Ministerie van Volksgezondheid,
Welzijn en Sport

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Stichting Pierre Robin Europe

Philippe Pakter

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Per e-mail: pakter@pierrerobineurope.com

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Uw brief

Bijlage(n)
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Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum 15 september 2021

Betreft ERN Cranio Clinical Practice Guidelines for Pierre Robin Sequence Syndrome

Dear mister Pakter,

With this letter I reply to your letter regarding the concerns of your organization with the developmental procedure for a Clinical Practise Guideline (CPG) for Pierre Robin Sequence/Syndrome (PRS), as received by email on June 30th 2021 and by mail on July 9th 2021. This also replies to the emails you send on July 29th, August 24th and September 7th 2021 addressed to the minister of Health, Welfare and Sport.

In your letter, you request an intervention to change the composition of the Guideline Development Group (GDG) for PRS. You ask for involvement of a patient and of specific PRS experts within the GDG.

We contacted the coordinator of ERN CRANIO, after receiving your letter. We inquired how they involve patients during the development of the Clinical Practise Guideline, as we value patient centred guidelines in the Netherlands. This was a friendly request, because individual Member States do not have a formal position towards the ERNs and the methods they use in the development of new guidelines. Based on the information provided by ERN CRANIO, it appears that they offered opportunities for the input of the patient perspective; they explored the bottlenecks patients experience in advance and the patient organization is able to provide feedback on the draft documents at any stage. We also asked about the involvement of Tübingen University and Amsterdam UMC. ERN CRANIO informed us that the experts at these hospitals are involved in the procedure henceforth, as they will join the ERN soon. In the information you sent, we read that the experts from Tübingen University already gave feedback on the first draft of the guideline.

In the Netherlands, the National Healthcare Institute (Zorginstituut) has stipulated the criteria for care standards and guidelines. Standards that fulfill these criteria are included in a special Register. The Register is publicly available: www.zorginzicht.nl. The National Healthcare Institute's criteria cover such matters as: were all relevant parties, including patients, involved in drawing up the standard and is a layman's version of the standard available. The 'Leidraad

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opstellen richtlijn' gives directions on the development of a guideline. The document is attached for your information. In short the 'Leidraad opstellen richtlijn' states that involvement of a patient in the development group of a quality standard is one way to realise patient involvement, but there are other ways possible, as long as patients are involved in all the different stages of developing the quality standard. It is not for the Ministry of Healthcare to judge if the ERN CRANIO's procedure is in accordance with this. The Ministry has no part in assessing the patient involvement in quality standards. In the Netherlands, it is the National Healthcare Institute's (Zorginstituut) responsibility to assess guidelines before putting them in the Register. In conclusion, the National Healthcare Institute assesses patient involvement when they receive the guideline.

If your opinion is that the procedure of ERN CRANIO does not meet the minimum requirements that are set for guideline development from European policy and European regulations, we recommend to contact the ERN team at the Health and Food Safety Directorate General at the European Commission:
Directorate-General for Health and Food Safety, Unit B3 - European Reference Networks and Digital Health, Rue Breydel 4 – B232 8/004, 1049 Brussels/Belgium, SANTE-ERN@ec.europa.eu.

Sincerely

Managing director,

Birgitta Westgren