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Termination of research into Sorna Disease virus at the RKI Your  
letter (email) of 16th Oecember 2005

Oear Prof. Or. Patti,

Your above-mentioned letter to the Federal Minister, Ulla Schmidt, was passed on to the competent specialist division for a response.

On 31st Oecember 2005, the Robert-Koch-Institut terminated research into the Soma virus carried out by Working Group P 15.

The Institute's Oirector decided to disband research group P 15 on the basis of a long evidence-based appraisal process involving severa l expert opinions. Initiation of an appraisal process that led to this decision had become necessary since major doubts had arisen over the validity of the Soma virus diagnostic test system.

Ouring the appraisal process, attempts were made to confirm the findings hitherto obtained in diagnosing Soma virus by means of experiments using material from the Soma Virus Working Group at the RKI. However, it was not possible to reproduce the findings. It was, however, possible to show that the monoclonal antibodies used in the testing system bind non-specifically to se rum or plasma components. The results of this study have already been accepted for publication in the renowned 'Journal of Clinical Virology'.

The experts unanimously concluded that the diagnoses that were obtained using the test system developed by the Soma Virus Research Group must be generally called into question since the aritibodies employed in this test system lack sufficient specificity.

The opinion you expressed in your letter, to the effect that Soma virus infections are highly prevalent in humans, is not bome out by any scientific or medicai evidence. Many epi- demiological data collected worldwide are based on the non-valid testing system developed

Pade 2012 by PO Or. Sode of the RKI's Soma Virus Research Group. According to the current state of the peer discussion, humans can only be infected in extremely rare instances - if at all - and there is by no means any confirmed causal link between Soma virus infections and psychiatric episodes or conditions in humans.

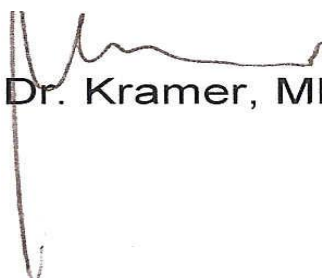
While the management of alleged Soma virus infections in humans by means of Amantadine you referred to was published by the Sode Working Group in 1997, the same year the RKI prohibited the provision of treatment recommendations drafted without sufficient clinical studies by PO Or. rer. nat. Sode. Susceptibility of Soma virus isolates to Amantadine was never verified in independent experiments since these isolates were not accessible to the public - a situation deeply regretted by the RKI, among others.

In parallel efforts, an expert panel on transfusion medicine also addressed the issue of a potential blood-borne transmission of Soma virus. In its relevant statement, the sub-group 'Evaluation of blood-associated pathogens' of the Working Group on Blood at the Ministry of Health concludes that there is no evidence to support the human pathogenetic importance of Soma virus. Specifically, there is no evidence of viraemia which might lead to blood donor infectivity.

On being informed about the decision to disband the Soma Virus Research Group at the RKI by the Institute's Director, this Ministry reviewed this step as part of its supervisory control; among other things, by studying the underlying documents and obtaining additional expert opinions. In the course of this procedure, the main parties involved were individually heard.

The decision and approach taken by the RKI to discontinue research into the Soma virus, were legitimate and proper under supervisory control aspects and are therefore approved by this Ministry.

Yours .sincerely

  
Prof. **Dr. Kramer, MPH**