

CTR pilot project

Info session on CTR 23 September 2021

Agenda

- Some reminders on the BE CTR pilot project and dossiers
- Progression of the CTR pilot project over the years
- Adaptations in 2021
- Conclusion



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BE CTR pilot project

- Has started in May 2017
- CTA dossiers submitted in the CTR pilot on voluntary basis
- Assessed following the spirit of the Regulation in collaboration with voluntary ECs => one single decision for Belgium at the end



BE CTR pilot project

The pilot project follows the spirit of the regulation :

- CTR dossier with Part I and Part II (fully electronic submission)
- FAMHP is National Contact Point (NCP) for sponsors (CTRpilot@fagg-afmps.be)
- Exchanges with College which selects the independent EC (law of 7 May 2017)
- CTR assessment report templates
- One round of questions and only 12 days for the sponsor to answer the Request For Information (RFI)
- One single decision and approval E-mail at the end of the process
- Modifications of approved pilot initial dossiers submitted as Substantial Modifications within the CTR pilot project



BE CTR pilot project

The pilot project follows the spirit of the regulation :

BUT

- No interaction with other member states, unless for CTR pilot VHP plus process
- Timelines of the law of 7 May 2004: from T0 : 15 days or 28 days (+ 30 days for ATMP/GMOs contained use)
- With 2 approval letters attached to final conclusion (Law 7 May 2004)
- Without EU Portal and database



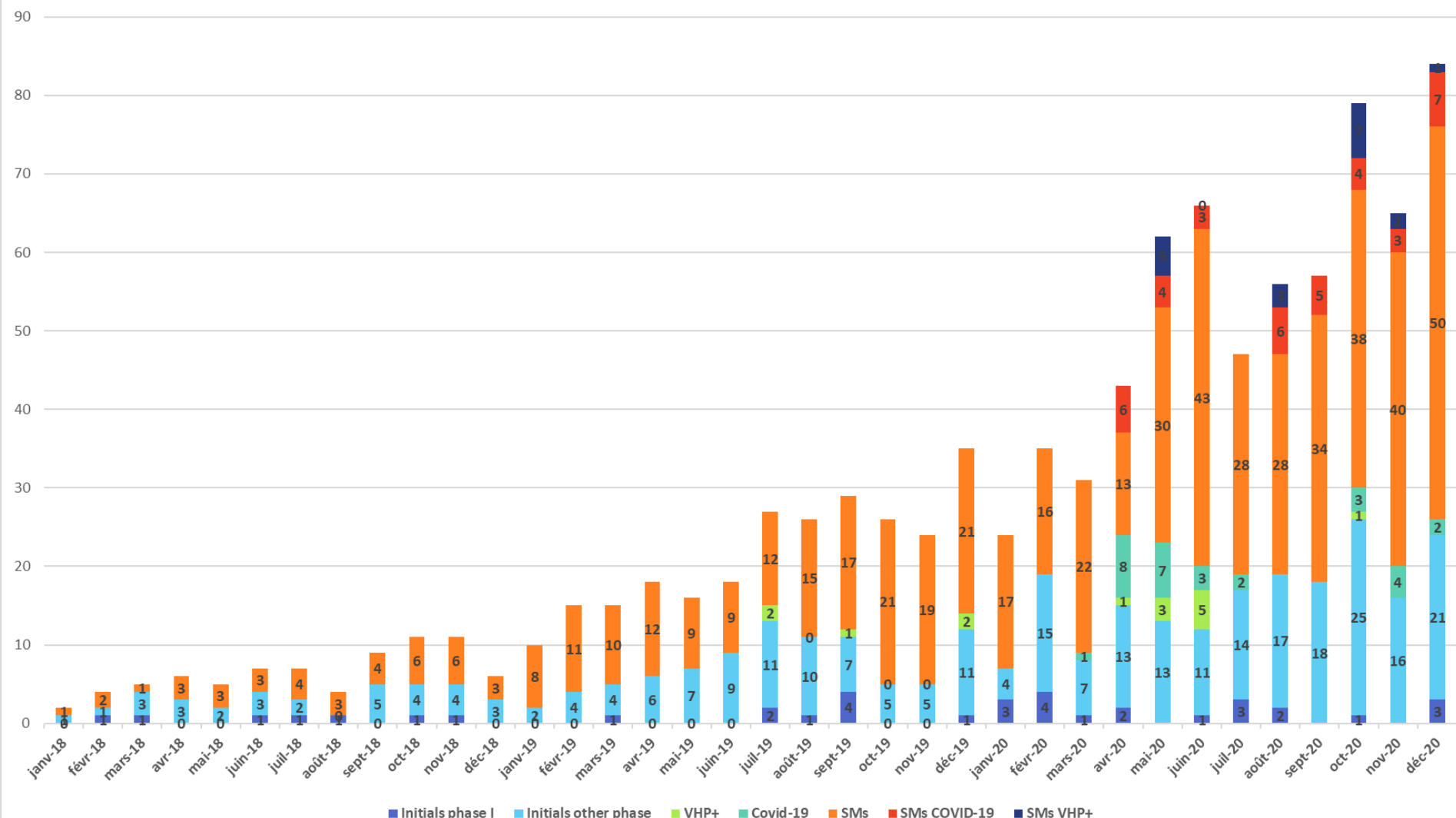
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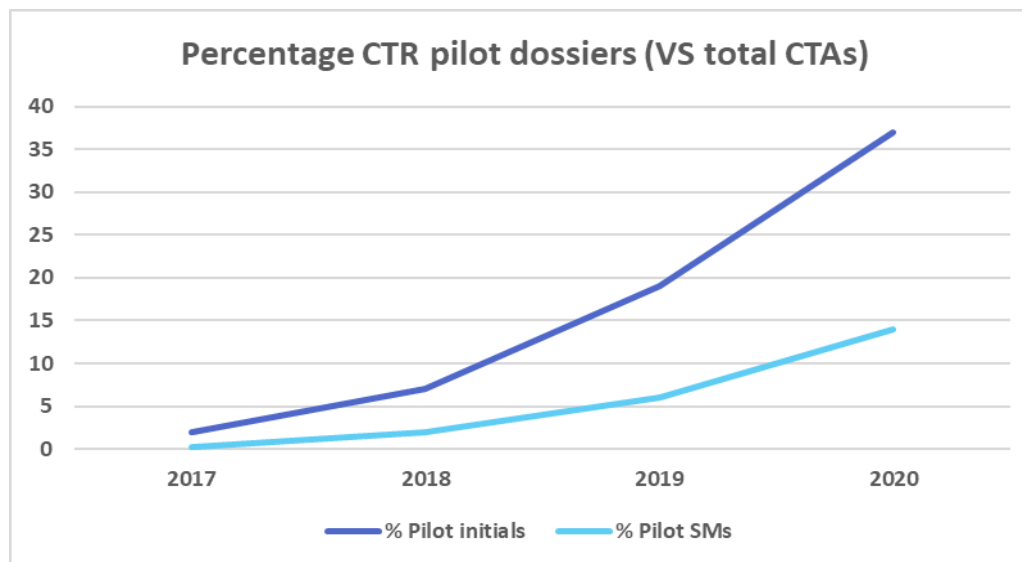


Progression of the CTR pilot project

Nbr of dossiers received per month (TS)



Progression of the CTR pilot project



Type dossier	2017	2018	2019	2020
% Pilot initials	2	7	19	37
% Pilot SMs	0,2	2	6	14

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Adaptations in 2021

- Beginning 2021 around 40% of the initial CTA dossiers were submitted in the CTR pilot project

=> Constant progression of the CTR pilot 😊

- But second wave of the Covid pandemic

=> Direct impact : increase of the Covid-19 CTA dossiers

=> Indirect impact : decrease of our capacity for non-Covid-19 dossiers (Pilot and Directive)

=> delays were experienced in the handling of a part of the CTA dossiers



Adaptations in 2021

- Therefore it was decided to momentarily limit the number of CTR pilot **initial trials** accepted per period of time (2 per week) in view of a stabilisation of the situation
- The principle of timeslots doesn't apply to Covid-related initial trials nor Substantial Modifications
- It was unfortunately not possible to come back to the full acceptance of CTR pilot dossiers due to constant of the high Covid-19 dossiers workload



Adaptations in 2021

End of the CTR pilot project for initial dossiers

- It has been decided that the last possible time slot for the submission of an initial CTR pilot dossier will be available on 14/10/2021 (alignment with EU level decision for VHP dossiers)
- This means that this dossier will have to be submitted between Monday 11/10/2021 and Friday 22/10/2021
- This will allow all CTR pilot initial dossiers to be finalised before CTR comes into force on 31/01/2022



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Conclusion

- The CTR pilot project started slowly in 2017
- But the number of CTR pilot submissions raised constantly from 2018
- Indeed, the process has many advantages:
 - Excellent preparation for CTR for all, especially sponsors
 - Single submission for multi sites trial
 - No need to align with the meeting dates of a particular EC
 - Single authorisation (from agency/Ethics) – competitive timelines.
 - Single authorisation of amendments – very competitive timelines
 - Easy addition of an extra site (after 3m)
 - Zero fee



Conclusion

- But very high administrative workload in absence of the EU portal and occurrence of the Covid-19 pandemic => capacity issues and some delays
- However, it remains a fantastic experience as preparation of the implementation of CTR and CTIS
- CTR pilot project continues with the submission of the Substantial Modifications until 31/01/2025 at the latest



Conclusion

CTR pilot project accomplishment (estimation of the situation when CTR will be implemented):

- 500 CTR pilot initial dossiers
- 1200 CTR pilot Substantial Modifications
- 17 CTR Pilot VHP plus initial dossiers (5 with Belgium as RMS)
- 50 CTR pilot VHP plus Substantial Modifications
- A huge number of notifications



Conclusion and questions

Thanks a lot for your interest and participation

- Do you have questions ?
- Don't hesitate to send us your questions to CTRpilot@fagg-afmps.be



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