Statement from the Paul-Ehrlich-Institut on "Post-Vac Syndrome" after COVID-19 Vaccination (dated 19 May 2023)

The Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, received a total of 1,547 reports of suspected cases of adverse reactions at different intervals after COVID-19 vaccination that contained reference to chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME) with similarities to Long COVID/Post COVID; postural tachycardia syndrome (POTS), including symptoms referred to as post-exertional malaise (PEM); or symptoms referred to as "Post Vac". These reports were received in the course of medicines safety monitoring from the start of the COVID-19 vaccination campaign (27 December 2020) until the last evaluation date on 19 May 2023. "Post Vac" is not a term that refers to a medically-defined disease and is not subject to a clear case definition for reporting a suspected adverse reaction to a vaccine product. According to the present findings, the term describes a variety of long-term symptoms that are also associated with Long COVID/Post COVID. These suspected case reports included an above-average number of symptoms per case, which makes it difficult to attribute a case to a certain syndrome without further diagnostic information. Indeed, it is very common to find important clinical information to be missing from the suspected case reports, in particular the time at which the first symptoms occurred and their duration or whether the symptoms are still present. This means that the diagnostic certainty of the reported symptoms cannot be assessed in most cases. Even a coincidental connection with a COVID-19 infection often cannot be unequivocally refuted.

A search was carried out on 19 May 2023 using the MedDRA Preferred Terms (PTs) of Chronic Fatigue Syndrome (CFS, PT 10008874), Post Vaccination Syndrome (PT 10036242), Postural Orthostatic Tachycardia Syndrome (POTS, PT 10063080), and Post-Acute COVID-19 Syndrome (PT 10085503, Post-Exertional Malaise, LLT 10069634) in the adverse reaction database of the European Medicines Agency (EMA). However, the only distinctions that can be drawn from the publicly available evaluations are those by the region from which the suspected adverse events have been reported to the EMA database. The suspected cases from the EU were compared with the reports from Germany and could be presented separately.

The comparison of the number of reported suspected cases of the previously mentioned symptom complex following COVID-19 vaccination is shown in the following diagram.

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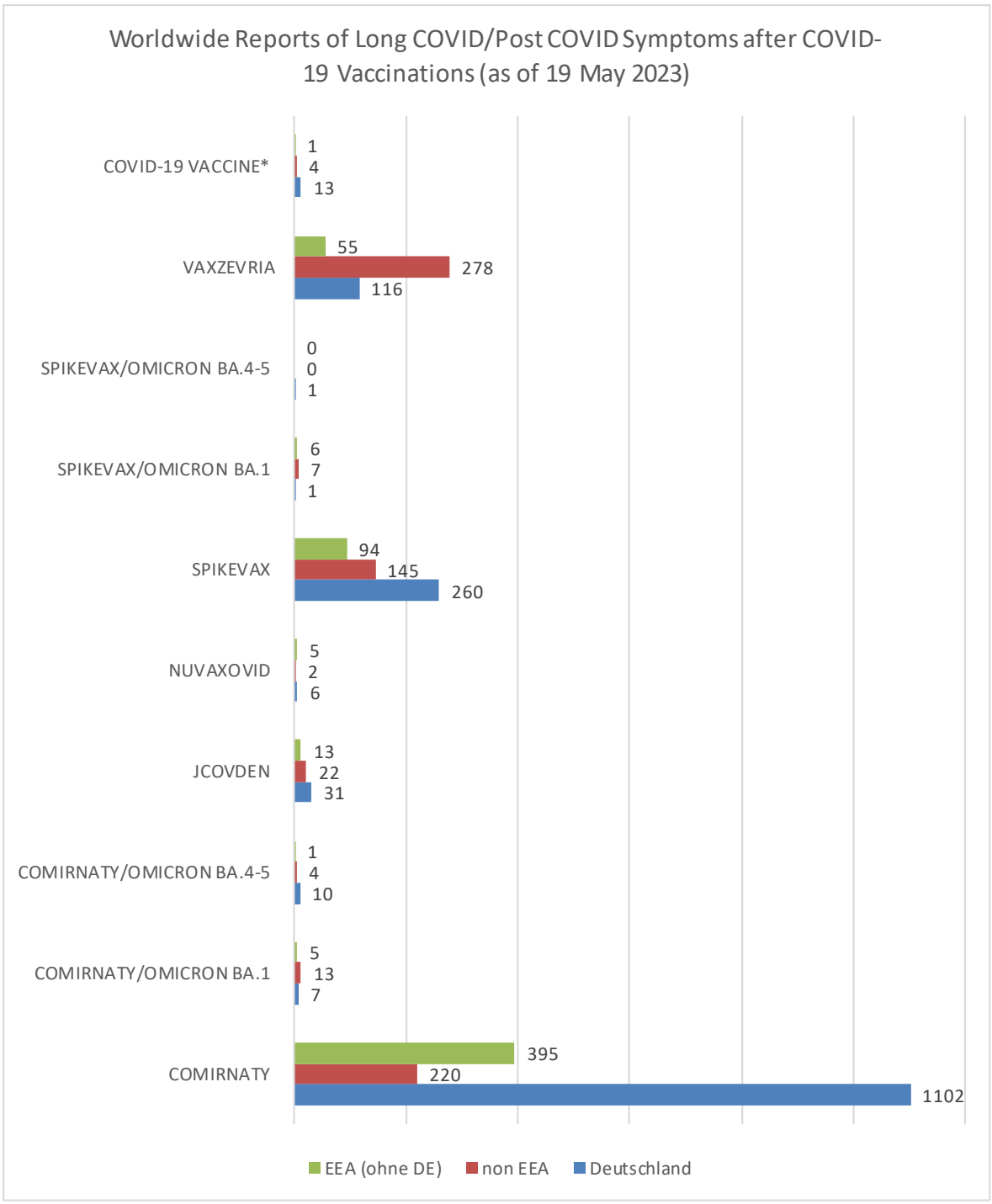

*COVID-19 Vaccine stands for reports of suspected cases in which the COVID-19 vaccine is not specified or a vaccine cannot be clearly assigned due to a missing batch number.

When comparing the absolute numbers of reports of suspected cases presented, it seems notable that at the time of the evaluation, more than 50% of all suspected cases registered worldwide (n=2,817) with these symptoms were reported from Germany (n= 1,547). It should be noted that by no means were 50% of all vaccine doses administered worldwide administered in Germany.

It should also be noted that reports of suspected cases are not identical to adverse reactions and that the number of suspected case reports does not allow conclusions to be drawn about the actual frequency of the reported reaction in the vaccinated population, as the number of people vaccinated per region is not known. A conclusion on a causal relationship between a reported suspected case of a side effect and vaccination cannot be drawn on the basis of this comparison.

One important consideration that must be taken in account in the evaluation of suspected cases is the number of vaccinations carried out with each vaccine. More than 192 million COVID-19 vaccines have been administered in Germany so far. A comparison of the administered doses of COVID-19 vaccines and the number of reported suspected cases referring to symptoms included in the previously mentioned symptom complex results in a reporting rate of less than one suspected case per 100,000 vaccinations (0.73/100,000). These suspected cases are therefore extremely rarely reported with temporal association to COVID-19 vaccinations.

Based on the information available to the Paul-Ehrlich-Institut on reports of suspected cases of Long COVID/Post COVID-like symptoms (see the selection of MedDRA PTs) from Germany, there is no safety signal for the occurrence of these symptoms after vaccination with a specific COVID-19 vaccine product. Furthermore, there is no medically plausible indication of a direct causal relationship between the occurrence of the previously mentioned Long COVID/Post COVID-like symptoms and COVID-19 vaccination.

Results from a detailed analysis carried out on 31 March 2023 are contained in the final report on the safety of COVID-19 vaccines, published in the Bulletin on Drug Safety, Issue 2, June 2023.