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Ms. Ursula VON DER LEYEN, President of the European Commission
European Commission
Rue de la Loi 200/ Wetstraat 200
1049 Bruxelles/Brussel
Belgium

Paris, 14 September 2022

By international RAR letter n°XC404752355EN

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

Subject: Request for the European Medical Agency (EMA) and the Pharmacovigilance Risk Assessment Committee (PRAC) to hold a hearing to obtain 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 suffer menstrual cycle disorders as a result of this vaccination

Madam President of the European Commission,

I am speaking to you in my capacity as counsel for the "Where is my period?" collective[1] , represented by Ms. Mélodie FERON, which brings together several tens of thousands of women in France who have suffered undesirable effects of the Covid 19 vaccination on their menstrual cycle and who have given evidence of this.

Some suffer from early menopause when they are barely 20 years old. Others, despite being in menopause, have their periods again. Some no longer have them or have them for several weeks and are in such a therapeutic impasse that only hysterectomies are proposed as a solution to their suffering.

A book containing their testimonies has recently been published and will be translated into different languages for international distribution.

Exhibit 1 - Press kit of the collective "Where is my period?

[1] https://www.instagram.com/vaccin_menstruel/?hl=fr

I. THE FINDINGS OF THE "WHERE IS MY PERIOD?

The "Where is my period?

That vaccination against Covid 19 began in the general population in December 2020,

That very quickly empirical observation made it possible to note that even vaccinated people could still transmit the disease,

That nevertheless this vaccination has been made compulsory for the entire population, directly or indirectly, through the establishment of vaccine pass mechanisms,

That the "Where is my period?" collective has noted that for months, an abnormally high number of teenagers and women of all ages, even menopausal, have been experiencing gynaecological disorders such as: amenorrhoea, menorrhagia, adenomyosis, endometriosis, PCOS, miscarriage, premenopause, hysterectomy, etc., within a short period of time of their vaccination.

That her observation is shared by women all over the world, who are grouped in affiliated collectives in the USA, Canada, Australia, Switzerland, Germany, the UK, Austria, the Netherlands etc...,

That the collective "Where is my period?" has collected thousands of similar testimonies,

and that a book containing them has been published,

That these testimonies were also brought to the attention of the French Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPECST), which carried out a study on the undesirable effects of vaccines against Covid 19 and heard the collective "Where is my period?" on this occasion,

That the OPESCT concluded in its **report of 9 June 2022**[2] : "given their volume of testimonies and therefore the implausibility of a temporal coincidence with vaccination in all the women who experienced these disorders, **it is very surprising that they are not considered a proven effect of the vaccine**. This can only reinforce the mistrust of the pharmacovigilance system and the doubts about the safety of vaccines...",

That the PRAC and EMA reached conclusions contradictory to those of the OPESCT at their **meeting on 10 June 2022**[3] **: "The PRAC finds no association between Covid 19 mRNA vaccines and menstrual absence...Overall, the PRAC considered that the available data do not support the causal association and an update of the product information for either vaccine"**

These findings are astonishing and cannot remain unchanged at a time when the European Commission is recommending that women of all ages and health conditions receive a fourth dose of the Covid vaccine,

That these side effects, which women report to the collective, have a very significant impact on their quality of life, but also on that of their families,

[2] https://www.senat.fr/rap/r21-659/r21-6591.pdf

[3] https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-7-10-june-2022-prac-meeting_en.pdf

That women's menstrual disorders and the pain that accompanies them are all too commonplace,

In the absence of an explanation of these effects by the medical profession, women are anxious about their consequences, in the short, medium and long term, and in particular the repercussions on their fertility,

That treatments for Covid 19 that do not cause menstrual disorders or risks to pregnant women exist and have been used successfully in various countries (India, Japan, Senegal, Romania...) but were rejected by the EMA and PRAC at the beginning of the pandemic on the basis of studies that did not consider the empirical experience of these countries,

That this non-recommendation should be debated again insofar as vaccination against Covid 19 does not prevent the transmission of the virus, that *"vaccines protect moderately against infection"* and *that "the individual benefit for the young population is difficult to demonstrate"* according to Mr. DELFRAISSY, President of the French Scientific Council[4] ,

That in France, while 71% of the side effects of the Covid 19 vaccines affect women and 29% affect men according to the ANSM (Agence Nationale de Sécurité du Médicament) report of June 2022, which is a violation of the principles set out in the UN Convention of 3 September 1981[5] on the elimination of all forms of discrimination against women, there has never been any consideration of adapting the dosage of Covid 19 vaccines for women, nor of developing vaccines specifically for them,

That, moreover, a vaccination, imposed directly or indirectly by a State on a woman which not only does not effectively protect her or those around her, but also risks rendering her sterile, may be considered a violation of the UN resolution of 26 November 2012[6] prohibiting genital mutilation of women,

That the European texts provide for the possibility for the EMA and the PRAC to organise public hearings for the purpose of obtaining the views of the public **on the acceptability of the risks associated w i t h a medicinal product or a vaccination**,

That the collective "Where is my period? "observes that the known and unknown risks of vaccination against Covid 19 on women's fertility are no longer acceptable today in view of the evolution of the coronavirus pandemic whose average lethality rate for all age groups combined is 0.58%, is zero up to 20 years of age, 0.01% for adults aged 20 to 30, 0.05% for the 40 to 50 age group, 1% for the 60 to 70 age group and 11% for people over 80[7] ,

That a public hearing by the EMA and the PRAC on this subject is necessary.

[4] https://www.facebook.com/sciencespolille/videos/conf%C3%A9rence-pr-delfraissy-immunologue/1580674918985194/ : Science Po Lille conference of 15 March 2022 : "*Except that, and I am the first to have told you this,* ***these vaccines protect moderately against infection. You can't say that it doesn't protect: it protects moderately. So, as a result, the younger the age group, the more difficult it is to demonstrate the individual benefit***

[5] https://www.ohchr.org/fr/instruments-mechanisms/instruments/convention-elimination-all-forms-discrimination-against-women

[6] https://press.un.org/fr/2012/AGSHC4061.doc.htm

[7] https://www. e4n. fr/Covid-19-risque-de-mourir-jeunes

II. ACTIONS CARRIED OUT BY THE "WHERE IS MY PERIOD?

2.1 Evolution of pharmacovigilance data since the start of the implementation of COVID 19 vaccination in France

As mentioned above, vaccination in the general population began in December 2020 in Europe and was accelerated in France from the summer of 2021, when the health and then vaccination passes imposed on the entire population from the age of 12 were introduced.

Menstrual disorders were immediately reported.

On August 8, 2021, the ANSM published on its website a status report on the surveillance of Covid 19 vaccines - Period from July 23, 2021 to July 29, 2021[8] : "Concerning menstrual disorders, the CRPVs have continued their analysis of cases reported following vaccination with Comirnaty and Spikevax. For Comirnaty, 261 cases of menstrual disorders, including 30 serious cases (most often associated with other adverse events such as flu-like syndrome), were analysed in women with a median age of 36.5 years. The vast majority of cases had a spontaneous favourable evolution within a few days. To date, we cannot establish a link between vaccination and menstrual disorders, as the causes of these disorders may be multiple..."

Then, **in September 2021**, the Minister of Health, Olivier VERAN, although alerted to the cycle disorders of women vaccinated against Covid 19, declared that these were "temporary and benign".
He admitted, however, during an interview on a mainstream TV channel that these disorders were "under-reported in pharmacovigilance". Nevertheless, he acknowledged in an interview on a mainstream TV channel that these **disorders "were under-reported in pharmacovigilance"[9] .**

However, the menstrual disorders reported were not benign nor transient, but also continued to increase markedly after the mass injection in France of the 3ème dose of Covid 19 vaccine, which started in the general population in winter 2021.

The ANSM report for June 2022[10] , based on data from the Regional Pharmacovigilance Centres (CRPV) between 24 May 2022 and 16 June 2022, indicates that 729,900 injections were carried out in France during this period and more than 145 million injections since the beginning of the epidemic (for a French population of 67.8 million people of all ages as of 1 January 2022), i.e. an average of 2.1 injections per person, including infants.

It can be seen that over the period from 24 May 2022 to 16 June 2022, the ANSM notified 729,900 injections and 4,103 cases of adverse reactions reported, which **makes one case of adverse reaction for every 181 injections**. **This figure is much higher than the national average since the start of vaccination, with one case of adverse reaction for every 856 injections**. If we work only with the proportions, we obtain **4.7 times more adverse events** over the last period than the general average since the beginning of vaccination in France. It should also be borne in mind that

[8] https://ansm.sante.fr/actualites/point-de-situation-sur-la-surveillance-des-vaccins-contre-la-Covid-19-periode-du- 23-07-2021 to 29-07-2021

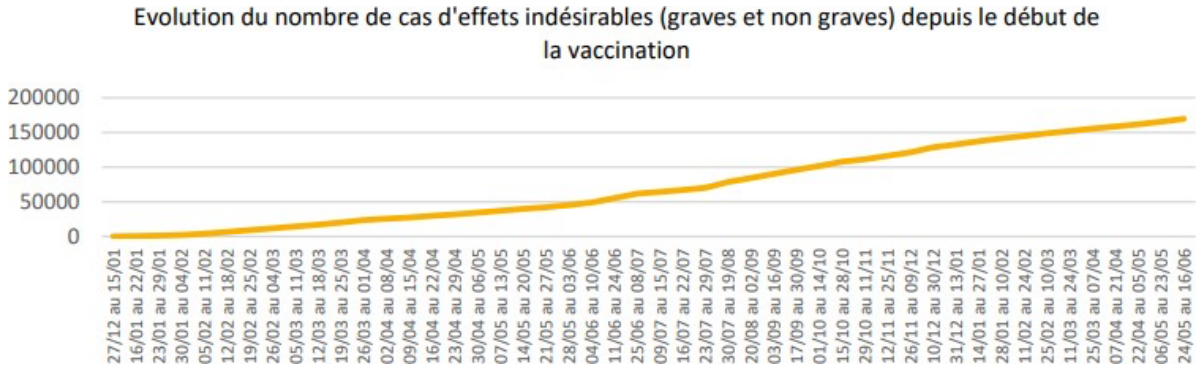
[9] https://www.ouest-france. en/health/vaccine/menstrual-disturbances-post-vaccine-of-temporary-disturbances-and-benigns-according-to-olivier-veran-f4b2ff46-20f4-11ec-8998-56362f09f2a2

[10] https://ansm.sante.fr/dossiers-thematiques/Covid-19-vaccins/Covid-19-suivi-hebdomadaire-des-cas-deffets- undesirable-vaccines

these figures are themselves underestimates given the under-reporting of effects adverse drug reactions in pharmacovigilance.

The main suspicion is related to booster shots, with people currently being vaccinated coming for the second or third dose. If the trend in adverse events is proportionally higher in the June 2022 ANSM report (it will also be necessary to check whether this trend is confirmed or whether it is an exception which will have to be explained) than in the other periods, it may be a question of the toxicity of the injections, the risk for the patient increases with the number of injections and perhaps the mix of products on the market.

The graph below showing the evolution of adverse events in France from the start of injections on 27 December 2020 to mid-June 2022[11] shows a worrying regularity.



Source: ANSM

The report also shows that women are more affected than men, 71% versus 29%.

Menstrual disorders are not unrelated to these figures.

1. The intervention of the "Où est mon cycle" collective and the recognition by the French health authorities of a link between cycle disorders and vaccination against Covid 19

At the beginning of January 2022, Ms. **Mélodie FERON created the collective "Où est mon cycle?"**

In less than 4 months, the collective's Instagram account collected thousands of testimonies from women suffering from **serious or unresolved menstrual disorders** following the Covid 19 vaccination *(see exhibit 1: "Where is my period?" collective press kit).*

At the same time, **in February 2022**, a petition on the side effects of the Covid 19 vaccines gathered more than 33,600 signatures on the Senate website, leading to the referral of the Parliamentary Office for the Evaluation of Scientific and Technological Choices (OPESCT), which was entrusted with a mission to study these undesirable effects.

[11] https://ansm.sante.fr/uploads/2022/06/30/20220623-vaccins-Covid-19-fiche-de-synthese-ansm-2.pdf

The "Where is my period?" collective then asked the OPECST to hear it on behalf of the thousands of women victims it represents.

The OPESCT granted this request and the collective also sent several hundred testimonies written on CERFA forms, i.e. bearing the handwritten words of the signatory: "Knowing that the certificate will be used in court and aware of the provisions of Article 441-7 of the Penal Code, which punishes the drawing up of a certificate stating materially inaccurate facts, hereinafter referred to: "The drawing up of a certificate stating materially inaccurate facts is punishable by one year's imprisonment and a fine of 15,000 euros."

These testimonies were established in the form of legal attestation to compensate either for the complexity of reporting adverse effects via the platforms set up by the health authorities, or for the refusal of health professionals to do so despite their patients' requests.

Thus, these testimonies are indisputable unless it can be shown that the women who wrote them were deliberately lying in describing the cycle disturbances they have experienced since vaccination.

Exhibit 2 - 5 Testimonies reported on CERFA forms as examples

The hearing of the "Où est mon cycle" collective was held on 6 April 2022 and a report was drawn up by Maître FARRUCH, bailiff in Paris.

The minutes accurately record the statements made by the OPESCT reporters, both MPs and Senators, and those of the collective, including the following:

> **"Mélodie FERON**: I represent about 10,000 women in the collective. It is a collective that I opened on 7 January, I have just over 1,000 testimonies and to date 120 CERFA forms of official testimonies filled in by women.
>
> I noticed that all categories of women and ages were concerned, all categories of population. I have testimonies from the age of 8 onwards for young girls who had their periods or at least blood loss that was triggered the same day as the vaccination.
>
> Thirteen-year-old girls who had been menstruating since the age of 10 and at the age of 12 when they were vaccinated have not been menstruating for 8 months, they also have breast atrophy.
>
> Women in their 20s who have been told they have an early premenopause and women in their 70s who have sent me testimonies of metrorrhagia. We have all sorts of symptoms, amenorrhoea, which means no periods, menorrhagia with lots of periods, lots of miscarriages and the development of endometriosis and adenomyosis in a very rapid way.
>
> I have taken a lot of advice from gynaecologists and adenomyosis is not a disease. It's a so-called slow disease and in fact there is a lot of evidence with supporting medical documentation that shows that women previously had nothing to declare in terms of gynaecological work-up that would have indicated the presence of a disease of this kind ....

Mélodie FERON: I just wanted to add something, I just wanted to add something, I received a testimony from a very young girl that I wanted to read to you, especially to you as a paediatrician, **to whom the doctor refused the declaration in pharmacovigilance.**

"My daughter is currently 13 and a half years old, she has been regular since she was 10, until August 2021 she had extremely regular 28 day cycles. In mid-July 2021 she received her first dose of Pfizer vaccine, she was then 12 years and 10 months old. In mid-August she received her second dose of vaccine after this second injection, she was 13 days late in her cycle. The following cycle she was 3 weeks late and since the end of November 2021 she has not had a period. Her breasts have atrophied to the point that she no longer needs to wear a bra. I am very worried about her fertility.

For this testimony, **the doctor refused to give a testimony and to help declare it to pharmacovigilance**. It is in CERFA with all the other testimonies given.

Me Diane PROTAT: ...You have already produced reports on other subjects, **you know very well that with 50 deaths, we stopped using glyphosate**. I've been dealing with questions of side effects, I've been working on files for 10 years, I've never seen anything like this... We're a year away from vaccination, the WHO and EMA figures that you can consult, that the MPs consult, that everyone consults, **are stratospheric** .... "

Exhibit 3 - Bailiff's report of the hearing of the "Where is my period" collective before the OPECST

On 24 May 2022, the OPECST organised a public hearing, broadcast by the Public Sénat channel, in order to give all the evidence received before submitting its conclusions.

During this public hearing, the ANSM speakers indicated that ***they "were surprised by the number of reports of adverse effects on menstrual cycles from the Covid 19 vaccination"***[12] **.**

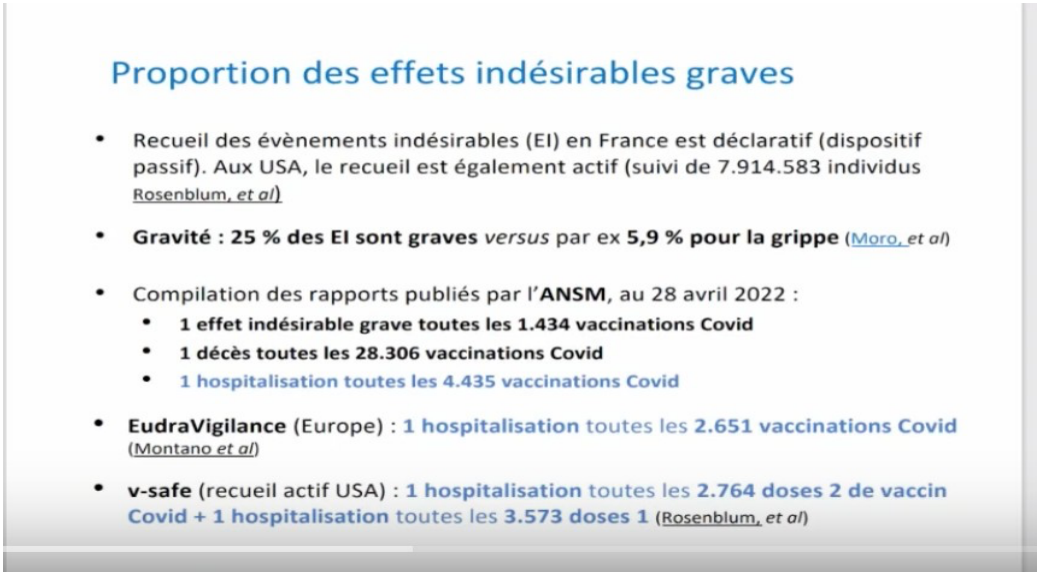
More precisely, the ANSM staff made the following comments: **"(...) Europe decided to reopen the signal in February 2022 on two specific points, i.e. the point of heavy bleeding that interferes with daily life and the point of amenorrhoea, i.e. absence of menstruation for more than three months, so this is the investigation that is underway and we are awaiting the results of the investigation at the European level for June of this year. We were not the only ones, the Norwegians, the Swedes and the English insisted on saying that there was a lot of volume."**

Exhibit 4 - Extract from the public hearing broadcast by the French Senate on 24 May 2022, intervention by ANSM officials

[12] *https://www. youtube.com/watch?v=moySD4CtQkQ*

During this public hearing, Ms. Aure SAULNIER[13] , an independent virologist, was also heard:

> "I speak for myself...it is **observed that reactogenicity is higher in subjects at lower risk of severe Covid.**
>
> ...we have a collection in France: **25% of serious adverse events** that can be compared to **6% for an influenza vaccine** and when we compile the data that are in the specific reports **published by the ANSM on 28 April 2022** and I have included all the details in the slides in the appendix if you wish, we observe :



Proportion of severe adverse effects

- Collection of adverse events (AEs) in France is declarative (passive provision). In the USA, the collection is also active (follow-up of 7,914,583 individuals *Rosenblum,* et al*)*

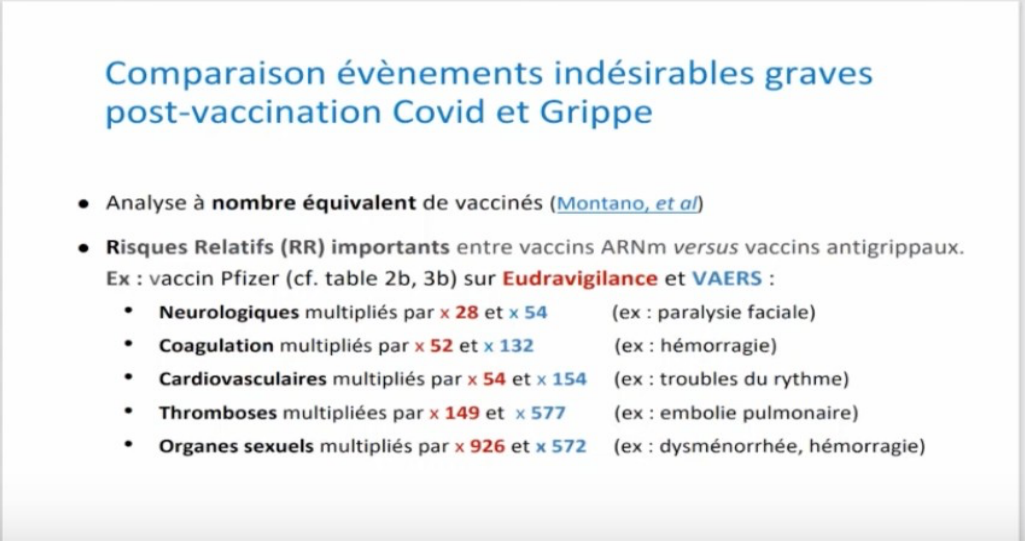
- **Severity: 25% of AEs are severe** versus e.g. **5.9% for influenza** *(Moro, et al)*

- Compilation of reports published by ANAM, as of April 28, 2022:

  - 1 serious adverse event for every 1,434 Covid vaccination
  - 1 death for every 28,306 Covid vaccinations
  - **1 hospitalization every 4,435 Covid vaccinations**

- **EudraVigilance** (Europe): **1 hospitalization** for every **2,651 Covid vaccinations** *(Montano, et al)*

- **v-safe** (active collection USA): **1 hospitalization** for every **2,764 doses of 2 Covid vaccines** + **1 hospitalization** for every **3,573 doses** of 1 Covid vaccine (*Rosemblum, et al*)



Comparison of serious post-vaccination adverse events between Covid and influenza

- Analyse an equivalent number of vaccines (Montano, et al)
- Significant Relative Risks (RR) between mRNA vaccines and influenza vaccines
- E.g.: Pfizer vaccine (see table 2b, 3b) on **Eudraviligance** and VAERS :
    - Neurological multiplied by **28** and 54 (e.g.: facial paralysis)
    - Coagulation multiplied by **52** and 132 (e.g.: hemorrhage)
    - Cardiovascular multiplied by **54** and 15 (e.g.: rhythm disorders)
    - Thrombosis multiplied by **149** and 577 (e.g.: pulmonary embolism)
    - Sexual organs multiplied by **926** and 572 (e.g.: dysmenorrhea, hemorrhage)

...there's another interesting Danish study which is based on high level of evidence i.e. randomized controlled trials, which show that **mRNA vaccines were not associated with a reduction in overall risk of all-cause mortality and this, according to the authors, is due to deaths from cardiovascular causes**

...Covid vaccines account for an unprecedented proportion of serious adverse events

...long-term effects are not currently documented in available clinical trials and there are questions about the impact of repeated stimulation of the immune system by different vaccine boosters..."

[13] *https://www. youtube.com/watch?v=Wf_1NsdSuFY*

Exhibit 5 - Extract from the public hearing broadcast by the French Senate on 24 May 2022, speech by Ms. Aure Saulnier

On 9 June 2022, the OPESCT issued a progress report which stated, in part, (page 46 and 47):
Menstrual disorders :

"In their two analyses, the CRPVs reported the concern caused by the occurrence of these problems, although they were not serious in the majority of cases. This is also what emerged from the hearing of the "Where is my period?" group, which collected the testimony of many women who had experienced menstrual or gynaecological problems following their vaccination.

For the public, the fear of an effect on fertility is the most prevalent. Groups and associations have reported cases of amenorrhoea in young women or a drop in ovarian reserve in women undergoing MAP. They also report numerous gynaecological disorders (endometriosis, adenomyosis) discovered in women following investigations following menstrual disorders, in people who previously had no gynaecological problems. Serious cases of haemorrhage leading to removal of the uterus have also been reported. However, the CNGOF is not aware of an increase in this medical procedure, which can have serious consequences.

Given their volumetric nature and the implausibility of a temporal coincidence with vaccination in all women who have experienced these disorders, it is very surprising that they are not already considered a proven adverse vaccine reaction. This can only reinforce mistrust of the pharmacovigilance system and doubts about the safety of vaccines. The communication that tried to reassure that menstrual disorders are frequent, self-limiting and may be due to stress is not acceptable to people who have never experienced such situations. Furthermore, the lack of explanation of the underlying mechanism leads the people concerned to imagine the worst.

The ANSM's initiative to bring together the CRPVs, the CNGOF and the associations and groups of women victims of adverse effects during May 2022 is to be welcomed - this initiative would nevertheless have deserved to be implemented earlier. Dialogue, sharing of information and explanation of the mechanisms probably involved is certainly the best strategy.

It should be recalled that, as of May 2022, the director of the ANSM, Mrs. Christelle RATIGNIER CARBONNEIL, has taken the hopeful initiative of inviting associations and groups, including "Where is my period? to participate in meetings on the appearance of menstrual disorders in women following vaccination against Covid 19, in order to shed light on this subject.

Following these exchanges between institutions, health professionals and patients, a public information meeting on pharmacovigilance and cycle disorders was to be held on 6 July 2022 but **unfortunately had to be cancelled on the morning of the meeting, as the director of the ANSM, the main speaker, had contracted a symptomatic form of Covid 19, despite her multiple vaccinations, which prevented her from taking part in the meeting[14] .**

Finally, at the same time, **on 20 June 2022**, **Ms. Christelle RATIGNIER CARBONNEIL was elected Vice-President of the EMA, in addition to her duties as Director of the ANSM[15] .**

3. The contradictory position of the EMA and PRAC and the lack of investigation by the European pharmacovigilance authorities

At a meeting of the PRAC **on 10 February 2022**[16] , it was stated that :

> "...The PRAC is evaluating reports of heavy menstrual bleeding (heavy menses) and absence of menstruation (amenorrhea) with the Covid 19 Comirnaty and Spikevax vaccines.
>
> The Committee had previously analysed reports of menstrual disorders (menstruation) in the context of the summary safety reports on the Covid 19 vaccines approved in the EU and concluded at the time that the evidence did not support a causal link between these vaccines and menstrual disorders.
>
> **Given the spontaneous reports of menstrual disorders with both vaccines and the findings in the literature, the PRAC decided to further evaluate the occurrence of heavy menstruation or amenorrhea after vaccination..."**

At the end of this meeting, the PRAC considered that there were safety signals on cycle disorders and asked Moderna and BioNtech to provide additional information for its next meeting on 7 April 2022.

It should be recalled that according to the EMA "Glossary": "A safety signal is information about a new or known adverse event that is potentially caused by a drug that warrants further investigation.

14 https://www.facebook.com/photo/?fbid=328926039453358&set=a.296513022694660

15 https://ansm.sante.fr/actualites/christelle-ratignier-carbonneil-elue-vice-presidente-du-conseil-dadministration- de-lema

16 https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7- 10-february-2022

The signals come from several sources such as spontaneous reports, clinical studies and scientific literature. Signals come from several sources such as spontaneous reports, clinical studies and scientific literature...".

However, it appears from the minutes of the PRAC meeting of 7 April 2022 that Moderna and BioNtech did not provide the additional information requested on that date. Indeed, at no time do the minutes mention the disorders of the female cycle[17] .

However, at the PRAC meeting on **10 June 2022**, this adverse effect of vaccination was again mentioned:

> **"Update on the evaluation of heavy menstrual bleeding with Covid 19 mRNA vaccines**
>
> The PRAC is continuing its evaluation of heavy menstrual bleeding (heavy menstruation) with the Covid 19 Comirnaty and Spikevax mRNA vaccines.
>
> Heavy menstrual bleeding can be defined as bleeding characterised by increased volume and/or duration that interferes with the person's physical, social, emotional and material quality of life. Menstrual disorders are very common and can occur in the context of a wide range of underlying conditions, as well as stress and fatigue. **The PRAC reviewed all available data, including cases reported in clinical trials, spontaneous reports in Eudravigilance and data from the literature.**
>
> ...**PRAC finds no link between Covid 19 mRNA vaccines and menstrual absence.**
>
> **The PRAC concluded that there was insufficient evidence to establish a causal link between the Covid 19 Comirnaty and Spikevax vaccines and cases of menstrual failure (amenorrhoea).**
>
> ...Overall, **the PRAC considered that the available data did not support the causal association and an update of the product information for either vaccine**[18] **..."**

For example, the PRAC, while noting warning signs of menstrual disorders in women following Covid 19 vaccination, did not find a link between the two as of June 2022, unlike the OPESCT, and did not consider that there was a need to update information on these products for women.

Nevertheless, the PRAC iteratively asked the pharmaceutical laboratories MODERNA and BioNTech to send it additional elements by 24 August 2022 and provided for a
"The PSUR will be asked for a final assessment of the data on the cycle disorder issue for the PSUR meeting on 18 December 2022[19] .

[17] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-4- 7-April-2022

[18] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7- 10-June-2022

[19] According to the EMA glossary "PSURs are reports prepared by the marketing authorisation holder to describe the safety experience of a medicinal product worldwide during a defined period after authorisation. PSURs for medicinal products containing the same active substance or combination of active substances

However, on reading the minutes of the PRAC meeting of 1st September 2022, one can only note that MODERNA and BioNTech laboratories have once again failed to provide the additional elements requested .[20]

In this regard, it is worth noting that according to December 2021 data from the US National Institutes of Health's ClinicalTrials.gov website, Pfizer/Biontech's estimated end date for the Comirnaty vaccine (Phases 1, 2 and 3) is **February 8, 2024**[21] , and Moderna's estimated end date is **December 29, 2022**[22] .

However, it is at the end of the clinical studies that the EMA will decide whether or not to grant the Covid 19 vaccines a definitive marketing authorisation, **so it is not conceivable that the question of the possible link between the menstrual disorders suffered by tens of thousands of women in Europe and the aforementioned vaccines will not be resolved with certainty before 29 December 2022.**

3. THE DEMANDS OF THE "WHERE IS MY PERIOD?

The OPESCT report having welcomed the initiative of the "Where is my period?" collective, has made it possible to highlight the importance of the number of women suffering from menstrual disorders following vaccination against Covid 19. The collective is continuing this action in the general interest of women by formulating the following requests to the EMA and the PRAC

3.1. Request for referral to the PRAC and implementation of a procedure known as "EU referral procedures for safety reasons

On its website the EMA recalls that "An **Article 31** pharmacovigilance referral procedure should be initiated when the interests of the Union are at stake and following the evaluation of data relating to the pharmacovigilance activities of one or more authorised medicinal products, and when none of the criteria listed in Article 107i(1)(2) of Directive 2001/83/EC is met...The term "Union interest" refers in particular to the public health interests related to medicinal products in the Union **(e.g. in the light of concerns about the safety of a medicinal product)** and to the free movement of products within the Union"[23] “

The EMA adds on its website that "The management of safety signals is defined in Article 107h of Directive 2001/83/EC, Article 28a of Regulation (EC) No 726/2004 and Chapter III of

of active substances, but which have different marketing authorisations and are authorised in different EU Member States, are evaluated together in a single assessment procedure".

[20] https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-7- 10-June-2022

[21] https://clinicaltrials.gov/ct2/show/NCT04368728

22 https://clinicaltrials.gov/ct2/show/NCT04470427

[23] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-answers-article-31-pharmacovigilance-referral-procedures_en.pdf

Commission Implementing Regulation (EU) No 520/2012 No 726/2004 and Chapter III of the Commission Implementing Regulation (EU) No 520/2012 “

And that a safety signal can be defined as: "Information from one or more sources, including observations and experiments, that suggests a new potentially causal association, or a new aspect of a known association between an intervention and a related event or set of events, whether adverse or beneficial, that is considered sufficiently likely to warrant verification action".

Finally, Article 19 of Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the implementation of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council provides that:

> *"1. it shall be determined whether new risks have emerged, or whether existing risks have changed, by means of signal detection and analysis of a medicinal product or active substance.*
>
> *For the purposes of this chapter, a signal is information from one or more sources, such as observations and experiments, revealing, with a probability considered sufficient to warrant verification, a new association that may be a causal relationship or a new aspect of a known association between an intervention and an event or set of related events, whether the effect is beneficial or adverse.*

Thus, the thousands of testimonies collected by the "Where is my period?" collective and recognised as conclusive by the French ANSM and by the OPESCT report should be considered as new safety signals of which the PRAC has not yet been informed.

The PRAC and the EMA should therefore take them into account as soon as possible. This consideration is all the more urgent as **MODERNA and BioNTech** laboratories **do not respond to requests to send additional information!**

The contradictions between the conclusions of the PRAC, which **find no link between COVID-19 mRNA vaccines and women's menstrual disorders, and those of the French OPESCT, which consider that they should already be considered as a proven adverse effect of vaccination, justify the implementation of** the "Article 31 pharmacovigilance referral procedures" to ensure under the precautionary principle, that the COVID 19 vaccines currently circulating on the European market do not constitute a **risk to the fertility** and general health of European women, and at the very least that they do not affect their **gynaecological well-being** and quality of life.

At this point, it is also worth mentioning the problem of the vaccination of pregnant women, which has been implemented while **the studies on the safety of pregnant women and their breast-feeding infants are still in progress at the time of writing! and those on teratogenicity (the impact of a drug on foetal development) have not even been carried out**[24] **.**

Despite this, the ANSM and the French Minister of Health, Olivier VERAN, have invited pregnant women to be vaccinated in the first weeks of their pregnancy, starting in spring 2021.

[24] https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

Unfortunately, the "Where's my period?" collective has received numerous testimonies from women who suffered miscarriages close to the time of the Covid 19 vaccination and even a few hours after.

3.2.Request for a public hearing

The PRAC has the possibilitý to organise public hearings in the context of referral procedures relating to the safety of medicinal products under Article 20 of Regulation (EC) No 726/2004, Article 31 or Article 107i of Directive 2001/83/EC.

A document available on the EMA website recalls that :

> **" 1.3. The main purpose of a public hearing is to obtain the public's views on the acceptability of the risks associated with the medicinal product/medicinal substance/class of medicinal products concerned, in particular in relation to its therapeutic effects and the therapeutic alternatives available, and to obtain suggestions and recommendations on the feasibility and acceptability of risk management and risk minimisation activities.**
>
> **...The marketing authorisation holder(ś) has (have) the opportunitý to present its (their) views to the participants of the public hearing"**
> [25]

The "Where's my period?" collective is calling for such a public hearing to allow the European institutions and pharmaceutical companies to answer women's questions, but also **to allow women to make their views known on the acceptability of the gynaecological risks associated with vaccination against Covid 19.**

Mrs. Christelle RATIGNIER CARBONNEIL, as Director of the French ANSM, recipient of all the testimonies of the "Where is my period?" collective, wished to set up such a public hearing, which unfortunately had to be postponed, **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**

A public hearing will provide an opportunity for an exchange between all stakeholders, European and national institutions, pharmaceutical companies and patients, and will shed light in full 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 determine whether these are acceptable in relation to the benefits of the vaccination.**

Please accept, Madam President of the European Commission, the assurance of my highest consideration.

Diane PROTAT

[25] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/rules-procedure-organisation-conduct-public-hearings-pharmacovigilance-risk-assessment-committee_en.pdf

List of attachments

Exhibit 1 - Press kit of the collective "Where is my period".

Exhibit 2 - 5 Testimonies reported on CERFA forms as examples

Exhibit 3 - Bailiff's report on the hearing of the "Where is my period" collective before the OPECST

Exhibit 4 - Extract from the public hearing broadcast by the French Senate on 24 May 2022, intervention by ANSM officials

Exhibit 5 - Extract from the public hearing broadcast by the French Senate on 24 May 2022, speech by Ms. Aure Saulnier

Exhibit 6 - OPECST report of 9 June 2022

Certified copies by registered letter :

1. **Ms. Loraine NOLAN, Chair of the Management Board of the European Medicines Agency**
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2. **The Chair of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC)**
Ms. Sabine STRAUS
European Medicines Agency (EMA)
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3. **Ms. Andrea AMMON, Director**
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171 83 Stockholm, Sweden

4. **Ms. Christelle RATIGNIER-CARBONNEIL Director General of the**
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143-147 Boulevard Anatole France,
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5. **Ms. Claire HEDON,**
Human Rights
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6. **Mr. Pierre HENRIET,**
Member of Parliament for the 5th constituency of the
Vendée President of the OPECST
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Copies for information by simple letter :

7. Dear Mr. Klaus
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8. Madam Senator
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