

eConsultation: Understandable dose application rate for RTU spray products

In the course of recent PT19 referral, it was discussed whether an application rate (which is given as mg or mL of product per cm² of skin) should be also expressed, in the SPC, as a number of sprays per treated area. For this PT19 dossier, it was agreed by consensus in the teleconference where this dossier was discussed that this should appear.

As this is a question that has already been addressed in other referrals for PT18 or PT19 products, FR CA considers that a general consensus in this topic would be very useful to avoid any new referral on this aspect.

Conclusion agreed during the CG-30 meeting (3 July 2018):

As a way forward we propose that the general agreement of the coordination group is applied for new authorisations,¹ for existing products during the renewal procedure, or as part of applications for changes that would also affect the content of the labels on the basis of the following principles:

A distinction should be made between PT18 and PT19 products. Indeed, for PT19 products, the notion of “trained professional user” is not relevant and all users may have easy-to-understand instructions for use.

For PT19 products:

- **The application rate validated by efficacy tests is expressed in an understandable way:**
 - **For spray and aerosol it is suggested to express as number of pump strokes or duration of spraying per treated surface.**
 - **The expression of treated surface or volume is decided on a case-by-case basis.**
 - **This information is proposed by the applicant and should be validated by eCA**
- **The following sentence templates are used:**
 - **e.g. “children below 12 : 1 to 2 sprays per arm, 4 to 5 sprays per leg, 1 on the face and neck, once a day”**
 - **e.g. “above 12 y : 4 to 5 sprays per arm, to 6 to 7 sprays per leg, 2 to 3 on the face and neck, twice a day”**
- **This information appears in the “instruction for use” of the SPC**

¹ Including the mutual recognitions in parallel but excluding the mutual recognitions in sequence

For PT18 products:

1/ For PT18 products intended to non-professional users and non-trained professional users, the application rate validated by efficacy tests is expressed in an understandable way:

- For spray and aerosol it is suggested to express as number of pump strokes or duration of spraying per treated surface.
- The expression of treated surface or volume is decided on a case-by-case basis.
- This information is proposed by the applicant and should be validated by eCA
- The following sentence templates are used:
 - e.g. "4 to 5 sprays / m²"
 - e.g. : "An X second burst will treat an average sized room of 30m³"
- This information appears in the "instruction for use" of the SPC

2/ For PT18 products intended to trained professional users:

This information is not requested in the SPC. The application rate expressed as mg of product/m² is sufficient. This does not preempt the authorization holder to indicate detailed instructions for use in the label, but they will not have to be verified by eCAs and indicated in the SPC.