



PUBLIC CONSULTATION

Review of the draft Guidelines on compounding of medicines of 28 April 2014.

Submitted by



Optimise and Innovate Compounding

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1. About Fagron

Fagron was founded in Rotterdam (the Netherlands) in 1990 by Ger van Jeveren, the current CEO of the Fagron Group. Through a continuous focus on innovation, quality and solution-oriented thinking, Ger van Jeveren brought market leadership in pharmaceutical compounding to Fagron in the Netherlands in just 7 years and continued to direct further development and international growth, with the result that Fagron is currently the global market leader and active in 30 countries in Europe, the Americas, the Middle East, Africa, Asia and the Pacific. Fagron products are sold to 200,000 customers in over 60 countries around the world.

With 1,832 employees, Fagron generated a turnover of € 335 million in 2013.

Fagron's strategy is focused on the optimisation and innovation of pharmaceutical compounding. As a R&D scientific pharmaceutical compounding company, Fagron wants to widen the therapeutic scope of the prescriber to enable tailor-made pharmaceutical care. Through its activities, Fagron supports the unique selling point of the pharmacist and improves the patient's quality of life.

As the only multinational one-stop-solution for pharmaceutical compounding, Fagron develops innovative concepts and solutions that respond to the specific and individual wishes of compounding pharmacies all over the world. In Fagron's Innovation department, over 200 pharmacists are dedicated to developing and providing innovative concepts, products and formulas that will meet the demands of the pharmacist, prescriber and patient.

Fagron supplies semi finished products for use in pharmaceutical compounding, such as aqua purificata, basic solutions, powder mixtures, cream and ointment bases and vehicles. Fagron also offers high-quality pharmaceutical raw materials to pharmacies and to the industry. In addition, the product range also offers all equipment, instruments and accessories used by pharmacists for efficient pharmaceutical compounding. This includes scales, pestle and mortars, ointment mills, packaging equipment and packaging materials.

With our dedication to optimising and innovating compounding, we have developed and have introduced a new and extensive generation of innovative vehicles globally.

2. Fagron vision on compounding

The most important reason why compounded medications are prescribed is "patient non-compliance". This means that patients are for instance allergic to certain preservatives, dyes, and drug strengths or have problems swallowing capsules, and therefore require alternatively developed medications.

Compounding pharmacists are able to make a variety of changes to traditional



medications, including:

- Lower levels or elimination of dyes, preservatives, etc.
- Increased or decreased dosage strengths for infants or elderly people
- Alternative forms of medications, such as troches, lozenges, candies, gels and liquids
- Added flavours for better taste & easier ingestion

Besides this, pharmaceutical compounding also offers a solution to patients who require medications that have been discontinued by drug manufacturers or helps patients who may be facing a supply shortage of their normal medications.

3. Responses to consultation questions

1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding?

The draft guidelines clearly indicate the difference between simple and complex compounding. We have only a remark on page 11 of the draft which indicated a dosage level of 25mg, probably this is 25 mcg. There should be no fixed limit for this, but should depend on the risk profile/therapeutic broadness/toxicity of the raw material.

2. Do the draft guidelines clearly outline which requirements apply to pharmacists who undertake either or both types of compounding (simple and/or complex compounding), and which requirements apply only to pharmacists who undertake complex compounding?

The guidelines are clear on the requirements for simple compounding. On the complex compounding we doubt that compounding for parenteral medicine should be limited to only the ones with a maximum shelf life of 24 hours.

3. Is the content of the draft guidelines helpful?

The content is helpful and gives a good view on the expectations of the Pharmacy Board of Australia in relation to training and professional development. Fagron underlines clearly through our service of Fagron Academy that training and education is crucial in the profession of pharmaceutical compounding.

4. Is there any content that needs to be changed, added or deleted in the draft guidelines?



The risk management through separating only simple and complex compounding is too brief. In the latest resolution in Europe on compounding (EU resolution CM/Res AP (2011)1), a system of risk points is used. This system makes a better distinguishment in risk levels of compounding than only simple versus complex.

5. Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board to support the guidelines?

No

6. Is the purpose of the practice profile clearly explained in the draft guidelines?

Yes, this is several times mentioned in the document.

During the last years Fagron is discussing with several important universities all over the world on adding an additional year to the pharmacy degree only on compounding. Today there is not enough focus on compounding within the masters of Pharmacy. Although the expertise and knowledge on compounding makes a pharmacist unique.

7. Do you have any other comments on the draft guidelines?

No