FUEHRING Stefan (SANCO)
From: MERJ (Merete Jørgensen) [merj@novonordisk.com] Sent: jeudi 30 septembre 2010 13:18 To: SANCO PHARMACEUTICALS Cc: LBWR (Lill-Brith von Arx); MERS (Merete Schmiegelow); VBJE (Vibeke Bjerregaard); christinelisejulou@efpia.org Subject: Novo Nordisk additional comments to Implementing guidance - for EudraCT SANCO/C/8/SF D(2010) Importance: High

Submission of additional comments to: Implementing Technical Guidance - List of fields for result-related information to be submitted to the 'EudraCT' clinical trials database, and to be made public, in accordance with Article57(2) of Regulation(EC) No 726/2004 guidelines 2008/C168/02 and 2009/C28/01 Novo Nordisk A/S is supporting the comments provided by EFPIA and would in addition to these contribute with the additional comments below. Section 2, page 3, Timing:

Adequate reporting of results of paediatric studies within the 6 months timeframe will in many cases not be possible, if the 6 months is calculated from Last Subject Visit. We support the general suggestion from EFPIA to expand the timeframe to 8 months, with the option of expansion for a specific reason as stated in the Regulation. In addition to suggesting an extension of the 6 months period, a way forward could also be to clarify of the definition of 'study completion'. I.e. if Study completion is defined at date of availability of the last data point/lab analysis result.

Section 2, page 3, follow-up submission: In contrast to clinicaltrials.gov which requires a yearly review of the accuracy of the trials registration, the results provided to the EU clinical trials database will be locked after a period of 1-2 years. Why is this seen as necessary? Update should be possible whenever more recent results are present.

Section B. Page 18, Row B37: In the Population section, it is suggested that they use the same terminology as in ICH-E9 Biostatistics, I.e. Full Analysis Set (FAS) in stead of ITT.

Section B, Page 27, Row R64: Suggestion that additional statistical measures are allowed under a category of other. Within Statistics a lot of innovation is made, and these new methods should also be allowed to be referenced.

Section B, Page 37, Row R112: Proposal is to harmonise with clinicaltrials.gov on presenting the Adverse Event information. It is important to request a harmonisation to the way safety information is generally submitted and presented in regulatory documents. This is at present not the case with the current table for non-serious adverse events at clinicaltrials.gov. The issue is that the cut-off used to determine the more frequent events is applied for the non-serious events alone, whereas in regulatory documents in general the cut-off is applied for the total number of events i.e. counting both Serious and non-serious (same type of event might occur both as categorised as serious and as non-serious). On behalf of Novo Nordisk A/S Kind Regards
5/11/2010

Merete Jørgensen _____

Merete Jørgensen Director Global Clinical Registry

Novo Nordisk A/S Vandtårnsvej 114 Building VTB1.B1 DK-2860 Søborg Denmark +45 4444 8888 (phone) +45 30 79 17 28 (mobile) +45 39699173 (fax) merj@novonordisk.com

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