EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

List of questions for the workshop on paediatric diabetes

General questions:

1. For non-inferiority studies in paediatric diabetes, which would be considered an acceptable delta for HbA1c, vs. insulin or metformin?
2. For new insulin analogues (prolonged or rapid action), do you think that actual data in adolescents with type 2 diabetes are not necessary, as they can be extrapolated from available data in type 2 diabetes in adults and in type 1 diabetes in adults and children? If not, what type of studies would you consider needed, before marketing authorisation?

Type I diabetes in children/adolescents

3. Do you think that there is a need for additional long-acting insulin analogues (in addition to detemir and glargine) in the treatment of type 1 DM in children?
4. Do you think that the incidence of hypoglycaemia should be a primary endpoint, or a co-primary with HbA1c, for children younger than 6 years of age with type 1 diabetes?
5. For the detection of the total number of nocturnal hypoglycaemia episodes in children, what is the best method between CGMS and repeated BG samples? (Please detail for children below the age of 6, 6 to puberty, puberty to 18).
6. If nocturnal or 24hr CGMS sampling is performed, for how many nights/days should it be conducted, in order to be able to compare the incidence with two different treatments?
7. Are there enough patients with T1DM below the age of 6 (between 1 and 6) to perform efficacy or safety studies with significant endpoints?

Type II diabetes in children/adolescents

8. Do you think that there is a need for long-acting insulin analogues in the treatment of type 2 DM in adolescents?
9. When studying the efficacy of a new drug for type 2 diabetes in adolescents, vs. placebo, is it acceptable to include in the study both naïve patients (i.e. non-drug treated) and patients currently taking metformin?
10. Since post-prandial glucose levels have an estimated greater effect size than HbA1c, their use as primary endpoint may help in reducing the number of patients needed for clinical trials in paediatric type 2 diabetes. Would this be acceptable in paediatric studies, if data on HbA1c levels are available in adults?

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