

## Further reporting requirements

Please follow the guidance below if you answered 'YES' to any of questions 5 to 8

### **Question 5: Have you and your child had to seek medical advice because of your child's flu-like illness or complications of this (e.g. chest infection, ear infection)?**

- There is no need to complete an Adverse Event Report form for new or worsening symptoms or complications which you consider to be consistent with progression of the child's flu-like illness episode unless they result in a Serious Adverse Event, which: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalisation or prolongation of existing hospitalisation, iv) results in persistent or significant disability / incapacity, v) is a congenital anomaly / birth defect, vi) other important medical event.

### **Question 6: Has your child had to stay in hospital for one or more nights for ANY reason?**

- Please complete a Serious Adverse Event report form for each hospital stay which lasted one or more nights, regardless of the reason for the hospital admission.

### **Question 7: Has your child had any of the following side-effects from his or her study medication?**

- Diarrhoea, vomiting, nausea and thrush are all known common side-effects of co-amoxiclav.
- Please complete an Adverse Event Report form if these side-effects are clinically severe. There is no need to complete an Adverse Event Report form if these side-effects are clinically mild or moderate.
- Please also complete a Serious Adverse Event Report form for any side-effect(s) which: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalisation or prolongation of existing hospitalisation, iv) results in persistent or significant disability / incapacity, v) is a congenital anomaly / birth defect, vi) other important medical event.

### **Question 8: Has your child had any new unexpected symptoms or illnesses since entering the study?**

- Please complete an Adverse Event report form for each new unexpected symptom or illness.
- Please also complete a Serious Adverse Event Report form for any symptom or illness which: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalisation or prolongation of existing hospitalisation, iv) results in persistent or significant disability / incapacity, v) is a congenital anomaly / birth defect, vi) other important medical event.
- There is no need to complete an Adverse Event Report form for new or worsening symptoms which you consider to be consistent with progression of the original influenza-like illness episode unless they result in a Serious Adverse Event according to the above definition.

### **Reporting instructions**

- Adverse Event Report forms and Serious Adverse Event Report forms should be emailed to [archie@phc.ox.ac.uk](mailto:archie@phc.ox.ac.uk)
- Please forward Serious Adverse Event Report forms within 24 hours becoming aware of the event.