



EUROPEAN COMMISSION

High Level Group of Independent Stakeholders on Administrative burdens

## MINUTES OF THE MEETING OF THE HLG ON 26 FEBRUARY 2008

Venue: Brussels, 26 February 2008, from 10h00 to 17h00

Present: See presence list

Excused: Mr. Candido Mendez

### 1) Opening

The meeting was opened by the Chair.

The draft agenda was adopted without comment.

The minutes of the meeting of 17 January 2008 have been adopted subject to adding a reference to the discussion about transparency.

### 2) Workshop on methodology and the work of the consortium

Mr. Phillipart, programme manager ABRP, kicked off by introducing the work of the consortium.

Mr. Edwin Kok welcomed members on behalf of the consortium and led through the workshop.

*The presentation by the consortium has been sent to members beforehand.*

### 3) FTA package 2008

The chair thanked Mr Berger and Mr Illy for their excellent work in preparing a draft opinion for the HLG and invited Mr Koopman to introduce the subject.

Mr Koopman informed about the political and procedural background on FTA in general and shortly informed about the state of play of the 2007 package.

He then gave a short summary of the background of the FTA package 2008. Mr Koopman also underlined the need to apply the principle of proportionality as regards the underpinning of the proposed FTA by figures.

Finally, Mr Koopman informed that five of the 16 possible measures [numbers 8, 9, 12, 13 and 14 according to the numbering of the report made by the reporting members] have been withdrawn following final discussions with the relevant services.

Mr. Berger, on behalf of Mr. Illy and himself presented the opinion.

Mr. Illy added that the right level to verify information was on that of regional business associations. He furthermore underlined the need for a more proactive approach regarding a fast track procedure.

*A document referring to the procedural issues from Mr. Illy will be circulated by the secretariat.*

The chairman invited members to make their views known.

Mr. Murray underlined that withdrawing proposals after reflection is not a failure. He disagreed that waiting for quantifications is necessary. He inquired as to how FTA are chosen. He added no. 4 to those items to be withdrawn from the list insofar as human medication is concerned. As regards no. 6 he inquired whether the consequences were intended or not.

Mr. Telicka inquired whether some of the withdrawn proposals should not be kept. As regards FTA in general he stated that all work of the group should be fast track. He supported Mr. Murray's remark on no. 4 and no. 6.

Mr. Hontelez supports remarks made on no. 4 and 6. He inquired in addition on the procedural issues and questioned the wisdom on rushing through proposals.

Ms. Fritsch asks for the report to be made available electronically. She stated that the list were not the proposals the group came up with. She would like to see many more FTA during the year. The proposed contest should not be limited to FTA type proposals. The group should be careful with welcoming proposals.

*The secretariat will provide members with the presentation of Mr. Berger.*

Mr Potdevin referred to no. 14 to 16. He underlined that the texts in question have once been discussed in Parliament and are therefore to be considered in order. Their implementation should perhaps be modernised.

The chair insisted on the consultative character of the group. The work of the Commission should therefore be welcomed in the most literal sense. He expressed his view that if the Commission goes for cutting red tape it should be supported. This goes in particular for FTA.

Mr. Linschoten stated that there is not much wrong with the proposals but he thinks that the independent role of the group has to be visible in its opinion. He argued against copying views of the Commission. He insisted on the need of quantification and stated that there is not much of fast track in this. There is moreover need for a fast track procedure. He further made clear that he found that the list was not long enough, in particular in view of the withdrawals. With respect to withdrawals, in his view the qualification of legislation as "recent" was not a valid argument for a withdrawal, and he therefore had the feeling that there were other reasons for the withdrawal. He reminded

the group of a letter from the Dutch Minister of Finance that alone contained 10 proposals of which only two made it to the list.

The chair stated that the group can only comment on proposals presented to it but supported that there should be more proposals.

Mr. Pesonen joins the chair in this and stated that the list needs the support of the group. He mentioned that timing is of the essence given that legislative proposals will only come in May. He underlined that it is not easy to modify or simplify legislation without changing the underlying sense of the regulations. He cites labelling of agricultural products as an example where the administrative burden has to be accepted in view of the need for the protection of consumers and producers.

Mr. Ludewig underlines the need for a speedy procedure in view of the length of legislative processes. The group has to meet expectations and he therefore supports proposals to that end. The group is not discussing the proposals as such or their political substance. The job of the group is to look only at administrative burden that may be reduced and to advise whether the proposals achieve the goal of reducing such burdens. Systematic quantification is the basis of its work.

The chair joins Mr. Ludewig in his remarks in particular regarding the goal of the group.

Mr. Koopman recalled that the Commission is seeking the view of the group. As regards the length of procedure he states that simply calling for a speedier procedure is not enough; proposals have to be specific to create an effect. In relation to the view sought the group should tell the Commission whether these or other proposals are adequate. Quantification can be important but is however not always possible. He quoted the variations directives as a good example for this. The Commission is however seeking more quantified data. He invited the group to ask the questions listed in the draft opinion to Commission services available today.

For reasons of timing the chair would like to proceed differently. Questions should be answered but not during the meeting unless they concern details on FTA.

Mr. Telicka underlined the timing aspect of the whole programme. He proposed that the Commission tries to enter remarks on the need for quicker procedures in the Council conclusions. The group has the unique opportunity to include such remarks in Council conclusions.

The chair rather sees the importance in the need to advise the Commission on proposals presented and not on any other proposals. He reminded the members that priority areas will be even more complex.

The chair invited the reporting member to wrap the discussion up.

Mr. Berger joined Mr. Ludewig that speed is of the essence but thinks that it is not the task of the group to present a new procedure. It is for the Commission to deal with these recommendations and put them to reality. As regards Mr. Potdevin's remarks Mr. Berger underlines that the reporting members did not interfere with political reasoning. FTA need a fast track procedure but do also have to guarantee a minimum impact. Discussions of measures with minimal impact make little sense in view of the opportunity cost of the group. As regards the contest Mr. Berger would like to stress the underlying idea of

creating more enthusiasm and impetus. There is need of popular support, the contest is however only one idea of many ideas possible.

Mr. Illy underlined the need for a bottom-up approach. In view of the commitment of the Commission to reduce administrative burden it is the group's duty to deliver an opinion. He reminded members that the objective to reduce administrative burden by 25 % was set by the European Council, and that it is therefore up to the EU to give political priority to the FTA.

Ms. Fritsch regretted that no answers have been given to the questions raised in the draft opinion. These questions should therefore be transformed into statements. She underlined that she was not aware till today that new proposals could be made.

The chair explained his reasoning for convening the group for a special meeting which was to give the group the possibility to say a word on FTA in view of the timing of the Spring European Council. The group later-on has to deal in a far more structured way with the priority areas. Politically it seemed more than advisable to discuss this among members. It should be noted that the group has asked the Commission to stall the process of adopting the FTA list and has therefore an obligation to give an opinion. A consensus would be good but failing that a majority vote would be possible, too.

Mr. Ludewig saw no difficulty to reconcile the positions. The statement proposed is generally positive. Questions asked in the draft opinion can be answered after this meeting.

Ms. Fritsch clarified that she was also trying to go ahead with the opinion.

Mr. Murray clarified that no. 4 might be a good proposal but not to be put on a fast track. He further comes back to his view that the line on keeping out issues of political discussions by listing them as FTA should be entirely dropped.

Mr. Hontelez fully agrees with Mr. Murray on no. 4. He inquires about the destiny of no. 8 as well as to the final opinion adopted. He was concerned to propose new procedures without having discussed them in detail.

Mr. Telicka reiterated his point on asking the Commission to call upon Council and EP to speed up procedures.

Mr. Linschoten proposed to give a general support to the Commission, to call for more measures and speedier procedures.

Mr. Hontelez suggested to delete part of the text of the draft opinion regarding no. 4.

Mr. Koopman suggested that the person responsible for proposal no. 4 explains the background.

Mr. Terberger, HoU ENTR F2, explained the differences between national and European procedures. The idea is to harmonise the procedures and to avoid that a pharmaceutical company would have to go through 30 different procedures (27 MS and 3 EEA). The 60% refer to the work of the regulatory department, i.e. to get any modifications of testing requirements *et al.* through the above mentioned 30 different national procedures (instead of one harmonised approach).

The chair underlines that this is exactly what reduction of administrative burden is about and thanks for this clarification.

The group adopted the draft opinion subject to a dissenting opinion by Mr. Murray and Mr. Hontelez. Both members are of the view that proposal no. 4 should not be treated as a fast track action inasmuch as it concerns humane medicaments but in the context of the “normal” administrative burden reduction activities.

*This vote rendered the one on Mr. Hontelez’ drafting suggestion obsolete.*

Mr. Illy made the formal remark that modifications need to be put to vote before the vote on the final opinion.

#### **4) Working program and future organisation**

The chair would like to receive the views of the consortium without any prior assessment by the Commission. He asked the Commission when company law would be available.

Mr. Koopman stated that the consortium will have to deliver by 30 March. Deliverables will be transmitted to the group after a quality check by Commission services.

Mr. Illy requested that his document on procedures be circulated. He further inquired as to whether a press conference was planned after the meeting and whether it was true that a press conference was held exclusively with German press after the constituent meeting.

The chair confirmed that there had been a meeting with the press after the last meeting. The opinion of the group would be submitted to the press tomorrow. Besides, there would be a talk of himself and Mr. Berger with some particularly interested journalists, but no press conference was foreseen.

Mr. Ludewig proposed to invite the consortium to present the results on company law on April 15<sup>th</sup>.

The chair and the Commission agreed with this.

#### **5) Distribution of priority areas upon members**

Ms. Fritsch, Mr. Gibbons, Mr. Potdevin and Mr. Ludewig will share the work of company law and will discuss this among themselves and inform the chair. Members will be informed immediately thereafter. The final distribution of priority areas will be circulated to members.

Adopted by the HLG in Brussels on 15 April 2008