

Memorandum of Understanding (MoU)

Between

European Society for Swallowing Disorders (ESSD)
represented by its president Prof. Pere Clavé

And

European Stroke Organisation (ESO)
represented by its president Bart van der Worp

This Memorandum of Understanding (MoU) sets for the terms and understanding between the ESSD, and the ESO to cooperate in the ESSD proposal for labelling of agents for fluid thickening to treat patients with oropharyngeal dysphagia.

Background

The ESSD and ESO are scientific organizations with similar missions: to encourage and provide research, education and awareness in their respective fields. Dysphagia is underdiagnosed and undertreated, diagnosis and treatment are not standardized and often lack scientific evidence and authorities and decision makers are generally unaware of the problem. Across Europe, patients with dysphagia do not receive the same level of diagnosis and treatment which is one of their basic rights. One of the main treatments consists of thickening fluids and there are thickening agents available to patients and classified as Food for Special Medical Purposes (FSMP) in most countries.

The ESSD has recently published a white paper on bolus modification concluding that there is evidence for increasing viscosity to reduce the risk of airway invasion and that it is a valid management strategy for OD (Dysphagia 2016 Apr;31(2):232-49). The ESSD also stated that human clinical trials should establish the optimal viscosity level for each phenotype of patients with dysphagia and terminology and viscosity measurements must be standardised. However, manufacturers do not specify dose, viscosity or composition of their products, and use qualitative descriptors, and the result is that patients are provided with similar sounding products with different therapeutic properties. We believe that this information (dose, viscosity and composition) would enhance the safety of patients and better comply with the EU regulation on labelling for FSMP.

The ESSD has developed a proposal to include specific information on the label of thickening agents and pre-thickened products based on scientific evidence and using the International System of Units.

Purpose

This MoU constitutes an agreement between the ESSD and ESO to promote the ESSD labelling proposal to authorities, health care professionals, patients and the public.

Objectives

- to bring into use the ESSD scientific labelling system for thickening agents and pre-thickened products in Europe (see below)
- to promote and spread the labelling proposal around Europe
- to promote the knowledge of dysphagia and its complications, and the proper use of thickening agents and texture modified foods for these patients
- to bring the labelling proposal to the attention of international scientific societies, related societies and national and European authorities
- to provide in each product a product data sheet with information for patients including the instructions for use, therapeutic information, and safety information.

The above goals will be accomplished by undertaking the following activities:

- to promote the labelling system within the societies
- to educate health care professional members of each society in the appropriate form of prescribing and use of thickening agents when diagnosing and managing dysphagia patients to approach the corresponding national authorities, dysphagia societies and related societies using the logo of both societies

Responsibilities of the partners

- Partners will seek to find consensus on global issues concerning dysphagia management and the use of thickening agents
- Partners will explain and promote the labelling system to their members, and cooperate offering information sessions
- Partners will endorse and promote the labelling system and the information for patients to international bodies, the industry and other stakeholders
- Each partner will appoint a member/members to join a committee made up of members of societies which sign similar MoUs and which will follow the implementation of the labelling proposal

Reporting and Evaluation

A report on the development of the proposal, steps taken, responses and agreements will be made each year and a plan for the following year will be drafted by the committee.

Funding

Activities to promote the labelling proposal will be funded by the ESSD subject to prior approval of the budget of the activity. Updates and meetings will be held at the congresses of the partners when possible.

Duration

The agreement is initially for a three-year period and can be renewed.

This MoU is at-will and may be modified by mutual consent of authorized officials from the ESSD and ESO. This MOU shall become effective upon signature by the authorized officials from the ESSD and the ESO and will remain in effect until modified or terminated by any one of the partners. Partners agree to inform the other partners of their decision to terminate their participation in the MoU in writing.

Contact Information

Partner name: European Society for Swallowing Disorders (ESSD)

Partner representative: Prof. Pere Clavé, MD, PhD

Position: President of the ESSD

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Partner name: European Stroke Organisation (ESO)

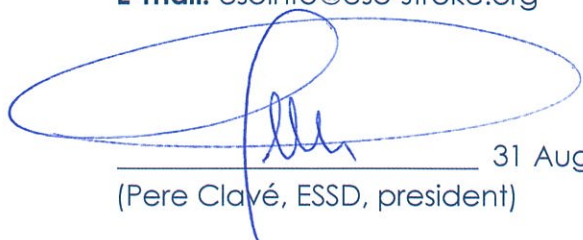
Partner representative: Dr. Bart van der Worp

Position: President of the ESO

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31 August, 2018
(Pere Clavé, ESSD, president)



31 August, 2018
(Bart van der Worp, ESO President)



31 August, 2018
(Urs Fischer, ESO Secretary)



European Society for
Swallowing Disorders

www.myessd.org



ESSD LABELLING PROPOSAL

ESSD requests manufacturers of thickening agents and pre-thickened products to include the following information on their products.

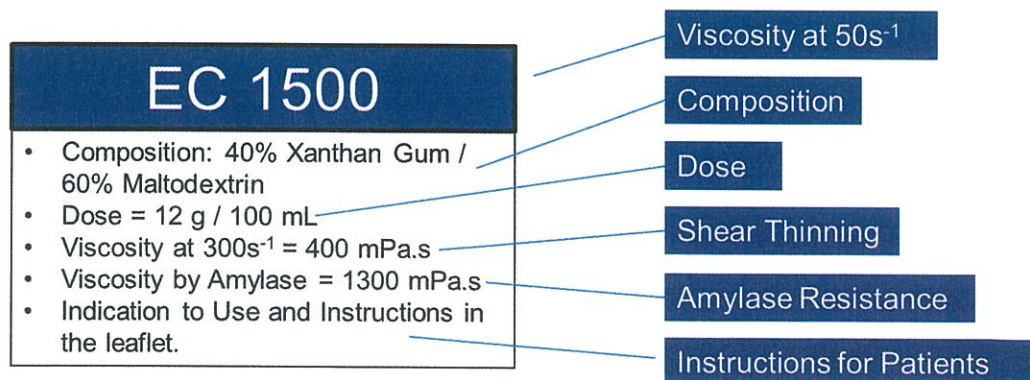
Product Label must include:

- The name of the classification system of viscosity levels for fluid thickening (EC) together with the apparent viscosity (mPa.s) at 50s^{-1} and 25°C (e.g. EC1500)
- SI Units of viscosity (mPa.s) to describe the levels of viscosity given (scientifically measured and reported)
- The composition and amount of thickening agent (Gums vs MS vs others)
- Shear thinning and amylase resistance
- Future: Other rheologic properties (cohesiveness) or stimulants

The composition of thickening agents must be indicated as the different types of thickeners (gum, starch) behave differently.

In the future, other rheological properties such cohesiveness or stimulants can be added

This is an example of the label with the information we consider necessary:



This label could also be adapted to thickeners commercialised in pots where different viscosities can be produced. In this case, manufacturers should give the viscosity values needed to treat almost all the population (previously determined and proved by clinical trials).

Composition: 40% Xanthan Gum / 60% Maltodextrin <i>Indication to Use and Instructions in the leaflet</i>			
Viscosity at 50s ⁻¹	Dose (g/100mL)	Viscosity at 300s ⁻¹	Viscosity with amylase
EC 300			
EC 900			

In addition, the information we request on the product data sheet is the following:

Instructions for use

- The amount of thickener (g/100mL) to reach the desired viscosity (e.g. EC1500) with mineral water and different alimentary fluids.
- The conditions/procedure to prepare each viscosity level

Therapeutic information

- Evidence on the therapeutic effect (safety and efficacy) and recommended viscosity levels for each phenotype of patients with OD
- Manufacturers should provide evidence of what they claim (clinical trials)

Safety information

- The effect of shear thinning at shear rates that modulate oral (50s⁻¹) and mesopharyngeal (300s⁻¹) flow
- The effect of salivary amylase on each level of viscosity

We also ask them to provide evidence on the therapeutic effect (safety and efficacy) for each viscosity level they recommend and for each of the main phenotypes of patients with OD (stroke, elderly, neurodegenerative disorders and head and neck diseases).