DECISION

No. 35/13.12.2010

on amendment of Scientific Council Decision No. 16/07.06.2010 concerning change of the implementation date of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics

The Scientific Council of the National Agency for Medicines and Medical Devices, established based on Minister of Health Order No. 1123/18.08.2010, reunited on summons of the NAMMD President in the ordinary meeting on 13.12.2010, in accordance with Art. 12(5) of Government Ordinance No. 734/2010 regarding the organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Art. 1. - Point 5) of the Annex to Scientific Council Decision No. 16/07.06.2010 shall read as follows:

”5) Marketing authorisation holders as well as companies conducting consultation with target patient groups on their behalf are to be accredited and regularly subject to inspection by the National Agency for Medicines and Medical Devices (NAMMD), based on documentation approved by the NAMMD President and validated by the Scientific Council.”

Art. 2. – The supplementation of the Annex to Scientific Council Decision No. 16/07.06.2010 is approved, including the following points:

“6) There number of accreditations for Marketing Authorisation Holders as well as for the companies performing consultation with target patient groups is unlimited.

7) The tests concerning consultation with target patient groups may be performed by any internal/external operator compliant with the norms and requirements under the national legislation regulating the respective field.

8) When the report of results of the consultation with target patient groups is performed by a NAMMD accredited operator, the Agency considers that the procedures have been followed, thus providing for expediency in terms of evaluation and approval.

9) For reports containing the results of the consultation with target groups, performed by a NAMMD unaccredited operator, the entire evaluation procedure shall also involve assessment of this operator compliance with the criteria related

to its technical and professional capacity as well as to its capacity to ensure the quality system as set by the NAMMD."

Art. 3. – The accreditation and inspection criteria for operators performing consultation with target patient groups are approved in accordance with Annex 1 as well as with the Form for Accreditation Certificate request, which are integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX 1

Documentation concerning NAMMD accreditation and inspection criteria of operators performing consultation with target groups for medicinal product package leaflet

1. Purpose

This documentation establishes the general criteria to be met by the operators about to perform the mandatory consultation with target groups for the medicinal product leaflet.

The National Agency for Medicines and Medical Devices grants, renews or withdraws the accreditations granted to operators by enforcing the rules and criteria mentioned in this documentation.

2. Applicability

The criteria mentioned in this documentation envisage applicants for accreditation to perform target groups consulting activities needed for the medicinal product leaflet and the approval to the National Agency for Medicines and Medical Devices.
For compliance with the consultation quality standards, the accreditation of operators by the National Agency for Medicines and Medical Devices is optional, while the number of operators who may seek and obtain accreditation is unlimited. NAMMD grant of accreditation does not provide guaranteed contracts to accredited operators of consultancy services by beneficiaries for which the accreditation has been granted. The contracting and conduct of consultation activities is the exclusive responsibility of accredited operators and beneficiaries. Consulting activities are performed by accredited operators on request by and at the expense of beneficiaries (Marketing Authorisation Holders).

3. Relevant legislation and regulations

- *Government Ordinance No. 72/30.06.2010* published in the *Official Gazette of Romania, Part I, No. 452/02.07.2010* on the set-up of the National Agency for Medicines and Medical Devices by merger of the National Medicines Agency and the Technical Office for Medical Devices.
- *Romanian Government Decision No. 734/21.07.2010* published in the *Official Gazette of Romania, Part I, No.* 531/29.07.2010 on the set up and functioning of the NAMMD.
- *Law No. 95/14.04.2006 on healthcare reform, Title XVII – The medicinal product*, published in the *Official Gazette of Romania, Part I, No. 372/28.04.2006, as amended.*
- *Scientific Council Decision No. 21/07.11.2008 on approval of the Guideline on consultations with target patient groups for the package leaflet*.
- *Scientific Council Decision No. 22/07.11.2008 on approval of the Guideline on consultations with target patient groups - meeting the requirements of Article 59(3) of Directive 2001/83/EC without the need for a full test - recommendations for bridging*
- *Scientific Council Decision No. 8/26.06.2009 on the approval of the Guideline on the readability of the labelling and package leaflet of medicinal products for human use*
- *Scientific Council Decision No. 6/23.03.2010 on approval of the Guideline on consultations with target patient groups for the package leaflet*

- *Scientific Council Decision No. 16/07.06.2010 on change of the implementation date of the Guideline on conduct of consultation with target patient groups in view of the Summary of Product Characteristics, approved through SCD No. 6/23.03.2010*
- *Decision No. 161/23.03.2010 on the performance of activity in the context of the Authorisation Department – National Procedures Evaluation Service starting with March 2010.*

4. Definitions and abbreviations

Accreditation – procedure by which a certain competent authority officially acknowledges the fact that a body or person is entitled to perform specific tasks.
Operator – active legal entity, whose scope comprises activities of the same type as those for which accreditation is requested; the term "operator" is broadly understood as profit or non-profit legal entities, including partnerships with no legal personality.
MA – Marketing Authorisation
NAMMD – The National Agency for Medicines and Medical Devices

5. Responsibility and authority

The accreditation criteria are formulated by the Authorisation Department – *National Procedures Evaluation Service* and by the *Pharmaceutical Inspection Department* and approved by the President of the National Agency for Medicines and Medical Devices.

6. Accreditation criteria

6.1. Criteria concerning the legal capacity

The operator requesting the accreditation should be a profit or non-profit legal identifiable entity, set up in accordance with legal provisions in force in Romania or in the country in which it operates, whose scope includes activities of the same type as those for which accreditation is sought. Moreover, partnerships with no legal personality who meet all accreditation criteria may apply for accreditation.
To prove compliance with the criteria, operators shall submit to the NAMMD supporting documents showing:

- Identification data: name, acronym, if applicable, legal status, single registration code, fiscal code, year of establishment;
- Contact data: office address, addresses of the operation offices, telephone number, fax number, e-mail address, website etc.;
- Data about the share structure, membership, affiliation or other type of connection with other bodies, professional associations etc.

Operators requesting accreditation will have to prove that they are not subject to a liquidation or bankruptcy procedure by provision of the ascertaining certificate.

6.2. Criteria on the economic and financial capacity

The operators seeking accreditation should bring proof of their established economic-financial status (transmission of the balance sheet). The assessment of this criterion shall be performed by considering the contracts executed and completed, with the same contracted object, i.e. social and marketing research services.
Moreover, **the list of contracts related to similar services performed in the past three years shall be presented**, containing the following:

- Names/titles of the contracts,
- Their final certified value,
- Financing source,
- Performance period,
- Beneficiaries, irrespective whether contracting authorities or private customers,
- Percentage (%) of participation of the provider from the overall contract value
- Description of the services provided under the respective contract.

Their share is proved by the operator, by submission of any documents deemed relevant in this respect, e.g. statements of partners in the respective contracts, contract copies etc.

6.3. Criteria concerning technical and professional ability

The operators requesting accreditation shall display their technical and professional ability(ies) by submitting conclusive documents related to their **technical endowment and expert staff**, as well as by listing the **technical offers meant to be forwarded to beneficiaries**.

6.3.1. Technical endowment (Facilities)

Operators should prove their electronic storage capacity, specialised software and audio/video recording capacities, as well as of an adequate site for the performance of activities related to the purpose of research. Moreover, proof shall be made of the archiving ability for documents in both paper and electronic format.
The operator should own a database of subjects in accordance with the conditions stipulated in SCD No. 6/23.03.2010. Compliance with these conditions shall be assessed by inspections performed by NAMMD inspectors.

6.3.2. Expert staff

The economic operator shall prove their technical and professional ability by submission of an affidavit concerning the use of their own network of operators specialised in social/marketing researches. The statement shall contain the centralising table showing its own staff used in the research projects in the past 5 years, as follows:

Title of project and purpose of research	
Period	
Amount of research	
Reference population	
Type of research (quantitative/qualitative)	
Number of specialised interview operators (1)	
Number of county/regional coordinators (2)	
Number of national coordinators (3)	
Number of research assistants (4)	
TOTAL staff used per the project (sum of rows 1, 2, 3 and 4)	

The previously mentioned statement has to be accompanied by:

- CVs of the persons responsible for the performance of the activities for which accreditation is sought. These CVs are accompanied by copies of the documents to confirm the indicated ability and/or expertise.

Project coordinator

- Higher education in fields such as sociology/ psychology/ economics/ statistics/ marketing (graduate or bachelor), as required
- Graduate master studies in the field of sociology/ psychology/ economics/ statistics/ marketing (graduate or bachelor)
- At least 5 years' experience in sociological research projects.
- The coordination of at least 10 social/marketing research projects in the past 5 years
- Experience in the elaboration of methodologies, the assessment and elaboration of qualitative research reports within at least 3 research projects
- The expert's CV shall be accompanied by certificates/documents (letters of recommendation, contract copies, delivery-receipt protocols etc.) issued or countersigned by the contracting authority or by the private client for at least 3 qualitative research projects and 2 quantitative research projects.

Medical expert

The person responsible for the identification of key messages included in the medicinal products leaflets:

- Higher studies of medicine and pharmacy
- Specialisation studies
- Experience as a physician/pharmacist
- Any other type of experience in proof of constant interaction with patients as well as the frequent use of medicinal product leaflets.

Expert analyst

- Graduate master studies in the field of sociology/ psychology/ economics/ statistics/ marketing (graduate or bachelor)
- At least 3 years' experience in research projects
- The coordination of at least 5 social/marketing research projects in the past 5 years
- Experience in the elaboration of methodologies, the assessment and elaboration of qualitative research reports in minimum 2 research projects
- Experience in the coordination of at least one national research
- The expert's CV shall be accompanied by the certificates/documents (letters of recommendation, contract copies, minutes of grant/receipt etc.) issued or countersigned by the contracting authority or by the private client for at least 2 qualitative research projects and 1 quantitative research projects.

To prove similar experience, copies of certificates or references issued by employers/beneficiaries shall be attached, accompanied by copies of the specified diploma papers/study certificates attesting the indicated professional expertise.
Following the analysis and approval of the accreditation criteria, but prior to grant of the final accreditation, the NAMMD shall indicate to the operator requesting accreditation two medicinal products authorised for marketing in Romania, for which the operator will have to perform readability studies. This study must be conducted on Romanian patients in accordance with the criteria of the Guideline on conduct of consultation with target patient groups for the leaflet, approved through Scientific Council Decision No. 6/23.03.2010. A technical offer shall be presented for each of the two medicinal products and it shall contain the following chapters listed below:

6.3.2.1. Technical offer

6.3.2.2. Research and sampling design

6.3.2.3. Relevance of the proposed survey

6.3.2.4. Methodology for data analysis, warranties granted to ensure data quality

6.3.2.5. The format/content of data analysis reports

6.3.2.6. Estimated performance chart

6.4. Criteria concerning quality system ensurance

In proof of quality system insurance, the operator seeking accreditation should submit the Standard Operating Procedures for the following activities: extraction of key-messages and judgement of their relevance, set up of the questionnaire, interviewing of the selected subjects, data interpretation, performance of the final report, archiving of documents on paper and in electronic format.

ANNEX 2

Application form
Grant of the accreditation certificate for performance of consultation with target groups for the medicinal product leaflet

(Please fill in all relevant sections in this form using capitals, legibly, in black ink)

Section 1. Application form: Administrative data

1.1. Details of the applicant

Authorisation number (if previously authorised):

Name of the applicant:

Name of the representative*):

Address:

Postal Code:

Telephone number:

Mobile phone number:

Fax number:

E-mail address:

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*) The original document shall be attached, attesting the position as a representative.

Copies of the documents assessing readability shall be attached:

- The constitutive documents of the trade company (its status and contract);
- Irrevocable conclusion of the judge-delegate for authorisation and record of the trade company or final court decision, on a case-by-case basis;
- If applicable, a copy of the record certificate with the National Trade Register Office with its annexes and, if applicable, the registration accompanying certificates specifications;
- If applicable, the fiscal registration code
- The ownership/rent title of the trade company site(s)
- IBAN account
- The ascertaining fiscal certificate

1.2. Information about the contact person (if different from above)

Contact name:

Name of represented company:

Address:

Postal Code: Telephone number:

Mobile phone number: Fax number:

E-mail address:

1.3 Information on the invoicing address (if different from the address of the applicant for accreditation certificate)

Contact person:

Company name:

Address:

Postal Code: Telephone number:

Mobile phone number: Fax number:

E-mail address:

Section 2. Details on the types of activities performed and their sites

2.1. Information on the site for performance of identification of key-messages in the leaflet and judgement of their relevance

Name of the site:

Address:

Postal Code:

Contact name:

Telephone number: Fax number:

Mobile telephone number:

E-mail address:

2.2. Information on the site where data centralisation and processing issued from consultation with patient target groups are performed *(only fill in if different from 2.1.*)

Name of site:

Address:

Code:

Contact person:

Telephone number:

Fax number:

Mobile telephone number:

E-mail address:

2.3. Information on the site for the set-up of reports *(fill in only if different from 2.1.or 2.2; please specify if the sites are the same*)

Name of site:

Address:

Code:

Contact person:

Telephone number:

Fax number:

Mobile telephone number:

E-mail address:

2.4. Other activities you would like to mention *(only fill in if different from section 2.1., 2.2. or 2.3 ; please specify if the sites are the same*)

Name of site:

Address:

Code:

Contact person:			
Telephone number:		Fax number:	
Mobile telephone number:			
E-mail address:			

2.5. Other information

The following information is necessary for the inspectorate/expert, but is not be included in the accreditation certificate.

Are you aware of the relevant SCD provisions for consultation with target groups of patients for the leaflet?	† yes † no
Are there Standard Operating Procedures (SOPs) available, for performance of activities seeking accreditation? Please attach a copy of the SOPs on paper or in electronic format.	† yes † no
Are your contracts available for inspection/review? Please attach a copy of the contracts on paper or in electronic format.	† yes † no

2.6. Equipment/facilities at the site of performance of consultations

On a separate sheet, please provide a brief description (ca. 500 words) of facilities available for performance of consultation with target patient groups.

Section 3. Appointed persons

Please specify below the staff categories working at the site of performance.

Staff	Number
Study coordinator	
Physician	
Pharmacist	
Sociologist/Psychologist	
Statistician/Marketing specialist	

For each staff category listed above, fill in one of the following pages.

3.1. **Study coordinator**

A relevant CV should be attached for the study coordinator; the appointment of the study coordinator should be signed by the appointed person and by the applicant.

Surname:

First name:

Office address:

Postal Code:

Telephone number:

Fax number:

Mobile telephone number:

E-mail address:

Skills (relevant for the accreditation certificate):

Experience (Brief description of the jobs and responsibilities relevant for the accreditation certificate):

Please specify the social/marketing researches in which you have been involved and required in accordance with the Accreditation Criteria (6.3.2.)

Membership in professional associations:

I hereby confirm that the previous details are correct and valid according to my knowledge and opinions.
I agree with my appointment as study coordinator.

Signature (of the appointed person): .....

Date: .....

Name in print: .....

Signature (of the applicant): .....

Date .....

3.2. **Medical expert**

A relevant CV should be attached for the proposed medical expert/expert pharmacist; the appointment of the medical expert/expert pharmacist should be signed by the appointed person and by the applicant.

First name:			
Surname:			
Office address:			
Postal Code:		Telephone number:	
Fax number:		Mobile telephone number:	
E-mail address:			

Skills (relevant for the accreditation certificate):

Experience (brief description of the relevant jobs and responsibilities needed for grant of the accreditation certificate)

Membership in professional associations:

According to my knowledge and opinions, I hereby confirm that the previous details are correct and valid.
I agree with my appointment as expert physician/pharmacist
Signature (of the appointed person): .....

Date: .....

Name in print: .....

Signature (of the applicant): .....

Date .....

3.3. Expert analyst

A relevant CV should be attached for the expert statistician; the appointment of the expert researcher should be signed by the appointed person and by the applicant.

First name:			
Surname:			
Code:		Telephone number:	
Fax number:		Mobile telephone number:	
E-mail address:			

Skills (relevant for the accreditation certificate):

Experience (brief description of the relevant jobs and responsibilities needed for grant of the accreditation certificate)

Please specify the social/marketing researches in which you have been involved and required in accordance with the Accreditation Criteria

Membership of professional associations:

I hereby confirm that the previous details are correct and valid in accordance with my knowledge and opinions. I agree to be appointed expert researcher.
Signature (of the appointed person): .....

Date: .....

Name in print: .....

Signature (of the applicant): .....

Date.....

Section 4. Data concerning the activity of the institution/consortium

Please specify the relevant contracts/ studies previously performed, while stating the date of performance, activity performed, site, number of persons involved, number of investigated persons, contract details, outcome of the inquiry.

Section 5. Comments

Please specify any other information deemed helpful in support of your application. Furthermore, you could specify any change of the addresses, appointed persons etc.

Section 6. Declaration

I hereby request the grant of the accreditation certificate to the hereby appointed holder, with regard to the activities specified in this application.

5.1. Activities shall be compliant with the information in this application or submitted in relation thereof.

5.2. According to my knowledge and opinions, the details in this application are accurate and complete.

Signature (of the applicant): .....

Date: .....

Name in print: .....

Position as a signatory: .....