Your TEAM-PRRC association Newsletter N°9

July 31th, 2022

Editorial

Dear members, bonjour!

Summer is already there and IVDR is now in application since 2 months.
The sector is worried about the situation and the small quantity of notified bodies.
In its 50th plenary meeting in June, the CAMD proposes that the work on solutions move forward as a matter of urgency. You can find here the minutes.

Then EU health ministers met to discuss the status of MDR implementation. You can find here the document about information provided by the Commission on the status of the work. And if you want to watch the video, it is here.

Some ideas have been launched by ministers to limit the damages, as:
- Increase resources of competent authorities to speed up NB notification
- Simplify conditions to put legacy devices on the market
- Simplify requirements to put safe and lower volume devices on the market
- Simplify conditions to put essential, higher-risk devices on the market
- Reduce the administrative burden on manufacturers
- Extend the transition period
- Etc…

Many organizations like Biomedical Alliance, Medtech Europe and COCIR have also raised the alarm about the limited number of notified bodies and the potential disappearance of essential medical devices. We invite you to read their reports:

- Biomedical Alliance press release
- Medtech Europe survey report analysis
- COCIR : **« Proposed actions to enhance Notified Bodies capacity and preparedness »**

This definitively demonstrates that we need to stand together and help each other in this alarming situation. That's why TEAM-PRRC organizes an event in Brussels in November 3 and 4, 2022, to meet in person and to share knowledges and experiences to become "Compliant Together" (**more information in page 6**).

The TEAM

In this Newsletter:

Regulatory Watch

- **EUDAMED : new schedule delay**

A new official timeline was published on July 6, 2022 on the European Commission website.This timeline presents new milestones for the different modules of EUDAMED. It is worth noting that there is a one and a half year delay compared to the previous timeline published in April 2022.

Initially expected for March 2020, Eudamed should be finished in the second quarter of 2024.

- **Blue Guide: new version -** "The "Blue Guide" on the implementation of the EU Product Regulation 2022"

The changes made are mainly the result of taking into account Regulation (EU) 2019/1020 on market surveillance and product conformity, as well as changes to the medical device regulation.

- **Europe: 31st notified body according to MDR**

The 31st but the 1st Spanish Notified Body under the MDR: the National Center for Certification of Medical Devices (CNCps), based in Madrid (Notified Body number 0318) was designated on July 14.

- **Harmonized standards (RDM and RDMDIV): new publications under preparation, expected in Q4 2022.**

The May 2021 mandate for harmonized standards to the DM and DM-DIV Regulations of 2017 is likely to be amended as requested in June 2022. Harmonized standards are expected by May 2024.
The changes regarding harmonized standards to the 2017/745 regulation are listed below:

  - Addition of EN ISO 1135-4:2015 (transfusion), EN ISO 1135-5:2015 (transfusion) and EN ISO 10651-4:2009 (ventilators), EN 1865-6 (ambulances), EN ISO 11737-3 (sterilization), ISO 13004 (sterilization), ISO 18362: 2016/AMD1 (DM using cells), EN ISO 22441 (sterilization), ISO 80369-2:2021 (connectors), EN ISO 80601-2-84 (ventilators) and one standard without reference (respiratory infections)

  - Deletion of ISO 9978, ISO 14117, ISO 14708-1, ISO 27185, ISO 27186 and IEC 60601-4-5

- **Team-NB has published a position paper on the technical documentation assessment approach for "multiplex" IVD Devices.**

Multiplex" IVDDs are devices for which at least 2 markers are simultaneously detected through the diagnostic procedure.
The approach proposed by Team-NB in this document entitled "Notified body approach for the Technical Documentation assessment approach of multiplex in-vitro diagnostic devices" calls for focusing on verifying the technology used in the IVDD and then applying a risk-based approach to decide which specific marker data should be reviewed.

- **European Commission: further update of MDR and IVDR implementation schedule**

The European Commission published on July 14, 2022 a new update of the implementation schedule of the European Regulations (EU) 2017/745 (RDM) and (EU) 2017/746 (RDMDIV), entitled "IMPLEMENTATION ROLLING PLAN".

Your association:

We did our General Assembly in June 24th. All the resolutions have been adopted and the internal regulation has been updated. Daniel PETIT and Jean-Louis DIVOUX left their position in the Board but they will continue to help us to check your application in the association. We thank them a lot for their commitment and the huge work they did for the development of TEAM-PRRC.

We have enlarged the organization creating the Representatives PRRC Team on each Member States.

Condition and duties are detailed below:

Role:	Condition:	Duties are:
Representative PRRC – Member States	Should be at least 1 year as Active Member in the association	· Represent and communicate about TEAM-PRRC in the Member States in which he/she lives · Lead potential members to TEAM-PRRC · Keep an open communication with the Board · Manage webinars in the language of the country based on TEAM-PRRC webinars · Translate the templates proposed by TEAM-PRRC, if useful · Collect feedback from the field and data about national laws (from Competent Authorities) · Attend relevant events on behalf of TEAM-PRRC (as accepted and directed by the association)

We already have 4 Representatives PRRC and we thank them for their commitment.

- René DROST for The Netherlands
- Anna AMICH for Spain
- Piero COSTA for Italy
- José MALTA for Portugal

You can find their profile in our website : https://www.team-prrc.eu/page/934833-our-team

We also have some contributors who will take in charge the new versions of our Position Papers:

- Nadine ADIA and Emile UNK

And some other contributors who will share with us the sanctions for each Member States :

- Carole ROBIN and Aude VIDAL.

We still look for some contributors for :

Round Tables: the contributor can help us to collect the questions

FAQ: these are the Questions & Answers + Forum

We continue to maintain our close relationship with the relevant stakeholders including but not limited to EU MDCG. We will communicate in your name and provide your feedback by considering the legal text and rules of proportional applications. Towards that aim, we do need your support and inputs. Please send us your questions, your opinion, and your thoughts regarding the PRRC's duties, responsibilities and any other related topics.

The "FORUM" is operational in our site, in your member space. Use the opportunity to exchange with PRRCs and CHAT! We have also created the **LinkedIn closed group** in LinkedIn called "**TEAM-PRRC Forum**" to facilitate the exchanges between members. This closed group is only open to members of the association.

To recall, the membership is in 2 steps:

1- You enter your profile data and we check and approve it
2- You pay the membership fee and we give access to your member space

The fees to become an active member are fixed to 250€ for a year and the renewal is fixed to 200€ per year.

You association is also preparing Round Tables and webinars, and try to negotiate some discount with other organization that can be interesting for PRRCs.

Round tables open to all, free of charge, were a success to make known the association all over the world and to be able to have some feedbacks from PRRC.

Consequently, we will focus this year to webinars and other training program in 2022.

Short News

- **4 Position Papers published:**
  - Position Paper No1 on qualifications of the PRRC
  - Position Paper No2 on contracts and location
  - Position Paper No3 on the responsibilities of a PRRC within a Manufacturer
  - Position paper No4 on the responsibilities of a PRRC within an Authorised Representative.

- **Specialised PRRC topic webinars will be organized every month or every 2 months**
- **Collaboration with RAPS to develop a training dedicated to PRRCs.**
- **A face-to-face event in Brussels in 3 and 4 November, 2022.**
- **A job description template in process**

Just for you (our active members)!

This tab (**For U**) in our Website includes opportunities and discounts from our cherished sponsors, specifically reserved for our active members. There are attractive prices on training, news feeds and regulation watches, along with documents and templates for your everyday activities… and much more!!

Let's meet IN PERSON in the inaugural TEAM-PRRC ANNUAL SUMMIT event, in November 3 & 4 2022, in Brussels.

Save your seat in the link below:

-Special price for members with this link : click here
-If you want to attend the event and you are not a member of TEAM-PRRC, please use this link : click here

Places are limited and you can benefit from early bird fees until September 20.

You can download the program here (at the bottom of the page of our website).

See you there!

MDlaw annual membership: 43 EUR – 125 EUR – 330 EUR

TEAM-PRRC member promotion: **50% on all membership levels**, starting at 23 EUR per month! The discount coupon is shared in membership area {to be used at the checkout of the Store}.

20% Special discount for all the webinars to any Team-PRRC member (up to date with his membership fee).

Online **MDR (EU) 2017/745** training course (French only); 6 months continuous access and including 2-hour-live session of Questions and Answers: TEAM-PRRC members special rate: 750€ (instead of 1000 €).

Special 20% discount on one year "Premium" subscription to "Flash de DM Experts" articles.

And more!

Our sturdy partner MDlaw wrote a very interesting article, on language requirements and sanctions under MDR in Belgium.

They exceptionally agree to share it only for TEAM-PRRC members. Find it here :
Language requirements & sanctions under the MDR: Belgium
Pdf file will be available in the Active member space.

Past Events from January to July:

In January 11th, TEAM-PRRC has organized a Round Table, free of charge and open to all, presented by Ronald BOUMANS, member of TEAM-PRRC Board and Erik VOLLEBREGT was our guest.
This session demonstrated that the PRRCs are still searching for their role and responsibilities.

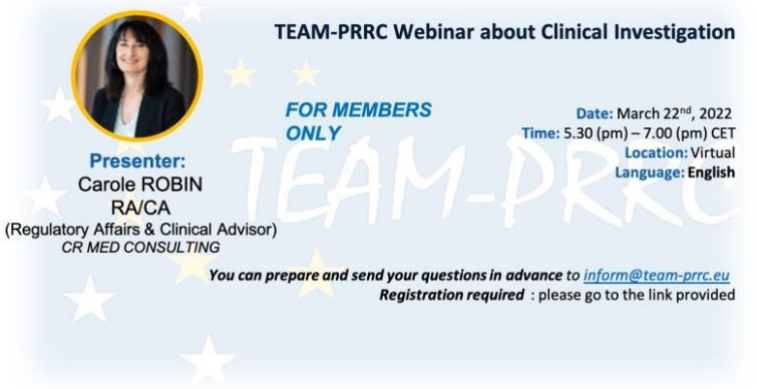
TEAM-PRRC webinar in 8th February, 2022 – dedicated to members.

The presenters Anne Jury and Elem AYNE shared more explanations regarding :

1) Position Paper N°1: qualifications required to become a PRRC
2) Position Paper N°2: contracts and location

TEAM-PRRC webinar planned in January and February,– free of charge and open to all.

This is a webinar about **Cybersecurity and the role of the PRRC**, presented by Cécile Théard-Jallu, a healthcare lawyer. She has presented the presentation twice in French and English.



TEAM-PRRC webinar planned in 22th March, 2022

This was a webinar about the **clinical investigation** presented by Carole Robin, a member of our association and an expert in Clinical Investigation.

TEAM-PRRC webinar planned in April 2022

This was a webinar about **Vigilance** presented by Monir El Azzouzi from Easy Medical Device who shared with us what a PRRC should know about vigilance.

TEAM-PRRC Round Table planned in April 2022

This was a round table to discuss and read together the MDCG 2022-4 guidance on appropriate surveillance regarding the transitional provisions.

TEAM-PRRC webinar planned in April 2022

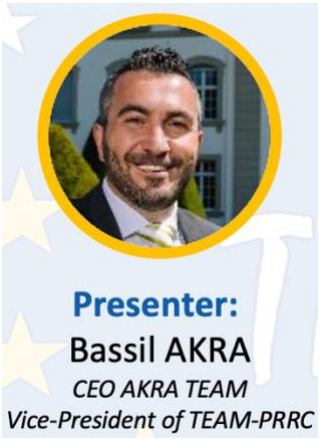
We received many questions about **the sanctions**. That's why, a webinar has been planned about the sanctions. This webinar was leaded by Carole Robin and Aude VIDAL.

TEAM-PRRC webinar planned in April 2022

This webinar has been presented for the second time by Ronald BOUMANS, from the Board, about How a PRRC should communicate with authorities.

TEAM-PRRC will continue to provide webinars and round tables session to be able to help PRRCs answering their questions about their daily activities.

To come



TEAM-PRRC webinar (in ENGLISH) planned for September 22th, at 4.00 pm CET – dedicated to members, about IVDR.

>>>>> The link to attend will be shared by email and on LinkedIn later.

As you know, 26th of May, 2022 is the year of the application of IVDR. That's why it will be important for us to propose to our members a webinar about that regulation and the PRRCs for IVD sector. **This session is planned for September 22th and will be presented by Bassil AKRA, our vice-president.**

We will continue to plan other webinars, and if you want to discuss one topic in particular, do not hesitate to write us directly to inform@team-prrc.eu .

Join us now and you could attend all these webinars, with the opportunity to get the answers to all your questions. Look forward to meeting you!!

A big thanks to our sponsors: visit them on our website!

We wish all medical devices actors a good summer ahead for the application of the IVDR and all the best for the PRRCs in their function.

The TEAM