EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Human Medicinal products (CHMP)
Committee for Veterinary Medicinal products (CVMP)

Overview of comments received on 'Guideline on the use of Near Infrared Spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations' (EMEA/CHMP/CVMP/QWP/17760/2009 rev 1)

List of interested parties (organisations or individuals) that commented on the draft document as released for consultation:

Stakeholder no.	Name of organisation or individual
1	AESGP, Association of the European Self-Medication Industry
2	Bodgan Kurtyka, FDA
3	Bristol-Myers Squibb
4	BÜCHI Labortechnik AG
5	Baxter AG
6	Cefic, The European Chemical Industry Council
7	EDQM PAT WP, Ph.Eur. Process Analytical Technology Working Party of the European Directorate for the Quality of Medicines and HealthCare
8	EFPIA, European Federation of Pharmaceutical Industries and Associations
9	EGGVP, European Group for Generic Veterinary Products
10	IFAH-Europe, International Federation for Animal Health
11	Dr.-Ing. Ralf Marbach, Finland
12	Merck, Sharp & Dohme Europe Inc.
13	CBG MEB, Dutch Medicines Evaluation Board
14	Novo Nordisk A/S
15	Novartis Pharma AG
16	PDA Europe, Parenteral Drug Association
17	Thermo Fisher Scientific
18	Wyeth Pharmaceuticals

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Summary of comments received

The guideline on the use of Near Infra Red Spectroscopy was published for public consultation in 2009 (Doc. Ref: EMEA/CHMP/CVMP/QWP/17760/2009 Rev1). Many stakeholders have taken the opportunity to comment on various aspects of the draft revised guideline. In view of the amount of comments received, the drafting group organised a break out session to discuss and clarify the comments received from the following interested parties: EDQM, BUCHI, Cefic, EFPIA and PDA Europe. This break out session took place during the Quality Working Party meeting in May 2011.

Following the fruitful discussions at the break out session, the guideline was further revised to implement the conclusions from that meeting. Given that important changes have been made in the new version of the guideline, this new version is now published for a second round of public consultation. A summary of the main comments received during the first public consultation is presented below to clarify the changes made in this new version. The drafting group wishes to thank all stakeholders for their valuable contributions to the revision of this guideline.

The table below summarises the main topics on which the stakeholders commented and sets out the position of the drafting group

General comment	Outcome
Scope of the guideline and PAT Various comments were received on what the scope of the guideline should cover.	The scope of the guideline has been discussed during the break out session. It was agreed that additional guidance about NIR applications in PAT should be given in the guideline.
Sampling Several stakeholders commented on the sampling requirements defined in the guideline.	The requirements in relation to sampling have been discussed at the break out session. A long and successful discussion showed that sampling is a key issue in NIRS. It was agreed that it is very important that regulators get detailed information about samples, their properties and how these samples are used in the NIR method life cycle. The drafting group agreed to clarify the section on sampling requirements and has updated that section of the guideline accordingly.

General comment	Outcome
Terminology Many stakeholders pointed out that a clear and consistent terminology should be used in the guideline.	The terminology to be used in the guideline has also been discussed at the break out session. The participants expressed that there is a need to harmonize the terminology with the terminology used in other related analytical fields (chemometric, IR etc). The drafting group acknowledges the comments. Harmonisation of terminology is difficult because different terms and definitions are used by other parties. The drafting group doesn't see the possibility to change this situation soon. Hence, the drafting group proposes to consequently use the terms which are defined in the guideline. If applicants would like to use different terms it is mandatory to define and explain those in detail in their dossier.
Model Life Cycle and Change Control (GMP and variations) & Method transfer Several stakeholders proposed to clarify the section on NIRS lifecycle and post-approval requirements.	The participants of the break out session requested clarification of the terminology used in this section. It was agreed that the guideline should address the two different levels of complexity that exists with a transfer. The drafting group has revised the guideline to reflect these two scenarios (see section 7.3). Furthermore, it was agreed that in case of a transfer a comparability protocol is needed to determine whether the observed differences between instruments require a recalibration and revalidation. If so, this results in a variation submission. In case the results of the comparability protocol demonstrate negligible differences, method transfer is subject to GMP.
Chemometrics (Need of Pivotal Statistical Key Parameters) Some stakeholders commented on whether the guideline should, or should not, set thresholds for pivotal statistical key parameters for model validation.	The need to define pivotal statistical key parameters (and tresholds) has been discussed at the break out session. The guideline has been revised to take into account the agreement reached at the break out session.

General comment	Outcome
Data Requirement Many stakeholders pointed out that the guideline should be more clear in relation to the data requirements for initial applications and variation applications in which NIR is used.	The data requirements have been discussed at the break out session, and because of the divergent views, complete agreement was not possible. The drafting group considers that the data requirements depend on the scope of the NIRS procedure, its intended use.