

Dear Peter Arlett,

my comment is on the use of the electronic reporting system and the use of MedDRA:

many small companies have difficulty to maintain a sufficient support of systems, including those for electronic reporting and coding. On the other hand the number of cases may be very small (<10/year).

End of story is that reports cannot be sent within the correct time frame or only with fragmentary content.

Proper reporting of single cases may be hindered by the forced use of specified electronic reporting tools.

The way to come to a MedDRA coding and electronic reporting may consume valuable time in these cases.

Shouldn't there be an escape clause for those cases with the option to report immediately and use classical forms and e-mail?

With my best regards

Dr. med. WOLFGANG MATTHIES
Stufenplanbeauftragter for Ecolab Deutschland GmbH

Henkel KGaA, Düsseldorf
Phone: +49-211-797-6812
Fax: +49-211-798-2534
E-Mail: Wolfgang.Matthies@henkel.com
Internet: www.henkel.com