Region Hovedstadens Apotek

PC12240

Optimising the Process for Incoming Requests for New Extemporaneous Products

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WHAT WAS DONE?

A procedure for handling requests for new extemporaneous products was developed in The Capital Region Pharmacy of Denmark.

WHY WAS IT DONE?

In the clinic, a need for a new extemporaneous product may arise. This could either be in the form of a product needed in a new strength, a new packaging or similar, or a completely new pharmaceutical not available in Denmark.
When a product is needed the request is to be sent to the Hospital Pharmacy Drug Information Center. The clinical pharmacist asseses the clinical relevance of the product. Furthermore, they research to check that no registered product exist to cover the need for the desired product.
However, there was no clear process for handling requests in the Capital Region Pharmacy Production, which resulted in prolonged process times, and very often the requests were rejected without a reason or not processed at all.

HOW WAS IT DONE?

A standard operating procedure was made to determine the proces. This included a form to be filled out by the Pharmacy Drug Information Center.

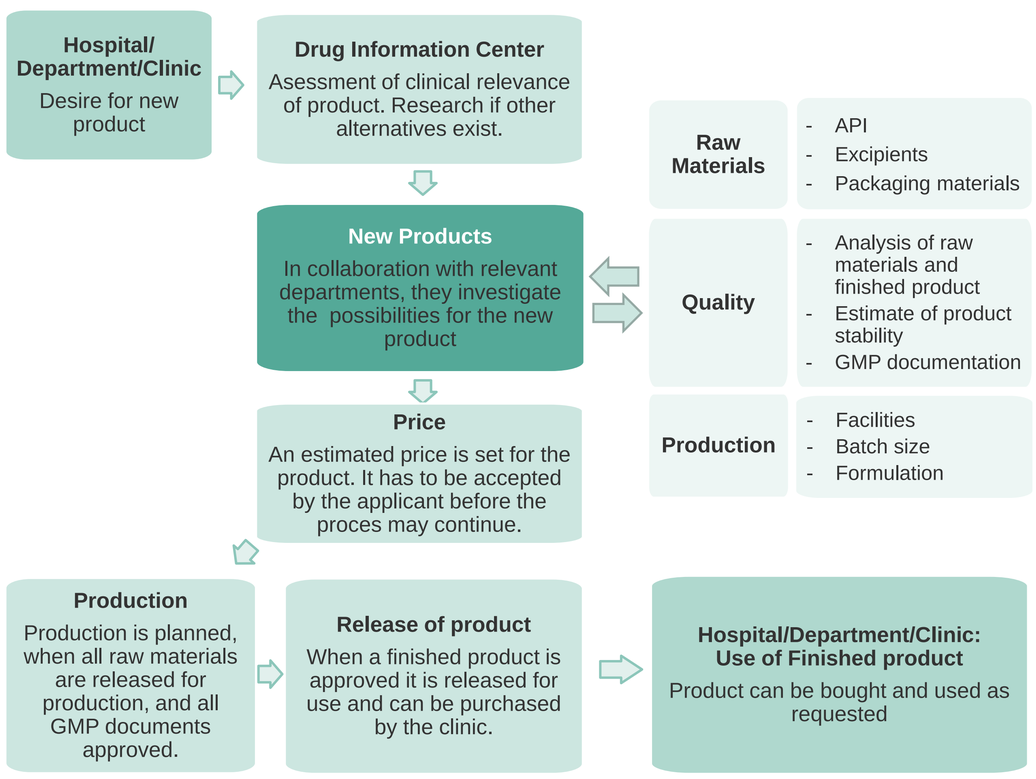
The form contains the information needed to start up a new product, including drug information and strength, dosage form, indication along with any specific requirements.

A small unit was formed consisting of academics employed in the production departments with expert knowledge about both sterile and non-sterile production. The purpose of the unit is to handle the requests for new extemporaneous products and asses if they can be made in the production.
– Is it possible for us to manufacture? Type of product? Can we obtain the raw materials in an appropriate quality? What are requirements for analysis of raw materials as well as the finished product? What is the stability of the product?

Request for Extemporaneous Product		
Hospital:	Date:	
Contact (subscribing physician):		
E-mail:	Phone no.:	
Clinical Pharmaceutical service, pharmacist:		
E-mail:	Phone no.:	
1. Case Manager		
2. Clinical Pharmaceutical Service-case no.		
3. Pharmaceutical Drug (-s) (Monograph name or CAS no.)		
4. ATC-code		
5. Indication		
6. Dosage form/Route of administration		
7. Strenght		
8. Dosage and daily dosage		
9. Therapeutical window (dosage interval for therapeutical dosage)		
10. Reason for use		
11. Proof (e.g. an article)		
12. Is there already an alternative marketed drug, non-registered product og extemporaneous product available?	Yes: Close case	No: Case continues
13. Requirements for excipients		
14. Requirements for packaging		
15. Expected Amount (Single patient or general use, Amount per year)		

The evaluation is made in communication with other departments such as Purchasing (Raw Materials), Quality Control, Quality Assurance and Stability as well as the relevant production department.
If the outcome is positive, the request is handed to the production department to determine and fill out all the documents needed, and to eventually finalize production. If the outcome is negative, a rejection is sent to the clinic with a reason for rejection.

Flow diagram of Procedure for new products in the Capital Region Pharmacy:



WHAT HAS BEEN ACHIEVED?

Based on data from the last four years, we now know how many requests we receive and what type of products are requested.
In the below table is an overview of all requests since 2019. The table shows that it varies a lot whether requests are for sterile or non-sterile products. Furthermore, we receive a lot of requests which may be simpler (e.g a change in product size of an existing product) or more complicated due to e.g facilities (requests for antibiotic/cytotoxic products). These are categorized as ”other”. On average we have received about 23 requests per year.

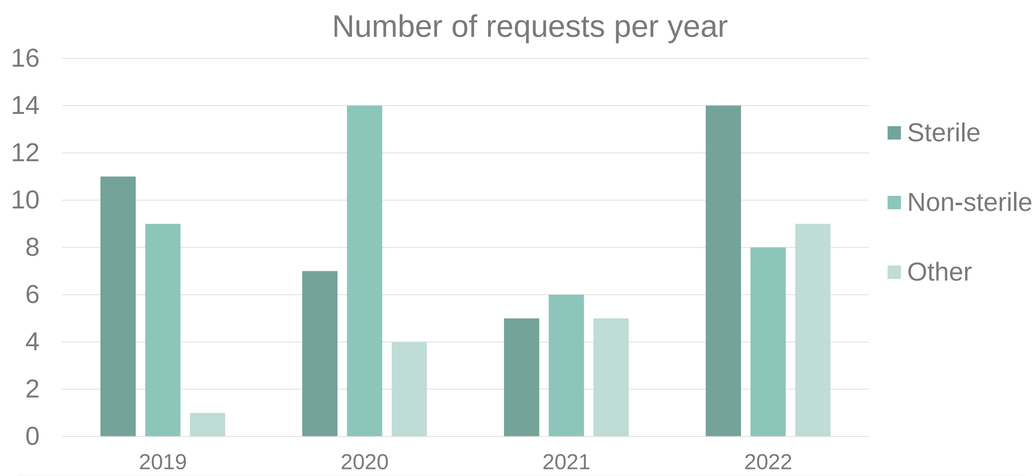


Table 1: Sterile: All sterile products. **Non-sterile**: Tablets, ointments, oral suspensions etc. **Other:** A variety of products, e.g kits, changes to secondary packaging, new packaging size of existing product.

Based on our data, we also have an overview of which products were made and why/why not, as well as processing times for implementing new products.
The critical steps in implementing new products are:

- ❖ Finding the raw materials in the right quality.
- ❖ Formulation.
- ❖ Price (price of raw materials, analysis, production etc., versus need and expected sales).
- ❖ Primary packaging.

There is now a clear path of communication into the pharmacy and between relevant departments. This ensures that the request is maintained and that essential pharmaceuticals will be developed in a timely manner. If we are not able to make the product, a justified rejection is sent as quickly as possible, enabling the clinic to look for alternatives.

EXAMPLES OF NEW REQUESTS:

Hydration fluid for children (sterile)

- To eliminate mixing errors, a group of senior pediatricans agreed that they needed a hydration fluid made ready to use specifically for children, for use at all pediatric departments.
- A request was sent to the unit for new products.
- All raw materials were already available and similar products made at the pharmacy.
- Based on this, a new extemporaneous product was ”easily” made from the formulation requested.

Chlorhexidine flushing fluid (sterile)

- Previous registered product went out of market. Request to us for necessary product.
- We don’t carry a container similar to previous product. Specific request for the lid/neck. We contact our supplier for possible lids. No solution.
- Suggestion to the clinic for other containers that we do carry. The clinic received an example, and the containers were accepted.
- Raw materials are found through our regular suppliers
- A new extemporaneous product is made.

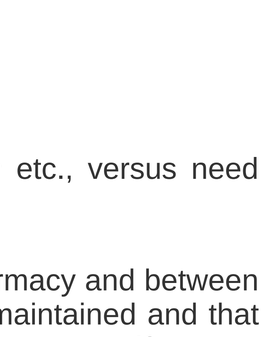


Fig. 1: Example of lids needed for the product.

WHAT NEXT?

It is currently not easy to take in new products that require specialized handling or facilities, such as cytotoxics, antibodies and hormones.
The unit need specialist knowledge within these types of products.
There is also potential for the unit to grow, including adding on personnel with this specialist knowledge.
To speed up the proces for more common requests, a local SOP with detailed description of the procedures for implementing different types of products is in scope.

ACKNOWLEDGEMENTS

We wish to conclude with a word of thanks to all our colleagues in the department for their hard work in making this a success.