

# Slot booking system in EU and cancellation

**CMDh meeting with Interested Parties**  
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Agence française de sécurité sanitaire  
des produits de santé

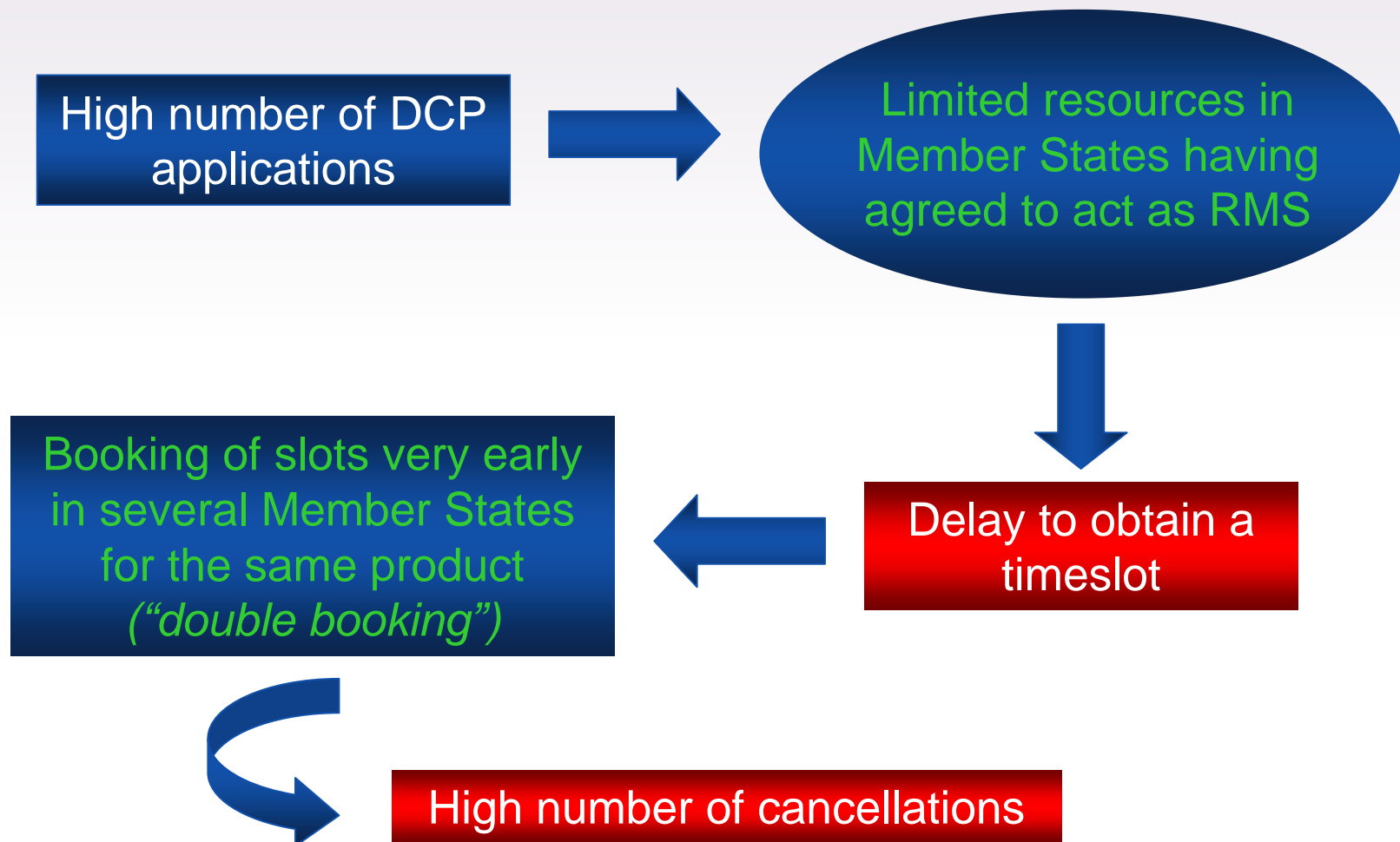
# Introduction

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- Due to the **success** of the decentralised procedure, the delay for obtaining a slot became longer and longer:
  - **several months to more than 18 months**  
*(depending on the chosen RMS)*
- **Big pressure** on the EU Registration System for decentralised procedures
- Need for companies to “**secure**” the slot in order to start the procedure in due time

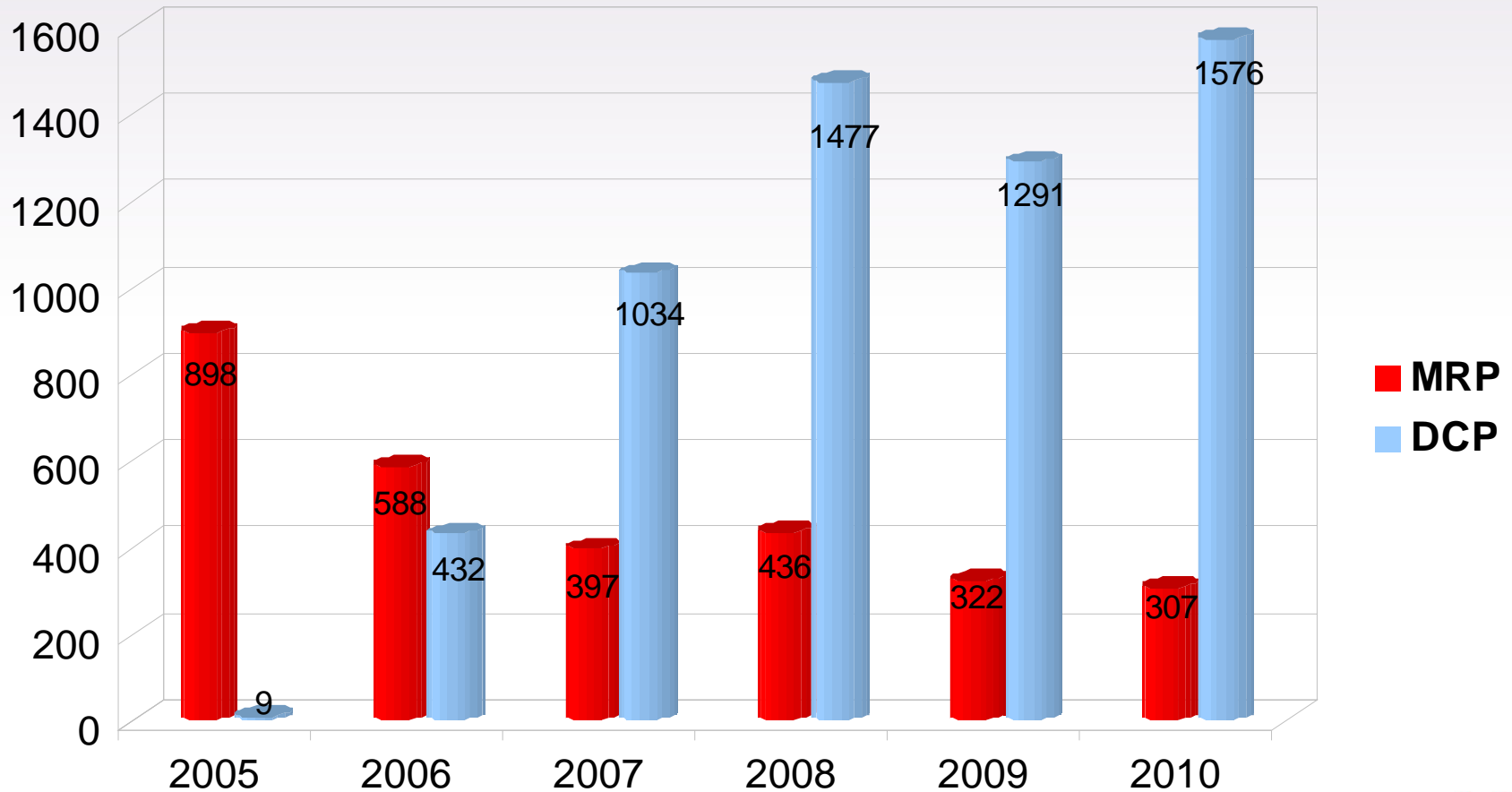
# Introduction

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# MRP/DCP

## Procedures started: 2005 - 2010



# Consequences

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Member States have taken measures to better manage the high number of requests for timeslots and improve the visibility of the registration process:

- Increased availability of timeslots
- Improvement of the booking system with new rules and recommendations published on their websites
- New organisation in the evaluation process: efficient use of resources, risk-based approach etc.



**Creation of the HMA/CMDh Taskforce on Resources for MRP and DCP to analyse the problem and identify ways to achieve progress**

# Slot booking system in EU

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**2 systems** for booking timeslots are mainly used by the Member States:

- System where the slot request can be made **at any time during the year**
- System where the slot request has to be submitted **within specific “windows”**



**Transparency on slot booking system has been increased by publishing information on the CMDh website regarding Member State systems for allocating timeslots**

# Information on slot booking systems in place in each Member State – CMDh Website

<http://www.hma.eu/92.html>

## DECENTRALISED PROCEDURE - REQUESTS TO ACT AS RMS

*Doc. Ref.: CMDh/020/2009/Rev4  
March 2010*

The Heads of Medicines Agencies' Task Force on Resources in DCP in cooperation with CMDh has developed a common request form to be used when asking a National Competent Authority (NCA) to act as Reference Member State in a decentralised procedure. The Heads of Medicines Agencies has agreed to publish the request form on the CMDh website as well as on all national competent authorities websites.

The request form (<http://www.hma.eu/219.html>) should be submitted to the NCA in accordance with information provided by that NCA. Below is a list of links to the NCAs' webpages where their recommendations for requests to act as RMS are published.

MEMBER STATES	SUMMARY OF NATIONAL BOOKING SYSTEMS & LINKS TO NATIONAL WEBPAGES
FRANCE	<p>Applicants wishing to apply for a marketing authorisation through the decentralised procedure with FR acting as RMS are advised to inform AFSSAPS at an early stage about their intentions by sending in electronic and paper formats of the common request form duly completed with an official letter to the project manager in charge of the therapeutic class (see information available on the AFSSAPS website).</p> <p>The AFSSAPS will allocate timeslots 3 times a year for the following year i.e. in 2010, timeslots are allocated for 2011.</p> <p>The timeslot request has to be confirmed by the applicant 6 months before the submission date agreed by AFSSAPS.</p> <p>A timeslot is allocated for a medicinal product with an agreed submission date. Neither the medicinal product nor the submission date can be changed.</p> <p>AFSSAPS can put products on a "waiting list" which are ready for a quick submission following a cancellation of a slot.</p> <p>Further details are published on the AFSSAPS website: <a href="http://www.afssaps.fr/var/afssaps_site/storage/original/application/07aad0b4b47b5d1570eb7df63d7b9f51.pdf">http://www.afssaps.fr/var/afssaps_site/storage/original/application/07aad0b4b47b5d1570eb7df63d7b9f51.pdf</a></p>

# Cancellation of slots

## Percentage of cancellations in 2010

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Between **40 and 50%** of **cancellation** of slots in **2010** in the Member States most involved as RMS in DCP

### Main reasons given by the companies:

- 1- **The dossier is not ready:** difficulties encountered in finalizing the dossier, data not yet available, negative results of the studies etc.
- 2- Slot allocated by another Member State: « **double booking** »
- 3- **Change in the registration strategy** of the company

# Cancellation of slots

## Consequences

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- The number of cancellations reached a high level with **nearly half of the slots cancelled in 2010**
- This situation is quite **similar in the majority of Member States** who are regularly involved as RMS in DCP with the same percentage of cancellations
- **Many cancellations are very late** and prevented the reallocation of slots cancelled to other dossiers
- Some Member States anticipate this situation by making **“surbooking”** of timeslots

# Cancellation of slots

## Consequences

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### → Negative Consequences for the Member States

- Fewer procedures started in several Member States in 2010 although resources were available
- Cancellation of slots has a **major impact on the organisation and management of resources** within the National Agencies:
  - difficulties to have an efficient use of internal resources due to lack of visibility of the number of procedures expected



**It is very easy for companies to book a slot and cancel it afterwards without any constraints.**

**New rules should be adopted to limit this phenomenon**

# Possible options for further discussion

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- **Central information of booking systems in EU**
- **Slot booking fees**
- **Sharing information about companies identified as making a lot of slot cancellations**
- **Other proposals?**

**→ need to choose the right measures to improve the system**