

## Clinical Practice Guidelines and Pulmonary Hypertension: More Disagreements Than Facts

### To the Editor:

We have cautiously read the revision that was made jointly by the Spanish Cardiology Society and the Spanish Pneumology and Thoracic Surgery Society (SEPAR) regarding the care standards for the management and treatment of patients with pulmonary hypertension.<sup>1</sup> At least 3 facts are cause for concern.

First, it is striking and alarming that a document signed by two important scientific societies does not present a single independent author. As seen in the publication, each and every one of the authors has links to the manufacturers of the drugs that are used for the treatment of this disease. The independence of the clinical investigation (above all else in society documents and guidelines) cannot be considered to be an “accessory,” but rather a fundamental element for guaranteeing the transparency of the opinions. The former editor of the *New England Journal of Medicine* clearly expressed this, and an extensive bibliographic background supports the need to provide transparency of the opinions of experts and scientific societies.<sup>2-4</sup> Even more so, the declaration that “the financing needed for the preparation of this document has been obtained through unconditional support provided to SEPAR and the SEC by Actelion Pharmaceuticals España, Ferrer Grupo, GlaxoSmithKline, Pfizer, and Schering España” makes it almost inadmissible. The pharmaceutical industry is not a charitable entity. It is an opinion shared by many that “unconditional” help does not exist.<sup>5</sup>

Second, it is notable that a document from 2008 decides to ignore the existing controversy on the available “evidence” related to the quality of the methodology used in the clinical investigation on pulmonary hypertension.<sup>6-8</sup>

Finally, in the end the document is a quasi-translation of the European Clinical Practice Guidelines. However, this is precisely the point that makes it out of date. In fact, the EMEA is actively reviewing the practicality of continuing to do clinical studies using the same standards that have been created to date. Translating questionable documents for local scientific societies is more imposition of an obedience guide than promoting reflection and critical judgement.

Presenting challenges and proposing opportunities should be the primary concerns of scientific societies.

We should point out that this letter is not designed to create an individual approach, but rather to

discuss, openly and in the appropriate field, the role of scientific societies when recommendations are made.

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## Response

### To the Editor:

We have carefully read the letter from Drs Laffaye and Comignani regarding the Consensus Document from the Spanish Pneumology and Thoracic Surgery Society (SEPAR) and the Spanish Cardiology Society (SEC) on the “Care standards in pulmonary hypertension,”<sup>1</sup> the drafting of which we have coordinated. Statements are made in the letter from Drs Laffaye and Comignani to which we would like to respond.

First off, it is stated that there is no independent author among the signatories of the document. This

statement is supported by the fact that the authors of the document have performed consulting tasks for the pharmaceutical companies, have been investigators in clinical trials on drugs or have delivered talks at meetings sponsored by pharmaceutical companies. From our point of view, these activities have not affected the independence with which the members of the commission have acted when preparing the document, but rather reflects that the commission has been made up of persons with clinical experience in the field of pulmonary hypertension, which is why the pharmaceutical companies have requested their participation. In a disease as rare as pulmonary hypertension (PH), in which it is logical that there are few experts in the country, it is practically impossible for these experts to not have at least participated in clinical pharmacological studies in these patients as occurs in the current international clinical guidelines that address this disease.<sup>2-4</sup> In fact, we are of the opinion that participation in these studies provides a more objective view of the true safety and efficacy of the drugs, which can be seen when reading the published results.

We believe that questioning the independence of the authors of the document is inappropriate and in any case should not be based on conflicts of interest, which have been openly declared, but rather on the content of the statements and recommendations that are made in the document, a point that Drs Laffaye and Comignani have not raised.

The letter also mentions that “unconditional” help from pharmaceutical companies does not exist. To this we would like to point out that the scientific societies that guarantee the document recommend that the costs associated with the preparation of consensus documents (primarily derived from meetings of the members of the editing committee) be financed externally. For this reason, we have approached all companies in the Spanish market with drugs for PH. These companies made an equal contribution to the scientific societies, not to the authors. We believe that the fact that all of the companies with drugs for this disease made contributions in and of itself constitutes a guarantee that there is no bias towards any given drug. This method of unconditional assistance by the pharmaceutical industry is the same method that has been used to finance the third and fourth world symposium on pulmonary hypertension<sup>5</sup> and constitutes the basis upon which the current international practice guidelines have been prepared.<sup>2-4</sup> As we have previously stated, Drs Laffaye and Comignani have not stated that the document contains statements that may be conditioned by any specific company.

Third, the letter states that the consensus document lacks originality and reproduces the clinical guidelines prepared by the European

Society of Cardiology (ESC).<sup>3</sup> As stated at the beginning of the writing, the consensus document does not attempt to be a clinical guideline, but rather provides support designed to improve the quality of care for patients with pulmonary hypertension in Spain, and the recommendations prepared by the ESC, which have been translated into Spanish and published in the *Revista Española de Cardiología*,<sup>6</sup> have been used as a reference for clinical practice. For this reason, a good part of the document is inclined to recommend a care structure that is based on reference centres, whose requirements and services are explained in detail. These contributions, though confined to Spain, are completely new and precede the recommendations that are currently being prepared by the ESC for their new clinical practice guide on pulmonary hypertension, on whose editing committee sit 2 persons who participated in the preparation of the Spanish consensus document.

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