survey, four action plans will be undertaken for 2010-2013: (i) communication of information between caregivers, (ii) pharmaceutical care training of pharmacists, (iii) communication of information to the patient, (iv) patient empowerment and education.

Author for correspondence
André Rieutord, PharmD, PhD
Chief Pharmacist
Hôpital Antoine Béclère
157 Rue de la Porte de Trivaux
F-92140 Clamart, France
andre.rieutord@abc.aphp.fr

Co-authors
Nahed Nabouh-Fawaz, PharmD
Laura Bertault, PharmD
Séverine Barbault–Foucher, PharmD

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Standardising hospital compounding practices in France

Thomas Storme, PharmD, PhD

In France, a lack of suitable dosage forms for children means that hospital and community pharmacists have to prepare paediatric medicines extemporaneously. The most common form to be compounded and prepared in French pharmacy is hard capsules. This form is not the easiest form to administer but it has been chosen for its probable stability and its ease of compounding. When, given to newborn or young children, these capsules are to be opened and poured into liquid or food.

Since 2004, all batch preparations made by hospital pharmacies have to be reported to the French Health Products Safety Agency (AFSSaPS). This report contains information about the product, the producer and its indications. The aim of this survey is to identify obsolescent preparations and to detect essential ones. Essential preparations cannot be replaced by any therapeutic alternatives. In this case, the AFSSaPS will seek ways of optimising their manufacture and availability.

In 2006, hospital pharmacists were asked by the AFSSaPS analytical department how their batch preparations were checked. Forty-eight out of 133 compounding hospital pharmacies answered. Ten active pharmaceutical ingredients (APIs) were first identified. Compounded hard capsules containing these APIs are French hospital pharmacy 'blockbusters' according to the AFSSaPS database.

Since December 2007, French pharmacists compounding medicines have been required to follow the new version of *Bonnes Pratiques de Preparation* inspired by the industrial good manufacturing practice code.

The PUI-DLC group was founded in 2008. PUI means *Pharmacies à Usage Intérieur,* i.e. hospital pharmacy and DLC means *Département des Laboratories de Contrôles*, i.e. control laboratory department of the AFSSaPS. The main goal of this group is to improve the quality of batch preparations. Formulation and analytical procedures are being standardised throughout France. Once formulations and assays are defined for an API, a monograph will be drafted. The monograph will be published in the French National Formulary after consultation. Once agreed, these monographs will set the standard for the quality of batch preparation done all over France.

After dealing with these 10 most commonly used APIs, other hospital preparations can get into the pipeline on a group member proposal.

From a practical point of view, one hospital pharmacy is responsible for writing the monograph, another validates it and AFSSaPS laboratories check the analytical procedures. Analytical procedures are designed to be as simple as possible in order to be used by most of hospital or community pharmacies. These procedures must ensure preparation quality (identification and quantification).

In order to select the analytical methods to promote, pharmacies drawing up the monograph examine procedures already described among the network or in pharmacopoeias world wide. Analytical methods must be easy to use and suitable for checking all the strengths of the preparation.

Stability assays will be performed in order to define an expiry date.

As most of the preparations are designed for children, some excipients with potential side effects, such as lactose, should be avoided and replaced by starch or cellulose, when possible.

In addition, some general monographs that relate to small scale production control are studied. These general monographs are inspired by the 6th European Pharmacopoeia monograph 2.9.40, Uniformity of dosage units.

After more than one year of work, the first monograph – amiodarone hydrochloride 10 to 200 mg capsules – will be published in the first half of 2010 and three others will follow before the end of the year.

Author
Thomas Storme, PharmD, PhD
on behalf of the PUI-DLC work group
Secteurs Production - Contrôle
Pharmacie - CPDM
Hôpital R Debré (AP-HP)
48 Boulevard Sérurier
F-75019 Paris, France
thomas.storme@rdb.aphp.fr