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Very honoured customers,

leeches for medicinal application step increasingly into the medicament-legal focus. This can lead to substantial effects on the constant availability of the leech as multi-indication medicine for the future. With this info sheet we would like to inform you about these important topics and further developments to the leech therapy up-to-date.

1. Leeches are finished medicinal products

After the leech was classified as medicinal product in August 2004 (s. info sheet 01/05, point 1), since the entry into force of the 14. Novella of the medicament law on 6. September of 2005 the leech for medicinal application now rank as "finished medicinal product". All commercially manufactured medicinal products were classified as finished medicinal products excluded those manufactured under pharmacies (§ exp. 1 of the German Law on medicinal products, the Arzneimittelgesetz, hereinafter referred to as "AMG"). So far the finished medicinal product term was more specifically calm. Leeches for medicinal application could not clearly be assigned to the respective definition "finished medicinal product" and/or "prescription medicinal product" within AMG, since the manufacture and sales process in the Biebertaler Leech Center corresponded to elements of both medicinal product types. The responsible authority did for medicinal leech so far without a concrete conceptual allocation. Manufacturers of finished medicinal products must fulfill all special legal requirements for these medicinal products with a transition period to 2008. Apart from the authorisation requirement (s. point 2), this means also the conversion of the comprehensive Pharmacovigilance (s. point 3) for leeches for medicinal application.

2. Leeches require the medicament-legal authorisation

For finished medicinal products in the range of the European Union in principle the obligation for authorisation exists. For new classified "finished medicinal products" a transition period for requesting the authorisation was furnished until 1. September 2008. Up to this time also the request for authorisation for leeches has to be placed. From then on

leeches for medicinal application may not be brought in traffic without permission.

Starting from approx. 2009 thereby the further medicament supply of medicinal leeches in the European member states depends on the distribution of an authorisation for finished medicinal products by the European Union or the respective member states in which the permission was requested. The expenditure connected with the authorisation and the costs resulting from it are immense. Various medicinal products, whose effectiveness and compatibility are generally well-known, have disappeared due to the inefficiency regarding a medicament-legal authorisation from the market and/or until September 2008 will suffer this fate. A medicament-legal authorisation for medicinal leeches after the standards of the aforementioned procedure for obtaining marketing authorisation will only be possible with consideration of its specific characteristics as "living medicinal products".

3. Pharmacovigilance for medicinal leeches

Manufacturers of medicinal products are obligated after § 63 AMG to develop a system for Pharmacovigilance (collecting, arranging and judging assumed and unwanted medicament even effects). For medicaments with requirement for authorisation beyond that the direct obligation exists to register for heavy side effects to the responsible authority and to inform the experts and patients by means of specialized information and the package leaflet. For this it is necessary for the medicinal product manufacturer to receive information about potential side effects. For the comprehensive conversion of our responsibility as "manufacturers of leeches to medicinal application" we ask all therapists, which receive leeches from us, to communicate cases of suspicion on side effects. For this we compile a questionnaire at present which will be callable if necessary starting from January 2006 over our homepage www.leech.de

4. Price adjustment starting 1 January 2006

For the permission of the leech for medicinal application to 2008 cost-intensive scientific and medicinal investigations are necessary within the next years. We see ourselves forced to raise the prices for leeches in the next years as moderately as possible in order to place the financing of the authorisation surely. Starting 1. January 2006 we increase the prices for our leeches on the average by 5,2 % and thereby lie despite the aforementioned cost explosion for the production in the average level of price increases for medicinal products in 2006. Please find attached the new product and price list and the new fax order sheet. We ask you to use exclusively the new order sheet for your orders starting 2 January 2006 (date of despatch) since otherwise a further inquiry at you could be necessary and would probably lead to delays with the supply of your order.



5. Seminar list 2006

For 2006 we have planned the following seminars to leech therapy in Biebertal:

Date	Title of Seminar
25.02.2006	Basic seminar for human therapists
01.04.2006	Basic seminar for veterinary therapists
10.06.2006	Basic seminar for human therapists
11.06.2006	Specialized seminar for human therapists
30.09.2006	Basic seminar for human therapists
04.11.2006	Basic seminar for veterinary therapists
09.12.2006	Basic seminar for human therapists

The topics for the specialized seminar will be published within the next weeks on our homepage. For the first time we placed the topic seminar on a Sunday following the basis seminar on Saturday, in order to make it possible for the groups of therapy beginners and also the advanced to attend the seminar as a combination meeting. Please accomplish your registration for the seminars over www.leech.de or www.blutegel.de on which the next in each case seminar and the topic seminar are announced. Starting from 2007 we want to offer also topic seminars for veterinary therapists for the first time

6. Development of the InterNet Homepage

As already announced in our info sheet 01/05, we transformed our homepage and will make it accessible for our customers by the end of 2005. With the revision we want to make available additional information concerning leech therapy for our customers and interested patients and to offer a simple ordering type. The following innovations are intended in detail:

- Online-Shop

Registered customers receive the possibility to order on-line.

- Pressing and specialized information

Important press articles and scientific paper can be loaded by our customers directly as pdf-file from our homepage

- InterNet forum

We offer a two-stage forum:

1. Answers to questions around the leech therapy approved by a specialized committee.
2. A panel for therapists to medical questions concerning leech therapy with supporting evaluation by the specialized committee.

- Data bank for therapists

The inquiry after therapists, which was possible by telephone, fax and E-Mail so far, will also be possible by InterNet in future. The patient interested in a leech therapy gets three therapists in his proximity over the input of its postal zip code, which he than can contact. For datalegal reasons and others, we do not judge it as appropriate to publish a list of all registered therapists. Apart from the data of the therapists registered with us, also the indication areas are indicated. For this an actualization of your leech therapy offer is necessary, which you can accomplish and maintain in future. We therefore ask you to update your appropriate data starting from January 2006 under www.leech.de.

7. Establishment of an association for the promotion of the leech therapy

The rapid development of the leech therapy with its various requirements on the part of the patients - the therapists - of science - the medicament right - the nature protection and the animal protection, should be accompanied arranging and promoting by an independent committee of interested circles. Before this background considerable specialists from the associated fields of activity decided to establish an association for the promotion of the leech therapy. The founders' meeting will take place in spring 2006. The ZAUG GmbH will support the association and gladly receives requests of interested persons for membership.

8. Rhizarthrosis and leech therapy

According to the well-known study of the successful leech therapy with arthrosis at the knee joint at the clinical center Essen-Mitte (working group around Dobos/Michalsen), a clinical study over the employment by leeches with the painful arthrosis at the saddle joint of the thumb (Rhizarthrosis) is accomplished at present. We are very strained, which effect our leeches will have here with that altogether 30 test subjects. The study will be published in February 2006. In March 2006 a study over Epicondylitis with altogether 40 test subjects follows.

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