European Directorate for the Quality of Medicines & HealthCare

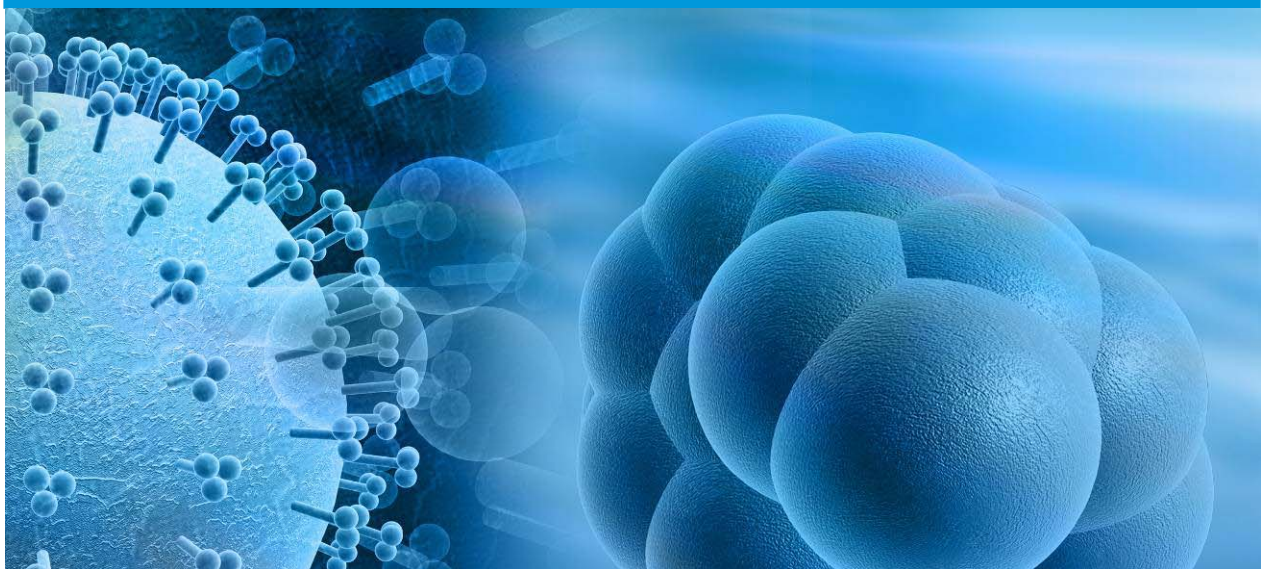
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 December 2011
EMA/902224/2011

Joint EMA/EDQM workshop on improved potency assays for inactivated influenza vaccines

Draft workshop programme

12 December 2011, 8.30-17.00 (UK time)
European Medicines Agency, London, United Kingdom



See websites for contact details

European Directorate for the Quality of Medicines & HealthCare www.edqm.eu
Council of Europe www.coe.int
European Medicines Agency www.ema.europa.eu

Programme overview

Scope

The lessons learnt exercise performed after the 2009 influenza pandemic recognised that the assays used for content of the hemagglutinin (HA) component in the influenza vaccine dose should be reviewed. During the pandemic and as part of the lessons learnt exercise, issues related to the interpretation due to variability/standardisation of the assays used for content determination were raised and particularly at the successive expert meetings held at the European Medicines Agency in July 2009, April 2010 and June 2010.

Quantification of HA by the single radial immunodiffusion (SRID) assay has been for many years the recognised/accepted method to monitor potency (content) of trivalent seasonal influenza vaccines for HA antigen. The current SRID method however requires, for each of the three HA antigens, strain-specific virus reagents which may not be available when the early batches of a vaccine have to be filled and released for either clinical trial confirmatory tests or to speed up the early access to pandemic vaccine doses. During the expert meetings and lessons learnt exercise, it has been raised that alternative assays to measure the content of HA should be investigated and their relative performance validated against the current SRID, before being used on a routine basis. The timing of use of such assays will need to be discussed (e.g. at an early stage of development/qualification of the new strain vaccine until the SRID test reagents become available, and/or for a more general use as alternative assays to SRID). Also techniques for the characterisation of neuraminidase (NA) component and its assays could be considered.

The guidelines on influenza vaccines are being reviewed as part of the lessons learnt exercise. In this context, it is proposed to hold a technical workshop to prepare the work and feedback the revision exercise of the guidelines. Furthermore it will be reviewed whether there are still gaps in the development and validation of alternative assays and how these gaps can be filled.

The development of assays for HA content may impact the batch release and official control laboratory network (OMCL) testing and potential future revision of the European Pharmacopoeia monographs for influenza vaccines.

Chairs and rapporteurs

Jean Hugues Trouvin (workshop co-chair)
Chairman of the CHMP's
Biologicals Working Party / AFSSaPS

Phil Minor (workshop co-chair)
NIBSC

Ton van der Stappen (Rapporteur)
Member of the CHMP's
Biologicals Working Party / MEB

Joep Bergers (Rapporteur)
RIVM

Programme details

Monday, 12 December 2011 – Room 4A

8.00 Registration and coffee

Please register with reception (ground floor) to receive your security badge.

8.30 Welcome and introduction

Jean Hugues Trouvin (workshop co-chair)
Chairman of the CHMP's Biologicals Working Party / AFSSaPS
Phil Minor (workshop co-chair)
NIBSC

8.45 SRD (current) assay

Reagents, origin, supply, timelines, calibration, antigen issues, antiserum issues
Una Dunleavy *(15 minutes)*
NIBSC

Usage of SRD/comments
Francois Cano *(15 minutes)*
AFSSaPS OMCL
Tony Colegate *(15 minutes)*
EVM (Novartis)

9.30 Alternative assays (non-SRD) used for IPCs and/or determination of Haemagglutinin content for drug substance and finished product: used in parallel with SRD or stand-alone – pros/cons

Characteristics for an improved potency assay & how the different methods compare in light of these characteristics
Pascale Gonnet *(20 minutes)*
EVM (Sanofi-Pasteur)

HPLC *(60 minutes)*
Dieter Pullirsch *(10 minutes)*
AGES OMCL
Francois Cano *(10 minutes)*
AFSSaPS OMCL
Hans Kapteyn *(30 minutes)*
EVM (Abbott)
Michel Girard *(note: presentation to take place later in the morning) (10 minutes)*
Biologics and Genetic Therapies Directorate, Health Canada

10.50 – 11.10 Coffee break

Coffee will be available outside the meeting room.

Other methods such as ELISA, SDS-PAGE, MS, SPR *(50 minutes)*

– ELISA

Ethan Settembre

EVM (Novartis)

Kendra Frederick

Protein Sciences

– SDS-PAGE

Jane King

EVM (Novartis)

CBER experience on alternative assays

Maryna Eichelberger *(15 minutes)*

Center for Biologics Evaluation & Research, US Food and Drug Administration

Comparison of alternative methods

Othmar Engelhardt *(15 minutes)*

NIBSC

12.30 Potential assays for investigating the Neuraminidase content

Elisabeth Neumeier *(10 minutes)*

EVM (GlaxoSmithKline Biologicals)

Towards qualitative and quantitative analyses of Neuraminidase in influenza vaccines - an update *(10 minutes)*

Sean Li

Biologics and Genetic Therapies Directorate, Health Canada

Assessment of Neuraminidase in vaccines – update from CBER *(10 minutes)*

Maryna Eichelberger

Center for Biologics Evaluation & Research, US Food and Drug Administration

13.00 – 14.00 Lunch

14.00 Moving forward - all participants - discussion

Feedback from the Vaccine Working Party: clinical relevance of alternative assays *(10 minutes)*

Michael Pfleiderer

Chairman of the CHMP's Vaccine Working Party / PEI

A) Haemagglutinin

i. Value/limitation of currently published studies on alternatives

ii. Validation of improved assays/clinical validation

iii. Is a measure of HA protein content sufficient? If not, what else would be required (validation)?

iv. Combination approach: - company specific assay for IPC + internationally agreed immunogen assay, or - internationally agreed protein assay + internationally agreed immunogen assay?

v. Stand-alone assay – how to validate?

vi. Develop Ph.Eur. mononographs?

vii. Industry experience and comments

viii. Consideration of SRD – how to improve variability/timelines, can they be?

ix. Future assays for novel vaccines

x. Recommendations for future studies/collaborative studies

B) Neuraminidase

16.00 – 16.30 Coffee break

Coffee will be available outside the meeting room.

16.30 Wrap-up / Concluding remarks