ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ & ΚΟΙΝΩΝΙΚΗΣ ΑΛΛΗΛΕΓΓΥΗΣ
ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ
ΜΕΣΟΓΕΙΩΝ 284, 155 62
ΧΟΛΑΡΓΟΣ
www.eof.gr

Πληροφορίες : Κ. Κεχαγιά

Τηλέφωνο: **+30-213-2040-242**

FAX: +30-210-6547202

e-mail: kkehagia@eof.gr

Χολαργός 23/06/2008

Αρ. πρωτ 41956

ΕΓΚΥΚΛΙΟΣ

Θέμα **Συλλογή στοιχείων για τη δημιουργία «Αρχείου Φαρμάκων με Παιδιατρική Χρήση» (Κανονισμός ΕΚ 1901/2006, άρθρο 42)**

Έχοντας υπόψη

1) Τον Κανονισμό (ΕΚ) αρ 1901/2006 του Ευρωπαικού Κοινοβουλίου και της Επιτροπής της 12ης Δεκεμβρίου 2006 για τα παιδιατρικά φάρμακα και για την τροποποίηση του κανονισμού (ΕΟΚ) αρ 1768/92, της οδηγίας 2001/20/ΕΚ, της οδηγίας 2001/83 /ΕΚ και του κανονισμού (ΕΚ) αρ 726/2004 φαρμακευτικά προϊόντα με παιδιατρική χρήση (άρθρο 42)
2) Την Οδηγία για το περιεχόμενο και το σχέδιο των στοιχείων που πρέπει να συγκεντρωθούν από τα Κράτη Μέλη για όλες τις υπάρχουσες χρήσεις των φαρμακευτικών προϊόντων στον παιδιατρικό πληθυσμό
(Doc. Ref. EMEA/503973/2007)
3) Την Απόφαση ΔΥΓ3(α) 83657 « Εναρμόνιση της ελληνικής νομοθεσίας προς την αντίστοιχη κοινοτική στον τομέα των φαρμάκων που προορίζονται για ανθρώπινη χρήση»
4) Τον Νόμο υπ αριθμ 1316/1983 « Ίδρυση, οργάνωση και αρμοδιότητες του Εθνικού Οργανισμού Φαρμάκων , της Εθνικής Φαρμακοβιομηχανίας, της Κρατικής Φαρμακαποθήκης και τροποποίηση και συμπλήρωση της Φαρμακευτικής Νομοθεσίας και άλλες διατάξεις

Σύμφωνα με το άρθρο 42 του Κανονισμού (ΕΚ) αρ 1901/2006 , οι κάτοχοι των αδειών κυκλοφορίας φαρμακευτικών προιόντων , τα Νοσοκομεία Παίδων (δημόσια και ιδιωτικά),τα ασφαλιστικά ταμεία, γιατροί και φαρμακοποιοί και κάθε άλλος εμπλεκόμενος με τη χορήγηση φαρμάκων, υποχρεούνται

«να συγκεντρώσουν όλα τα διαθέσιμα δεδομένα σχετικά με όλες τις υφιστάμενες χρήσεις των φαρμάκων στον τομέα της παιδιατρικής και να τα κοινοποιήσουν στον Εθνικό Οργανισμό Φαρμάκων και στον Ευρωπαϊκό Οργανισμό Φαρμάκων (ΕΜΕΑ) έως τις 26/01/2009»

Σύμφωνα με τον Κανονισμό (ΕΚ) Νο 1901/2006 είναι αναγκαία η συλλογή στοιχείων για **όλες** τις χρήσεις των φαρμακευτικών προιόντων που χορηγούνται σε παιδικούς πληθυσμούς , συγκεκριμένα σε ηλικίες από την γέννηση έως 17 ετών (συμπεριλαμβάνεται και το 17^{ο} έτος)

Τα στοιχεία πρέπει να αναφέρονται σε όλες τις υποομάδες του παιδικού πληθυσμού και αφορούν σε όλες τις υφιστάμενες χρήσεις δηλαδή
α) χρήση εγκεκριμένων προϊόντων στις ενδείξεις που περιλαμβάνονται στην άδεια κυκλοφορίας, αλλά και σε ενδείξεις που δεν περιλαμβάνονται στην άδεια κυκλοφορίας
β) χρήση φαρμακευτικών προιόντων που δεν έχουν λάβει άδεια κυκλοφορίας

- Η συγκέντρωση/κατάθεση των δεδομένων θα γίνει ηλεκτρονικά στην διεύθυνση **ped-inv@eof.gr**

ΘΕΩΡΗΘΗΚΕ ΓΙΑ ΤΗΝ ΑΚΡΙΒΕΙΑ
ΓΕΝΙΚΗΣ ΓΡΑΜΜΑΤΕΙΑΣ

Ο ΠΡΟΕΔΡΟΣ ΔΣ ΕΟΦ

Β. ΚΟΝΤΟΣΑΜΑΝΗΣ

ΕΛΕΝΗ ΑΡΓΥΡΟΠΟΥΛΟΥ

Συνημμένα έντυπα

1) Doc. Ref. EMEA/503973/2007 το οποίο περιλαμβάνει αναλυτικές οδηγίες για τον τρόπο και τα στοιχεία κατάθεσης
2) υπόδειγμα πίνακα συλλογής στοιχείων

Αποδέκτες

1) ΣΦΕΕ Λ. Βασιλέως Γεωργίου &Μ.Ασίας , Χαλάνδρι 15233
2) ΠΕΦ , Δεληγιώργη 12, 10437
3) Μη Μέλη Συλλόγων (όπως συνημμένος πίνακας)
4) Ελληνική Παιδιατρική Εταιρεία, Μιχαλακοπούλου 92, 11528 Αθήνα
5) Διοικητή Νοσοκομείου Παίδων Αγία Σοφία
   Θηβών τέρμα Μ. Ασίας , 11527 Γουδί
6) Διοικητή Νοσοκομείου Παίδων Αγ. Κυριακού,
   Θηβών & Λειβαδιάς, 11527 Γουδί
7) Διοικητή Νοσοκομείου Παίδων Βορείου Αττικής, 15236 Πεντέλης
8) Δντη Μαιευτηρίου Αθηνών , Αθανασιάδου 9, 11521 Αθήνα
9) Δντή Γεν Νοσοκομείου « Ελενα Βενιζέλου»
   Πλατεία Ε. Βενιζέλου 2, 11521 Αθήνα
10) Δντή «Παιδιατρικού Κέντρου Αθηνών¨» Διστόμου 5-7, 15125 Μαρούσι
11) Δντη Γενικού Νοσοκομείου « Ιασώ»
   Λεωφ. Κηφισσίας 37-39, 15123 Μαρούσι
12) Δντη Μαιευτηρίου Μητέρα
   Λεωφ. Κηφισσίας &Ερ Σταυρού 6, 15123 Μαρούσι
13) Διοικητή Γεν. Νοσοκομείο Παίδων Πατρών «ΚΑΡΑΜΑΝΔΑΝΕΙΟ»
   Ερυθρού Σταυρού 40, 26331 Πάτρα
14) Ασφαλιστικοί Οργανισμοί

European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

London, October 2007
Doc. Ref. EMEA/503973/2007

Guidance on the content and the format of data to be collected by the Member States on all existing uses of medicinal products in the paediatric population

INTRODUCTION

Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended, (referred to here as The Paediatric Regulation) aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations.

One of the legal requirements to achieve the objectives of the Paediatric Regulation is the establishment of an Inventory of Therapeutic needs, in particular with a view to identifying research priorities. The Paediatric Committee is in charge of providing guidance on the content and format of the data to be collected by the Member States. The responsibility to establish the Inventory of Therapeutic needs lies with the Paediatric Committee, following the collection of data on all existing uses of medicinal products in the paediatric population by the Member States. The guidance of the Paediatric Committee takes into account discussions held by the members of the Paediatric Working Party (PEG), the EMEA/CHMP's former temporary expert working party on paediatric medicines.

LEGAL BASIS

Article 42 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use, as amended, states that "Member States shall collect all available data on all existing uses of medicinal products in the paediatric population and shall communicate these data to the Agency by 26 January 2009. The Paediatric Committee shall provide guidance on the content and the format of the data to be collected by 26 October 2007.

TIMELINES

26 October 2007: Paediatric Committee to provide guidance on the content and format of the data.
26 January 2009: Member States to communicate data collected according to the guidance to the Agency.

GUIDANCE ON DATA TO BE COLLECTED BY MEMBER STATES

Principle

The Paediatric Regulation states that the data needs to be collected on **all** existing uses of medicinal products in the paediatric population, which is referred to as the survey in the following. The paediatric population means from birth to adolescent (up to and including 17 years old), and information needs to be collected on all subsets of the paediatric population. All existing uses include use of authorised medicinal products within as well as outside the terms of the marketing authorisation and use of unauthorised medicinal products.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
E-mail: paediatrics@emea.europa.eu http://www.emea.europa.eu

The data to be collected need to be such that they are of added value with a view to establishing - at the level of the Community - unmet needs and an inventory for research priorities. Use outside the Terms of the marketing authorisation and of unauthorised medicinal products is of higher interest for identifying the needs.

It is recognised that different Member States might have different sources of information and tools to collect part or all of this information, which will vary in its level of detail and completeness. For efficiency reasons, existing sources of information at the Member State level should be considered when collecting the data. Results should be consolidated by the Member State. The survey is expected to provide general statistics on the frequency and extent of use, and the survey should also take into account public health priorities. Information should be collected where such uses bear the highest risk to public health and with a view to informing the inventory of therapeutic paediatric needs.

Once consolidated and sent to the agency, this means that data provided by the Member States will be merged into an inventory of existing uses of medicinal products in the paediatric population at the level of the European Community.

Content and format of data to be collected

The information to be collected needs to be useful, bearing in mind the objective of the survey in identifying unmet paediatric needs, determining research priorities.
This is the list of items on the paediatric use of a medicinal product to be collected in a Member State:

- Member State and source(s) of information
- Name of medicinal product (MP) (international non-proprietary name [INN], if not available, active substance including salt, ester etc.)
- Is this an unauthorised MP in this Member State?
- Specification of use in the paediatric population (to be repeated for each product as necessary):
  - Condition/disease
  - Formulation (including extemporaneous preparations)
  - Setting where product is used (hospital dispensing / in-patient, out-patient, subspeciality / paediatrician / general practitioner etc.)
  - Age group where product used
  - Route of administration
  - Dose and / or dose range
  - Treatment duration
  - Estimate of extent of use (e. g., according to number of treatment episodes, of paediatric patients treated per year; or DDD [Defined Daily Doses] in total for the paediatric population using the Anatomical Therapeutic Chemical (ATC) classification of the WHO Collaborating Centre for Drug Statistics Methodology)
  - Is the specified use according to an explicitly authorised paediatric indication (SmPC section 4.1) or an explicitly authorised paediatric dosing (SmPC section 4.1) in this Member State?
  - Is the specified use outside the explicitly authorised paediatric indication (SmPC section 4.2) and outside the explicitly authorised paediatric dosing (SmPC section 4.2) in this Member State? (off-label)
- Information on safety as available
- Authorised indication(s) in children and adults, including age group(s) (if not available in Eudrapharm)

For communicating the data to the Agency, a structured electronic format (using an Excel spreadsheet) with a single table according to the preceding list of items should be used.

Sources of data to be collected, as examples

The tools used to collect information on use of medicinal products by the paediatric population can be linked to the Healthcare System of each Member State. Each Member State will need to specify the sources of information available within its territory as these will vary between different MS. It is

recognised that it may be easier to collect information for hospital medicines and prescriptions rather than ambulatory care or "over-the-counter" products[RHE1]. Other examples (not exhaustive) of sources could hold information on off-label/unauthorised use of medicines in children:

1. Databases in hospitals or held by hospital pharmacists (bulk prescriptions / dispensing for use in paediatric and neonatal care units or patient-related dispensing data)
2. National compendiums, especially if paediatric (e.g., BNF for children in UK)
3. Periodic safety update reports (PSURs)
4. Compassionate use databases (e.g., ATU in France)
5. Controlled sales systems
6. Pharmaceutical industry sales databases
7. Healthcare insurance companies
8. Social security registers
9. Prescription databases (drug utilisation databases, e.g., General Practice Research Database)
10. Existing (national) surveys (e.g., one-day prescription survey)
11. National paediatric associations' databases

If data on authorised medicinal products are in EudraPharm, the Member State does not need to replicate this information and just needs to indicate it.

In view of the requirement on marketing authorisation holders to submit paediatric studies in respect of products authorised in the community to competent authorities (Article 45 of the Paediatric Regulation), Members States could take this opportunity to collect information on the paediatric use of medicinal products from marketing authorisation holders.

The following examples were provided by members of the Paediatric Committee as sources of information to collect such information. This only serves to exemplify potential approaches.

Austria	Project on combining information from tertiary paediatric care hospital pharmacy, social security institutions and other sources
France	"1-day survey" in hospital pharmacies for paediatric or neonatal / intensive care wards; information on "Autorisations Temporaires d'Utilisations" (ATU; documentation of early access to new medicinal products for serious or rare diseases)
Germany	National committee and export groups on "off-label use" National committee "Complementary and Alternative Medicines"
Sweden	Computerised population-based prescription database produced by the National Corporation of Swedish Pharmacies

Adopted by the Paediatric Committee on 26 October 2007.

MEMBER_STATE_NAME

Member State	Source of information	Name of MP	Unauthorised MP?	Condition / disease	Treatment / prevention / ..agnosis?	Formulation	Setting	Age group	Route of administration