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Ms Ursula VON DER LEYEN
President of the European Commission
European Commission
Rue de la Loi 200/ Wetstraat 200
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Belgium

Paris, March 13, 2023

By international RAR letter n°RK687626790FR

And by email: **ursula.von-der-leyen@ec.europa.eu**

Case: "Where is my cycle?" v. European Commission - EMA and ANSM
Our ref : DP 2242

Subject: Request for the organization by the European Medical Agency (EMA) and the Committee for Pharmacovigilance Risk Assessment (PRAC) of a hearing to obtain the public's point of view on the acceptability of the risks associated with the Covid 19 vaccination, and in particular that of women in Europe who suffer menstrual cycle disorders as a result of this vaccination.

Madam,

I come back to you in my capacity as counsel for the collective "Where is my cycle?", represented by Mrs. Mélodie FERON, which groups together several tens of thousands of women in France and now in Europe, who suffer from the undesirable effects of the Covid 19 vaccination on their menstrual cycle: amenorrhea, menorrhagia, adenomyosis, endometriosis, polycystic ovarian syndrome, miscarriage or even hysterectomy

On October 14, 2022, "Where is my cycle" asked you to refer the matter to the PRAC so that it can open a procedure for examining the safety of vaccines against COVID 19 ("EU referral procedures for safety reasons") and organize a public hearing with the EMA to allow the European institutions and pharmaceutical companies to answer women's questions but also **so that women can make their views known on the acceptability of the gynecological risks associated with vaccination against Covid 19.**

Also, on September 28, 2022, "Where is my cycle", in application of Article 227 of the Treaty on the Functioning of the European Union, submitted a petition to the European Parliament to organize this public hearing.

On November 3, 2022, the President of the European Commission wrote in response that :

> "...The Commission has contacted the EMA in order to gather the most recent scientific information on these potential side effects...With regard to your request for a public hearing, please note that the decision to organize a public hearing is taken by the Agency on a case-by-case basis, depending on the urgency of the matter and for other justified reasons, in particular with regard to the extent and seriousness of the safety issue. At this point, no review of the safety of COVID 19 vaccines is underway."

Also on November 3, 2022, the EMA responded that:

> "The PRAC...concluded in October 2021 that the evidence did not support a causal link between these vaccines and menstrual disorders. Following spontaneous reports of menstrual disorders with both mRNA vaccines and findings in the literature suggesting that there may be short-term changes in menstrual patterns, including no menstrual bleeding (amenorrhea) and heavier-than-usual menstrual bleeding after vaccination...a signal evaluation began in February 2022.
>
> With respect to amenorrhea, which also includes early menopause and cycle interruption, the PRAC concluded in June 2022, based on evaluation of the available data, that there was insufficient evidence to suggest a causal action with mRNA vaccines. This issue continues to be monitored...
>
> ...Evaluating a potential link between mRNA vaccines and heavy and ongoing menstrual bleeding...
>
> Please note that the issue of early menarche (first menstrual period) is outside the scope of the above assessments...
>
> If the PRAC considers that the outcome of the signal procedure may have an impact on the risk-benefit balance of the medicinal product(s) concerned, an EU referral procedure may be triggered. In the context of an EU referral procedure, a public hearing could then be envisaged to allow stakeholders to express their views on the safety of the medicinal product(s) and the management of possible risks.
>
> In general, menstrual disorders are very common in the general population...with COVID-19 vaccines having been used in large vaccination campaigns worldwide...the high number of reports of suspected side effects is not surprising. In addition, media attention to this issue may also have led to an increase in spontaneous reports of these events.
>
> In any case, the high number of reported events observed after vaccination does not automatically mean that there is a causal relationship between that event and vaccination...they may have occurred due to other factors or simply by coincidence...
>
> ...We cannot comment on the figures provided by the ANSM however we would like to point out that data from safety databases such as Eudravigilance cannot be used to calculate the frequencies or incidences of potential side effects...please also note that self-reported data cannot be used to compare vaccines and their reactogenicity
>
> ...We want to reassure you that rigorous safety monitoring is in place for all COVID 19 vaccines.

However, the PRAC acknowledged at its October 28, 2022 meeting that the Comirnaty and Spikevax mRNA vaccines could cause menorrhagia and added this effect to the list of side effects for these two products: **"Comirnaty and Spikevax: heavy menstrual bleeding added as a side effect"**[1] , but nevertheless considered them generally temporary and benign.

On November 10, 2022, the EMA published a "safety update[2] " on COVID 19 vaccines confirming the addition of heavy menstrual bleeding as a potential adverse event and added:

> "There is no evidence to suggest that menstrual changes experienced by some people following vaccination have any impact on fertility...

From the above, it follows that:

- Although the PRAC and the EMA have recognized the potential link between vaccination against COVID 19 and heavy menstrual bleeding, they consider it to be mostly temporary and benign, whereas the testimonies collected by "Where's my cycle" show, on the contrary, that it is painful, repetitive and affects the quality of life of women in Europe,

- While you indicate that there is no evidence that this bleeding has an impact on women's fertility, the report of the National Institute of Statistics and Economic Studies (INSEE) on French demographics shows that the year 2022 saw a historic decline in the birth rate in France, the lowest level of births since 1946 with 723,000 births[3] . The same observation is made throughout Europe.

- That the EMA concluded in June 2022 that post-vaccine amenorrhea, which includes early menopause and cycle interruption, would not be causally related to mRNA vaccines but that this issue should continue to be monitored. However, for the past nine months, the EMA safety reports have not mentioned this issue, which therefore remains unresolved. "Where's my cycle" reminds us that it has collected numerous testimonies from women who experienced early menopause shortly after their vaccination against COVID 19,

- That you claim both that the high number of reported events observed after vaccination would not automatically mean that there would be a causal relationship between this event and vaccination that could have occurred due to other factors or simply by coincidence and that data from safety databases such as Eudravigilance could not be used to calculate the frequencies or incidences of potential side effects In these circumstances "Where's my cycle" would like to know what data and safety database the EMA used to establish that there is "a high number of reported events observed after vaccination". Perhaps it is also desirable to create a database of "post-vaccination coincidences" for comparison?

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[1] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-24-27-october-2022

[2] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccines-safety-update-10-november-2022_en.pdf

[3] https://www.francetvinfo.fr/replay-radio/question-de-societe/bilan-demographique-un-pays-qui-se-depeuple-est-un-pays-qui-s-affaiblit-et-qui-a-moins-de-gens-pour-cotiser-pour-les-retraites-souligne-jean-viard_5586708.html

- That you consider that the attention paid by the media to the question of post-vaccination menstrual disorders could have led to an increase in spontaneous declarations of these events, whereas on the contrary, women suffer from not being heard and not being given a voice in the media on this public health subject, which is of general interest.

Therefore, "Where's My Cycle" maintains its requests made on October 14, 2022 that:

1 - The PRAC finally opens a procedure for examining the safety of vaccines against COVID 19 ("EU referral procedures for safety reasons"). Indeed, only a signal procedure is currently underway, while the benefit-risk ratio of the COVID 19 vaccine seems to be questioned for women with regard to the menstrual disorders it may cause and while treatments are available,

2- The PRAC is organizing a public hearing to hear the public's views on the acceptability of the risks associated with the Covid 19 vaccination, and in particular the views of women in Europe who experience menstrual cycle disorders as a result of this vaccination.

"Where is my cycle" indicates here that the petition in this sense filed with the European Parliament in September 2022 was the subject of a declaration of admissibility and that by letter of February 13, 2022, the president of the Committee on Petitions, Mrs. Dolors MONTSERRAT, wrote to him to have asked the European Commission to open a preliminary investigation on the subject of his petition and added to have forwarded it to the Special Committee on the COVID 19 pandemic: Lessons learned and recommendations for the future of the European Parliament.

A public hearing will be the occasion for an exchange between all actors, European and national institutions, pharmaceutical companies and patients, and will allow to shed light in all transparency on the causes and consequences **of the cycle disorders** suffered by women in Europe since the launch of the mass vaccination against Covid 19 and to answer their questions:

- What is the database that the EMA uses to establish the frequency of side effects of mRNA vaccination if it is not Eudravigilance?

- On what basis did the PRAC conclude in June 2022 that there was insufficient evidence to suggest a causal action of mRNA vaccines on amenorrhea (which also includes early menopause and cycle interruption) reported by women as a side effect? Does the PRAC now stand by this conclusion and if so on the basis of what safety data?

- Can we exclude any risk of infertility in connection with post-vaccination menorrhagia?

- Can we exclude any link between the drop in the birth rate observed in Europe in the year 2022 and mass vaccination against COVID 19?

- Do COVID 19 treatments with fewer gynecological side effects than mRNA vaccines exist and are they available in Europe?

These questions should no longer be left unanswered, given that European countries have carried out large-scale vaccination campaigns over the past two years, and it is necessary to determine whether the gynecological risks that mRNA vaccines pose to women in Europe are acceptable in relation to the benefits of the vaccination, which are nowadays known to be limited to a possible personal protection against the severe forms of COVID 19, and the fact that there are drug treatments that are better tolerated from a gynecological point of view and whose effectiveness is not less than that of the mRNA vaccines.

Finally, I would like to remind you that Mrs Christelle RATIGNIER CARBONNEIL, as Director of the French ANSM and recipient of all the testimonies of the "Where is my cycle?" collective, wanted to set up such a public hearing, which unfortunately had to be postponed indefinitely, **so the collective has no doubt that she will support such a request with strength and conviction in her new capacity as Vice-President of the EMA.**

Please accept, Madam, the assurance of my highest consideration.

Diane PROTAT

Certified copies by registered letter :

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