Verbraucherschutz
Verein

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Director
Andrzej Jan RYS
Directorate SANTE/B "Health systems, medical products and innovation"
Directorate-General "Health and Food Safety"
European Commission
By email: andrzej.rys@ec.europa.eu

Vienna, 7 June 2022

Re: Regulation (EU) 2017/745 on medicinal devices – Reporting of irregularities in Austrian market surveillance

Dear Sir,

The "Verein zum Schutz von Verbraucherinteressen – Verbraucherschutzverein" (VSV – www.verbraucherschutzverein.eu) is an Austrian independent consumer organisation. Its aim is to defend the interests of consumers and patients vis-à-vis national and European authorities and economic players. The VSV is registered in the Register of Interest Representatives (No. 385900434121-64).

The VSV is conducting collective actions in two product liability cases concerning medical devices. In this context, based on the above-mentioned EU Regulation – and in particular its Articles 95 to 98 and 104 –, we wish to bring to the attention of the Commission the following instances of maladministration in the supervision of medical devices in Austria and request that they be investigated.

1. **Contraceptive coils of the company Eurogine S.L.**

with registered office in C. Raurell 21-29, Nave 3 08860 Castelldefels · Barcelona (Spain)

On 27 February 2018, the Spanish Medical Inspectorate warned of material defects in the side arms of a range of contraceptive coils and the risk that they could break off and remain in women's wombs, and announced a recall by the manufacturer Eurogine.

In December 2019, the German medical regulator also published this warning on its website.

Although the Austrian *Bundesamt für Sicherheit im Gesundheitswesen* (BASG – www.basg.gv.at/en) observed the activities of the manufacturer and its distribution company in Austria and assumed that pharmacies and specialists were warned directly as a result and that products in stock were exchanged, it had to be clear to the BASG that in many cases the women concerned did not become aware of the safety warning in this way.

Nevertheless, the BASG did not publish a safety information on its website until it was asked to do so by a daily newspaper and only on 28 September 2020 (sic!). To our knowledge, there was no corresponding press release.

It was only when the VSV started a collection campaign that around 1,400 women came forward to the VSV stating that they had been harmed by broken side arms of the IUDs. In the majority of cases, the side arms had to be removed under general anaesthesia, causing pain and anxiety. In a number of cases, however, women also report unwanted pregnancies because the IUD – due to the breakage of the side arms – had spontaneously come off unnoticed.

The VSV therefore supports claims for damages against the company Eurogine, but also official liability claims against Austria, because the BASG warned the public and thus affected women far too late.

It should also be mentioned that the BASG initially did not want to give VSV any information about how many women had filed whistleblowing reports with the BASG. Only after answering a parliamentary question to the responsible Ministry of Health were these figures released.

2. **Ventilators of the company Respironics Inc. (manufacturer)**

with registered office in 1001 Murry Ridge Lane, Murrysville, PA 15668 (USA)
and
Respironics Deutschland GmbH & Co. KG, Gewerbestrasse 17, D-82211 Herrsching (Importer)

Both companies are subsidiaries of the **Philips group**.

The companies produce and import respirators for home use; in particular for people suffering from sleep apnoea, these devices are partly vital.

In June 2021, the Respironics Inc. company ordered a recall of certain types of its ventilators only in the US because problems with the foam used for noise insulation lead to “serious injuries that may be life-threatening or cause permanent impairment”. The foam apparently degrades after some time of use and there is a risk of particles of the foam being swallowed or – worse – inhaled.

In the USA, investigations against the manufacturer have been ongoing for years and the Food and Drug Administration (FDA) has raised serious allegations against the manufacturer in a report dated 11 September 2021 (FEI Number 2518422). The manufacturer had been aware of the problems for years and had done nothing to remedy them.

In Austria, Philips only published a safety notice on 14 June 2021 pointing out potential risks such as respiratory problems and toxic and carcinogenic effects. These warnings were also sent to users via letter post. The users were told that the defective devices would be replaced. This replacement was and is proceeding only very hesitantly. Many of the 35,000 people affected have still not had their devices replaced.

This procedure poses a dilemma for the users: Do not continue to use the device in order to avoid risks or – because it is vital – continue to use it and accept the risk.

In this case, too, the BASG has so far only placed a message in the depths of its website and has not issued a press release. It is also not apparent that the BASG has ordered any measures for an accelerated replacement of the devices.

In both cases, the manufacturers argue in the product liability proceedings in court that only a few cases of health damage had been disclosed. This may not be surprising, given that the BASG pursues an almost cladistic information policy and makes itself such a supporter of the manufacturers.

We therefore ask you to investigate these abuses and to do everything in your power to ensure that they are quickly remedied. After all, the health of citizens in the European Union is at stake here. We also suggest informing the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the European Medicines Agency of the irregularities we flag in this letter.

Thank you for considering this submission that I would be happy to explain further if need be.

On behalf of the VSV

Dr Peter Kolba
Chairman of the VSV