Notes from the call between the Sleep PAG and ERS regarding the Philips statement, 16 February 2022 (online)

Present: Mark De Quidt, Gert Grundstrom, Joe Hoza, Piet-Heijn van Mechelen, Pippa Powell, Winfried Randerath, Luca Roberti, Chris Rogers, Sophia Schiza, Anita Simonds, Clare Williams.

Agenda item			Action
1. ERS statement	Winfried Randerath	Winfried summarised the reasons why the ERS statement was updated: • New data had emerged showing that the Volatile Organic Compounds (VOCs) emitted by the Philips devices were within safe levels. The German health authority BfArM independently evaluated the data to come to its conclusion. ERS did not have access to the raw data but in any case, it would be difficult to interpret by a non-specialist. • There is some evidence that the devices can release particles of foam which may cause symptoms such as cough and sinus problems, especially when users conduct ozone cleaning, which is not recommended. Health authorities have been collecting evidence about side effects and complications and have no reports of serious harm being caused. • Philips are continuing with their programme to replace or repair affected devices but the health authorities have concluded that given the evidence, they are not under an obligation to do this.	
2. PAG response	Luca Roberti/all	Luca expressed his disappointment that the PAG had not been involved in the recent ERS statement as they had with the first. He raised the following concerns: • The FDA inspection report published in December was alarming, for example finding that Philips had not conducted a proper risk analysis.	

		• Philips have apparently been aware of the situation for several years but have only acted recently. • A belief that there has been a lack of transparency from Philips. • Concerns that the new tests have been paid for by Philips so are not independent. • The device replacement programme in Europe is taking a long time. • Unlike in the US, the pharmacovigilance authorities in Europe have limited powers to monitor medical devices.	
3. Discussion	All	Winfried suggested that if PAG members feel there has been a lack of transparency from Philips, they could write a letter to the company requesting that more information is provided to patients and patient organisations. The ERS has an advocacy department which could investigate asking for better technical vigilance of medical devices. Piet-Heijn explained that in the Netherlands, the potential for bad publicity from dissatisfied patients has helped to get a replacement programme in place and everyone who wants a replacement device will get one. Chris reported that the programme is working well in the UK. Due to the worldwide chip shortage, clinics are getting about half their normal deliveries of CPAP machines so waiting lists are growing. Hospitals are needing to prioritise patients. He believed that in the UK, people are more likely to look to the FDA for advice than ERS. Anita confirmed that the FDA statement had generated concern amongst patients. She explained that Philips had not had a chance to respond to the FDA inspection. Winfried said that ERS must pass on relevant information to patients including giving reassurance as a result of a reduced risk. It is important to take a balanced and evidence-based approach. Piet-Heijn felt that the actions taken by Philips to repair or replace the devices was more about preventing claims against them from the US, with its more	

		litigious culture, than preventing actual harm. He had found the statement reassuring. Chris also found the statement helpful. He explained that his organisation's stance is that there is a much bigger risk of stopping CPAP than of using a Philips device. Luca asked whether the data from the recent tests was available. Winfried advised that this will need to be requested from Philips as BfArM have only published their interpretation of the data. Mark questioned why Philips was investing so much money in their replacement programme if there was a low risk of harm. Piet-Heijn said it was likely to be a way of protecting their core business.	
4. Actions		• ELF and PAG to work together on a letter to Philips. Clare will arrange a PAG call to do this and ELF will publish it in its newsletter. • ERS staff to consider whether the ERS advocacy department can make any representation to get medical devices better regulated in Europe.	CW/PAG WR/AS/SS