Consultation response

COMMISSION GUIDELINE ON THE FORMAT AND CONTENT OF APPLICATIONS FOR PAEDIATRIC INVESTIGATION PLANS

(ARTICLE 10 OF REGULATION (EC) NO 1901/2006)

CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

Deadline for public consultation: 18 December 2013

This is the response from the Neonatal and Paediatric Pharmacists Group (NPPG).

NPPG is a stakeholder organisation.

NPPG was formed in 1994, with the aim to improve the care of neonates, infants and children by advancing the personal development of pharmacists and the provision of quality pharmacy services in relation to practice, research and audit, education and training, communication and advice. Membership is open to any pharmacist, pharmacy technician or corporate body with a pharmaceutical interest in paediatric or neonatal pharmacy.

The group has links with various paediatric organisations. The Medicines Committee is a joint committee of the Royal College of Paediatrics and Child Health (RCPCH) and the NPPG. The Medicines Committee has highlighted paediatrics at Government level and as part of that framework the first national paediatric formulary (Medicines for Children) was produced. That venture joined forces with the BNF and in 2005 the first BNF for Children (BNFC) was distributed to all prescribers in the UK. The BNFC is now published annually and NPPG has input to the review and updating of the information contained. NPPG also works closely with several Department of Health groups, as well as NICE and the Health Commission.

Consultation item No 1: Do you have any comments on the format and content of applications for agreement on or modification of a paediatric investigation plan and requests for waivers or deferrals?

It seems appropriate to use the same format. Completion of only the sections which needs to be changed should simplify the process which may improve timeliness.

Consultation item No 2: Do you have any comments on the operation of the compliance check and/or the compliance statement?

We have no specific comments on this section.

Consultation item No 3: Do you have any comments on the assessment criteria for significant studies?

These criteria seem reasonable.

Consultation item No 4: Do you have any comments on the key elements of a paediatric investigation plan? Is it appropriate to list key elements in this guideline or should key elements only be specified in the individual decision of the Agency agreeing a specific paediatric investigation plan?

We are happy with the key elements listed. We do consider that it is appropriate to list the key elements for completeness and transparency.

Consultation item No 5: Please feel free to raise any other issues or make any comments which have not been addressed in the consultation items above.

Overall - we consider that the Paediatric Regulation has been a major step forward. NPPG welcomes the proposed changes which provide clarity for those who wish to submit a PIP. It is essential that a framework is in place to ensure that the pharmaceutical companies follow through their PIPs in a timely manner and therefore provide the information and formulations required.

We particularly welcome the clarification provided on the Formulation aspects of the document in Section 2.5.2. as it is important that suitable age appropriate formulations are developed for children. We would recommend that the EC through the EMA has specific systems in place to gather information from completed paediatric formulation studies to enhance the recent *Guideline on pharmaceutical development of medicines for paediatric use*.

We hope that these proposed changes improve the uptake of appropriate PIPs.