MENARINI

MENARINI BENELUX SA/NV
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Prof.
Ethics Committee

Zaventem, March 15th 2011

Subject: Study NeCaMic: end of the study notification EudraCT form
Your reference P2009/213 / 2009-014643-36 NeCaMic

Dear Prof.
Dear Mr.

We inform you that the Sponsor, MENARINI Benelux NV/SA, decided TO NOT PERFORM the clinical trial «Effects of the administration of Nebivolol versus Carvedilol on Microcirculatory endothelial function, arterial stiffness and wave reflection in healthy volunteers (NeCaMic Study).» (Référence EudraCT/ CCB 2009-014643-36),

since it is no more reasonable to undertake the proposed clinical trial, due to

- the many delays experienced in the planning of the proposed clinical trial previously foreseen to begin in September 2009,
- the time still needed to finalize the trial,
- the near expiry date of the medicines,
- the fact that the study has not yet begun, no patient being enrolled till now.

The Principal Investigator, Prof. , has been informed last week.

Please, find herewith the official EudraCT form for the notification of the end of this clinical trial.
We send it also today to the Belgian authority.

With kindest regards

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AFMPS – FAGG
La division R&D,
Dr [redacted]
Place Victor Horta 40, boîte 40
1060 - Bruxelles

Zaventem, March 15th 2011

Subject: Study NeCaMic: end of the study notification EudraCT form
Your reference: AFMPS/R&D/JSA/asa 195650

Dear Dr [redacted]

We inform you that the Sponsor, MENARINI Benelux NV/SA, decided TO NOT PERFORM the clinical trial «Effects of the administration of Nebivolol versus Carvedilol on Microcirculatory endothelial function, arterial stiffness and wave reflection in healthy volunteers (NeCaMic Study).» (Référence EudraCT/ CCB 2009-014643-36),

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- the time still needed to finalize the trial,
- the near expiry date of the medicines,
- the fact that the study has not yet begun, no patient being enrolled till now.

The Principal Investigator, Prof. [redacted], has been informed last week.

Please, find herewith the official EudraCT form for the notification of the end of this clinical trial.
We send it also today to the Ethics Committee.

With kindest regards

[redacted]

[redacted]

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : BELGIUM

B TRIAL IDENTIFICATION

B.1 EudraCT number :	**EudraCT number: 2009-014643-36**
B.2 Sponsor's protocol code number:	**MeBe/08/NEB-MICR/001**
B.3 Full title of the trial : Effects Of The Administration Of Nebivolol Versus Carvedilol On Microcirculatory Endothelial Function, Arterial Stiffness And Wave Reflection In Healthy Volunteers. (NeCaMic-study)	

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	☐
C.1.2	Legal representative of the sponsor	X
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation : Menarini Benelux SA	
C.1.4.2	Name of person to contact :	
C.1.4.3	Address :	
C.1.4.4	Telephone number : phone	Mobile:
C.1.4.5	Fax number :	
C.1.4.6	E-mail	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	X
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
•	Co-ordinating investigator (for multicentre trial):	☐
•	Principal investigator (for single centre trial):	☐
C.2.5	**Complete below** :	
C.2.5.1	Organisation: Menarini Benelux SA	
C.2.5.2	Name :	
C.2.5.3	Address :	
C.2.5.4	Telephone number : phone	Mobile:
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	Not applicable: study never started

D.2	**Is it an early termination?**[3]	yes ☐	no X

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.
3 Cf. Section 4.2. of the detailed guidance CT-1.

D.2.1	If yes, give date (YYYY/MM/DD):
D.2.2	Briefly describe in an annex (free text):
D.2.2.1	The justification for early termination of the trial;
D.2.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;
D.2.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	X
E.2.1	Date :	
E.2.2	Signature :	
E.2.3	Print name:	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	X
E.3.1	Date : 15/3/201	
E.3.2	Signatu	
E.3.3	Print na	

[redacted]

4 Section 4.3. of the detailed guidance CT-1.