

Executive Summary

Introduction

Zanamivir (Relenza™) is currently recommended for treatment of influenza in at-risk adults who present to their GP within 48 hours of the onset of symptoms (Technology Assessment 58 (TA58)(1)) The most recent review of guidance took place in 2002/3, at which point Relenza was not licensed for paediatric use and as a result, only oseltamivir (Tamiflu™) was recommended for treatment of influenza in children under twelve (treatment to begin within 48 hours of the onset of symptoms). Since this last review however, the Relenza license has been amended to include treatment in children aged 5 and above (2), and therefore the current review is being conducted primarily to consider whether Relenza should be recommended in this age group. In this submission we therefore focus on the evidence relevant to this question

Clinical Efficacy

The studies previously included in TA58 are tabulated in Table 1. Two of these studies, NAI30009 and NAI30010, are relevant for the treatment of children under 12, together with a further study, NAI30028, which was not completed at the time of the last review. The design and findings of these three studies are summarised below, and full clinical trial reports are included on the accompanying CD-ROM.

In addition, four studies of treatment in adults were identified but not included by the assessment group in the 2002/3 review of guidance, the reason given for this being unavailability of data. Results for three of these studies (NAI30011, NAI30012 and NAI30015) were in fact submitted to the 2002/3 review by GSK at the time, but the Clinical Study Reports are provided on the enclosed CD-ROM for completeness. Results are also now available from the fourth study (NAI30020), a synopsis of which can be found on the GlaxoSmithKline Clinical Trial Register (3) (no clinical trial report available). As these four studies are not related to the paediatric indication they have not been discussed in this submission, but they are listed in the "other studies" section, below.