From: Defabianis, Catherine [defabianis.c@pg.com]
Sent: 07 April 2008 15:08
To: NARHI Ulla (ENTR)
Cc: Bomont, Helen
Subject: Input on Legal Proposal on Information to Patients.

Dear Mrs Närhi,

Please find below input on the Document called Public consultation. Legal Proposal on Information to Patients .

First of all, we believe there is both the need and the ground (patients are ready for it) for a broaden information to patients.

We also agree there is a need to distinguish the non-promotional information that is allowed from the one that is not allowed. This part is very important as we should protect patients but allow the right information go through. The criteria in the text are however quite broad and should be more clearly defined.
We propose to reword the objective number 2 (point 2.2) as follows : Maintaining the ban on direct to consumer advertising for prescription medicines, whilst allowing non-promotional information (which needs to be clearly defined).

It would be important also if there is common consensus among EU countries to share the PIL and SmPC (what is currently NOT allowed in all European countries).

The proposed text seems then to open a door, but, in some paragraphs, it comes back to advertising definition, as follows basically, communication not covered by the definition of advertisement, should be regarded as information (see point 3.2)
The EU Directive is going a different way : it gives a very broad definition of advertising and then gives a precise list of what is not advertising (so based on directive, only these listed activities are information ; all others should be seen as advertising).
So, it is not clear, versus this point, how the attached text and the existing directive could match.

Would it be allowed to use the brand name when providing non-promotional allowed information ? this is not clearly specified in the text (3.2)
Also, what about if a prescription only medicine is alone on the market in a specific therapeutic area ? Would non-promotional info to the patients still possible ? with brand name ?

Regarding scientific studies (3.2), it is to note that such studies may not always exactly match the SPC, but it would be an important achievement if they are part of the material to share with consumers. It is however not clear if they must be shared as full publication or if it would be possible to use claims .
Clearly the second option is much more consumer friendly .
Also, what about comparative trials ? How to share them with consumers ?

Regarding the information monitoring, we believe it is important to have a National Control Board (i.e. made of mixed entities among which the local regulatory agency) that ensures the respect of quality criteria as well a EU Advisory Committee to oversee the work of the national board.

Definition and role of national co-regulatory bodies could then be made clearer in the proposal.

Local Regulatory Agencies to apply sanctions in case of non compliance is OK : sanctions types and levels should be defined and globally harmonised through the countries then. Would the Control Board make random checks to ensure compliance ?.
To not submit any material to the Board, would of course be preferable ; however shall this not be possible, we should target for the Tell & Do approach. Would it then be silent consent or OK systematically needed ? which exact reaction can these co-regulatory bodies take if they disagree ? .
Elements required from companies (Tell phase), and standards timings for examination should also be defined.

We do not really see a difference between active and passive information in terms of monitoring.
See points 3.3.1 and 3.3.2. : the attached text plans that for information passively received by citizens, marketing authorization holders (MAA) inform these national co-regulatory bodies about information activities described here above, before action is taken (Tell and do). But the proposed text plans in parallel that for information searched by citizen (i.e. internet or verbal discussions), the MAA announce such information activities to a national co-regulatory body which monitor the content without validating ex-post or ex-ante specific actions . So in the second item it is monitoring versus tell and do mentioned above : what is the rationale for such a difference ?)

Point 3.3.3 is not really clear (especially when it comes to based on complaints , not sure what this means..).
Answering requests from citizen should fit into private communication matters and should automatically not be considered as advertising (included in Medical Communication ?) : so is point 3.3.3. really needed in such a proposal ?

We deeply hope that this input will be of interest and stay at your disposal in case of questions.

Best regards,

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