or negative, on the day of its adoption.

This does not reflect the EFPIA proposal accurately:

- Firstly, because this relates in fact only to one specific part of the actual EFPIA proposals, the objective of which was to improve Regulatory Transparency from an overall perspective: i.e. with a view to meeting the expectations of the key customers (health professionals, patients, regulators, industry, etc.), and also to developing a sound and appropriate post-marketing communication system.

- Secondly, because EFPIA's proposals clearly stated that summaries of negative opinions should not be released until the official (15-day) period allowed to lodge an appeal (cfr. Regulation 2309/93) has passed.

  EFPIA is particularly concerned that an automatic publication of summaries of opinions (positive or negative) on day 210 would become the norm in all instances. Everybody has in mind the recent outcome of an appeal lodged on a negative opinion, which ultimately resulted in a positive opinion.

  Considering that from both legal and practical viewpoints it is foreseeable to appeal either a negative or a positive opinion, it would be logical that as a general rule, summaries of CPMP opinions be published only after completion of the appeal procedure, if one is undertaken, or not sooner than day 15 post-adoption if an appeal is not lodged.

- Thirdly, because the EFPIA proposals for improving regulatory transparency suggested that the content of the summary of opinion should be prepared in consultation with the applicant. This is not stated anywhere in the EMEA consultation document.

  As a matter of principle and good practice, the contents of the summary of opinion should be agreed with the applicant prior to its publication.

  From recent discussions at the joint meeting between EMEA-CPMP and interested parties in March 2000, we understood that it was foreseen that the applicant company would be invited to fill-in the draft template proposed in Annex I to the EMEA document. We would of course welcome this. May we ask that this be clarified in the EMEA document.

Annex I - Draft template to be used in case of a positive or negative CPMP opinion in initial review phase

The EMEA proposed template includes "brief" statements on the character (EMEA's emphasis) of the main clinical benefits and safety concerns. Some further guidance on what should be included here would be helpful in ensuring the consistency of summaries of opinion for different products. Similarly, there should be guidance on the brief statements on major grounds for refusal of an authorisation that are to be included in summaries of negative opinions.

In addition, we stress again that this information must be agreed with the applicant. In this respect, we would appreciate a confirmation in the EMEA document that the procedure foresees that the applicant company fill-in the proposed draft template.

*Footnote * (on page 2/5): "Summaries of Opinions are published without prejudice to the Commission Decision which is normally issued within 90 days from adoption of opinion".*

Our own analysis shows that the period between opinion and Decision exceeds on average this normal 90 day period.

Annex II - Draft template for revised opinion

It is not clear whether, in the event of an applicant lodging an appeal, the EMEA intend to publish both a summary of the initial opinion (Annex I) and a summary of the revised opinion (Annex II). We would like to stress again that we believe that summaries of opinions should only be published after completion of the appeal procedure, if one is undertaken, or not sooner than 15 days after the opinion if an appeal is not lodged.

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EUROPEAN FEDERATION OF
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Mr Fernand Sauer
EMEA
7, Westferry Circus
Canary Wharf
UK – London E14 4HB

April 4th, 2000

Dear Fernand,

Re: Public Consultation on the new EMEA transparency initiatives (Doc. Ref. EMEA/D/6135/00)

I would like to inform you that several members have expressed strong concerns about an automatic release of summaries of CPMP opinions on the day of their adoption becoming the norm. This specific issue therefore requires further in-depth discussion by the EFPIA Board.

As you know, the EFPIA Board, the EFPIA President Mr Jorge Gallardo and myself consider the improvement of transparency as an extremely important issue. I would like to take the opportunity of the next meeting of the EFPIA Board (14 April 2000) to ask everyone to approve the EFPIA consolidated position on the above new EMEA transparency initiative.

I appreciate that the official deadline for EMEA's public consultation on this document was April 1st. However, I would be grateful if you could wait until after April 14th for the official EFPIA position on your new initiative.

Yours sincerely,

p.p. ***Brian AGER***
Director General

Copy to : J. Gallardo

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Ref : JV/ma-0246

30 March 2000

Dear Mr. Sauer,

Subject: FEDESA position re. the EMEA transparency initiatives

In answer to your letter of 2 March announcing a public consultation on new EMEA transparency initiatives, I am sending you herewith the position of FEDESA concerning these initiatives. The FEDESA Board will probably confirm this consolidated position paper at its meeting on 5 April 2000.

The human doctor is only prescribing medicines, whereas the vet has a stock. The commercial consequences of this fundamental difference are important for consideration in the transparency initiative.

I regret having to be critical but the damages that applicants could incur would be so huge and of such importance that it is my duty to ask you to reconsider the EMEA policy in the light of the new information attached.

Without prejudice to the general aim to improve transparency, the companies are requesting a transparency policy that is not detrimental to the applicant.

Please let us know if you need further information.

Sincerely,

Dr. Johan Vanhemelrijck

Encl.: Position of FEDESA concerning the EMEA transparency initiatives

FEDESA

Position of FEDESA concerning the EMEA transparency initiatives

Doc. Ref. EMEA/D/6135/00

FEDESA members regret the very short consultation period on the EMEA proposal concerning an important issue, which could have a potential impact on the choice of the applicant between the centralised and decentralised system.

Until now, a cornerstone of the EMEA policy on transparency has been that the confidentiality and confidence of the applicant must be maintained. This fundamental policy should not be abandoned.

In considering the EMEA's proposal, the following question must be answered: does the timing and the content of the divulged information in any way give a commercial advantage to competitors of the applicant, to which the applicant has no possibility of defence.
In the case of a negative opinion, the image of the company and of the product can be damaged and it would be more difficult to have a new file approved.

After having studied the timing and content, the members of FEDESA feel that the interests of the applicant whose activities are divulged prior to commercialisation are potentially damaged, without him to be able to defend himself.

Indeed, the early announcement of the product name, substance and indication of treatment will alert competitors. Those competitors can then react by special sales promotions to the veterinary surgeon. Unlike the human practitioners, who are mostly only prescribing medicines, the veterinarian maintains a stock of medicinal products.

The competitor can therefore fill the market with their own equivalent product. The applicant cannot defend himself because it is unlawful to promote unlicensed medicines and at the time it is not a licensed medicine. It is just a medicine for which a positive opinion has been expressed.

Never the less, the animal health industry is keen to support all initiatives to improve transparency, where these do not compromise commercial confidentiality. Therefore FEDESA would like to recommend the following solutions:

1. The EMEA proposal could be balanced with an amendment to the legislation to allow the applicant to promote to our customers the positive opinion so as to minimise the potential damage to their product launch from the saturation of the market by his competitors.
2. The EMEA proposal could be amended so that can only be published before day 60 with the permission of the applicant, or in the event that the applicant makes the information public.

Under this condition FEDESA can accept the transparency document as established by EFPIA.

However, together with EFPIA, FEDESA is not sure that the proposal fully reflects the EFPIA position. The EMEA proposal creates the impression that certain aspects of the EFPIA position have been selected, while other inseparable aspects have been overlooked. Should this be the case, then the industry would like to point out that the entire EFPIA position as a proposal must be studied as well as the special conditions for veterinary products should be included in this position.
The issue is of great importance and it should be dealt with in full openness and transparency and not on the basis of partial information.

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25 April 2000

Dear Fernand,

Subject: EMEA transparency initiatives

I can confirm that the Board of FEDESA approved unanimously on 6th of April FEDESA's position paper concerning the EMEA Transparency initiatives. The Board also reinforced the offer to deal with this issue in full openness and transparency and gave instructions to start a more in-depth consultation. We would therefore appreciate to have consultation meetings before the June management board of the EMEA.

Thank you for considering this.

Yours sincerely,

Dr. Johan Vanhemelrijck

AESGP

Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Fachverband der Arzneimittel-Hersteller

03 April 2000

Mr Noël Wathion
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Dear Mr Wathion,

Public consultation on the EMEA transparency initiatives / Communication of pharmacovigilance issues

AESGP welcomes the initiative of EMEA to issue a public consultation paper on new EMEA transparency initiatives (letter dated 28 February 2000). In light of this letter and the meeting held on 17 March 2000 we would like to comment as follows.

AESGP highly appreciates the principles of transparency in the work of the EMEA. The provision of information to the general public related to regulatory decisions or scientific opinions has significant implications for all interested parties. AESGP considers that this kind of approach requires to a large extent a comprehensive communication policy, where all parties concerned have a role to play.

AESGP finds that the elaboration of a balanced communication policy with regard to patients (or users) and health professionals is of great interest and importance for both regulators and marketing authorisation holders. This policy would require a coherent post-marketing communication strategy aiming to achieve the best possible public awareness, taking into account the substantive interests of all parties involved. The procedures and channels of communication between all interested parties need to be clearly defined and agreed depending on the urgent and non-urgent safety issues with regard to medicinal products.

According to the revised document *"Points to consider for an EMEA communication policy"* (EMEA/MB/011/98 Rev 2, 3 December 1998), the EMEA has started to implement a new policy in relation to communication issues and in particular with regard to the immediate post-opinion stage. According to this paper *"(...) the Agency might be required to make public statements where (a) Detailed information about the application is already in the public domain (b) Misleading information might have to be corrected by means of factual clarification"*. The document does not describe the way the content of these documents might be agreed upon with the company or parties concerned before being released.

The practice of the EMEA so far has been to use various documents (called "press releases", "public statements", "position papers" or "position statements") to communicate pharmacovigilance issues. Those documents usually provide recommendations for regulatory action based on the safety profile of the product(s) concerned.

AESGP considers that such a policy would be best achieved through a transparent flow of information. This would be done in accordance with a procedure defined by the competent staff at the EMEA to guarantee the most suitable form of security agreed by all interested parties.

Early contacts with the parties concerned should be taken into consideration in the development of a post-marketing communication strategy. A balanced policy should be elaborated to ensure that all interested parties (in particular concerned company(ies) and/or trade associations) be involved in these channels of communication.

As a reliable and responsible partner in the area of pharmacovigilance, **AESGP considers it appropriate that the industry be involved in the further building - up of a pharmacovigilance network in Europe.** In accordance with a Community Regulation 2309/93/EEC, as amended, the EMEA co-ordinates through a pharmacovigilance network the pharmacovigilance activities within the EU. To reduce the disharmony among the European countries and improve the transparency in the field of pharmacovigilance, the industry should be involved at a very early stage in the EMEA initiatives regarding management of safety issues and establishment of a telematics network. Such an approach will enable the industry both to benefit from and contribute to communication and databases.

AESGP would be pleased to participate in any further discussions on how to improve the channels of communication on pharmacovigilance issues between all interested parties.

Yours sincerely,

Prof. Jasmina Mircheva
Director for Medical Affairs and CEEC

Jean-François Dechamp
Scientific and Regulatory Affairs Executive

CC: Mr Fernand Sauer

European Aids Treatment Group

EATG

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April 2, 2000

Fernand Sauer
Executive director
European Medicinal Evaluation Agency
7 Westferry Circus, Canary Wharf
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UK

Dear Sir,

In response to your letter dated 3 March 2000, I have the honour to send you comments from the European Aids Treatment Group on the new communications policy as defined on 22 February 2000, particularly on the *summary of opinion* on the day of adoption of an opinion of the CPMP.
In addition, we would like to suggest some strategies that could help to improve communication to patients, users and health professionals about marketed medicinal products.

About the agenda of the CPMP:

- Public announcement of medicinal products filing submissions, at the time of their submission, on the EMEA web site.
- Public announcement of the rapporteur and co-rapporteur member states at the time of their nomination.

About the summary of opinion:
If the medicinal product characteristics should include exceptional properties affecting safety and efficacy, then this should be part of the summary of opinion.
For example, if any dose induction is recommended to decrease the risk of hypersensitivity reaction, then we think it may be crucial to mention it in this summary.
There are many other examples where a property could be mentioned (i.e specific monitoring like monthly renal function test in the case of cidofovir – Vistide®, i.e a known interaction with another product that could have a dramatic impact on the bio-availability/efficacy), and we suggest to shortly refer to it in this summary.
The CPMP could mention such an important information, since it is clear that all efforts to bring this information to patients, users, health care professionals and clinicians should be emphasised.
We have several examples where misuse of a product due to lack of information or awareness lead to severe clinical situations. Most of these cases have been reported to regulatory authorities/national evaluation agencies and you are certainly better aware than we are about this reality.

Another suggestion is to add one document (Annex III) relative to new medicinal products that could be conditionally approved bases on preliminary safety/efficacy results for patients who have exhausted treatment options that could help to construct a new viable anti-retroviral regimen. During our last meeting with the CPMP on 14 December 2000, we advocated the need to adopt such an earlier approval and we think we could convince the CPMP. Of course we realise that more efforts will be needed before this new approval procedure becomes a reality, and we feel confident these efforts will be successful in a short term.

About post marketing communication to patients, users, health care professionals and clinicians.
We consider two types of communication:
1 addressing safety concerns

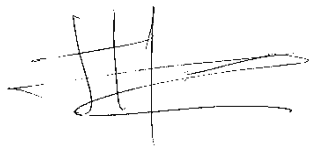
2 communication for the promotion of the product

1. Communication on safety concerns
   A. The EMEA should complete an exhaustive directory of European patients groups with the help of existing partners and of a public announcement to all parties that would show interest to receive such information.
   B. In case of any new information of importance regarding safety or efficacy, the EMEA could submit letters to the editorial board of medical publications. Another possibility could be to communicate with the scientific committees of European conferences to distribute relevant and/or recent data to the participants.

2 Communication for the promotion of the product

We believe the EMEA should have the competence to fine in case of inaccurate or misleading information distributed by the product manufacturer on the European scale or in specific member states whenever this is brought to the EMEA attention by an interested party. If this is not applicable, then the EMEA should refer to the appropriate judiciary body.

Sincerely,



Ana Sousa Passos
Chair of the Board of Directors

François Houyez
Board of Directors

Also followed by Nikos Dedes, Athens.

European AIDS Treatment Group e.V.
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Annex III -Draft Template to be used in case of a positive or negative CPMP opinion in the initial review phase, i.e. ~ day 210

For conditional approval

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for <name of the product>

International Non-proprietary Name (INN): <name of the active substance>

On *<date of the adoption of the opinion>* the Committee for Proprietary Medicinal Products (CPMP) adopted a *<positive/negative>* opinion** *<to/not to>* recommend the granting of a Marketing Authorisation for the medicinal product *<name of the product>* intended for *<treatment of /prophylaxis against/diagnosis of> <disease>* with the condition that phase III efficacy and safety results will confirm phase II results on which this Marketing Authorisation is grounded. The Applicant for this medicinal product is<name of the company>.

The active substance of *<name of the product>* is a *<therapeutic class -cfr. Arc system and brief description of mode of action>* .

(For a positive opinion)

. The benefits with *<name of product>* relate to its *<brief statement on the character of the main clinical benefits>* and its most significant side effects relate to *<brief statement on the character of the main safety concerns>*. These benefits apply to *<description of the patients' population that could benefit from <name of medicinal product> according to information gathered from phase II/III clinical trials >*

The approved indication is for *<the indication as worded in the CPMP approved SPC>. <It is proposed that <name of the product> is prescribed by physicians experienced in the treatment of <disease".* Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EP AR) and will be available in all European Union official languages after the marketing authorisation has been granted by the European Commission.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for *<name of the product>* and therefore recommends the granting of the Marketing Authorisation *<under the condition that confirmatory data from phase III trials will be produced>* for patients who have limited treatment options.

(For a negative opinion)

The grounds for the negative opinion relate to the following points:

. *<Brief statements on the major grounds for refusal of the Marketing A uthorisation)>*.

The CPMP, on the basis of efficacy and safety data submitted, considers that there is an unfavourable benefit to risk balance for *<name of the product>* and therefore can not recommend the granting of the Marketing Authorisation.

.....

* Summaries of Opinions are published without prejudice to the Commission Decision, which will normally
* be issued within 90 days from adoption of the Opinion.
* Applicants may appeal any CPMP opinion provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the Opinion.

EMEA
Mr. Fernand Sauer
7, Westferry Circus, Canary Wharf
London E14 4HB
United Kingdom

04 April 2000

Ref. : CDR/042000069/cm

BEUC comments on the new EMEA transparency initiatives.

BEUC warmly welcomes more transparency and openness from EMEA. The publication of a summary of opinion, no matter whether it is positive or negative, on the day of adoption by the scientific committee, provides a possibility for the people interested with the knowledge and expertise to follow closely the work of EMEA.

However, BEUC finds that the information given on these data templates is not very informative for the general public. Also for consumer organisations lack of resources, both in staff and money terms, makes it difficult to give this issue the right amount of time and work that it deserves. The use of this information for consumers and consumer organisations might therefore be very limited.

Publishing in a "lighter" form, e.g. on the internet for general consumers, could be a complementary information strategy for EMEA to consider in the post-marketing communication.

Yours truly,

C. deRoo

Charlotte de Roo,
Environment, Safety and Health Officer

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Fernand Sauer
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UNITED KINGDOM-E14 4HB

30 March 2000

Re: Public consultation on new EMEA transparency initiatives

Dear Mr Sauer,

Health Action International (HAI) welcomes the EMEA's efforts to become more transparent about its own workings and those related to the centralised authorisation procedure for medicines.

HAI is pleased to see the EMEA's proposal to start publishing information on negative opinions. This will be a valuable source of information that, at the moment, remains unavailable. At the same time, HAI foresees a significant increase in the number of "pre-emptive withdrawals" as pharmaceutical companies look for ways to control public reaction to a negative opinion. For that reason, we strongly believe that the public must be informed if a company chooses to withdraw its product from consideration before the CPMP has finalised its opinion about it.

We have the following detailed comments on the draft templates:

1. In the templates in Annexes I and II we would like the statement of the benefits of the product to relate only to *clinical* benefits in terms of the approved indications, and not to all potential clinical benefits.

2. We would like to see the benefits quantified in two dimensions:
a) how much benefit (range or average) in each approved indication;
b) the likelihood/ probability of benefit among individuals

3. In these templates we would like to replace the word "risk" with the word "harm", because risk refers to probability, not to a quality of harm or its intensity. Further, as with benefit, we need a brief description of the character and severity of the harm or disbenefit, and separately, of the likelihood of its occurrence.

4. With each approved indication we would ask the EMEA to express benefit and harm using terms such as absolute risk reduction and/or numbers needed to

treat/harm. This is particularly important when evaluating drugs that are intended to "prevent" disease.

5. Mention of a "benefit to risk balance" should be avoided because it suggests that the *character* and *degree* of a benefit can be compared with and balanced against the *probability* of harm. Since benefit and risk have totally different dimensions they cannot be "balanced".

6. In Annex II, line 2 of the template begins with the phrase "having considered new information". In our view it is necessary to state briefly the nature and the source of the new information. Without this the reasons for the decision are bound to remain a mystery.

7. In both Annexes I and II the concluding sentences for both positive and negative opinions begin with the phrase "The CPMP, on the basis of [quality, safety and efficacy] data submitted, considers..." This suggests that the CPMP considered nothing else, and for example did not consider the efficacy and safety of other drugs in the same or a closely related therapeutic class, or publications about the drug that were not submitted by the applicant company (possibly because the company was not aware of them). We believe that the CPMP does and must consider such other data, though it may not make a great effort to obtain them.

We therefore suggest adding the phrase: "together with other relevant data," so that the sentence would read "The CPMP, on the basis of [quality, safety and efficacy] data submitted, together with other relevant data, considers ..."

HAI appreciates the opportunity to comment on this initiative and looks forward to further constructive collaboration with the EMEA.

Yours sincerely

Bas van der Heide
Coordinator, HAI Europe

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Mr Fernand Sauer
EMEA directorate
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7 Westferry Circus
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London
UK – E144HB

Paris, March 30, 2000

Dear Mr Sauer

We welcome the EMEA's intentions aiming at more transparency. We do appreciate the release of some information on *negative opinions*, so far a gap in EMEA communication policy. But we think the number of 'preemptive withdrawals' will probably go up substantially as drug companies try and prevent the public knowing of a negative report. We think therefore that there should be transparency about these preemptive withdrawals.
In the section 'For a negative opinion', *quality* should also be an issue (as well as efficacy and safety).

In the section 'For a positive opinion' of the draft template, the brief statement should just relate to clinical benefits in terms of the licensed indication(s), and not to all potential clinical benefits. The draft is not clear at the moment.
We also fear that early release of information on *positive opinions* will accelerate pre-launching manoeuvres by drug companies. We would therefore recommend that EPARs be also released soon after these early opinions to help inform more accurately health professionals and consumers.

The ISDB will carefully watch how this new procedure will be implemented.

Most importantly, we believe transparency should not be confused with speed. What really matters is the quality of the EMEA's assessment, even if the conclusions are a bit less rapidly released, and eventually total communication of data as well as the arguments forming the basis of drug approvals.
EMEA has still a long way to go.

Yours sincerely

Christophe Kopp
ISDB President

GROUPEMENT PHARMACEUTIQUE DE L'UNION EUROPEENNE
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Brussels, 31 March 2000

Mr. Fernand Sauer
Executive Director EMEA
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

Dear Mr. Sauer,

Concerning your letter dated 3 March 2000 (Doc. Ref.: EMEA/D/MH/NM/6768/00), PGEU is glad to contribute to the public consultation on new EMEA transparency initiatives. Please find herewith PGEU comments.

Yours sincerely,

(p.o.)
Lisette Tiddens-Engwirda
Secretary General PGEU

GROUPEMENT PHARMACEUTIQUE DE L'UNION EUROPENNE
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Brussels, 31.03.2000

PUBLIC CONSULTATION ON NEW EMEA TRANSPARENCY INITIATIVES
PGEU CONTRIBUTION

At its meeting on March 24th, the executive committee of PGEU considered your document on the above topic. We fully agree with the proposal to publish *Summaries of Opinions* of the CPMP and CVMP in accordance with the draft templates dated 28th February 2000.

With regard to Post-marketing communications, we take the view that communication should be in both directions; from professions to EMEA as well as from EMEA to professions. To be specific, pharmacists throughout the EU should be invited to submit reports of suspected Adverse Drug Events in an agreed format. We have recently adopted a report on Pharmacovigilance by Community Pharmacists in the EU, and would be pleased to table this as an agenda item for a forthcoming meeting. It is a matter for discussion to discover the most effective channel for communication from EMEA to community pharmacists. This may prove to be via PGEU, national regulatory agencies, national pharmacy organizations, or a combination of these. We would welcome further discussion of this aspect in the near future.