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Access to generic medicines through an efficient regulatory system

Session 2: Achieving an efficient regulatory of Afssaps (Fr): Outcome of the discussion at the HMA during the French Presidency on the use of existing resources in the most efficient way

Agence française
de sécurité sanitaire
des produits de santé

afssaps

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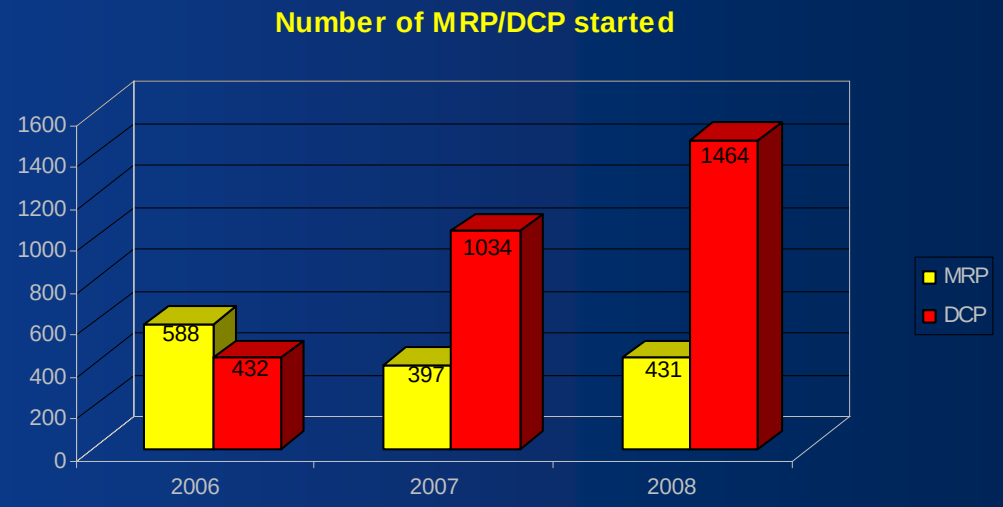
Why a discussion on resources at HMA level was needed (1)? A compelling issue of resources strains, if not resources gap

- Intensification of established tasks : example of pharmaceutical quality assessment, due to the increasing number of generic submissions and variations;
- Additional assignments deriving from legislation for NCA at national level, as contributors to centralised tasks (widening of CP scope) or at both levels (paediatrics);
- Some of the new missions are not matched by corresponding resources (either for lack of financing at European level - paediatrics, herbal - or due to budgetary and public workforce restrictions at national level).

Why a discussion on resources at HMA level was needed (2) ? A specific challenge in the field of marketing authorization.

- Spectacular increase in the number of submissions within the centralised procedure, which has trebled in four years to reach more 140 in 2008,
- Dramatic success of the decentralised procedure: more than 1000 submissions as soon as in 2007, more than 1400 in 2008,



- At the same time, national procedures are still very active, and even on the increase in some countries.

Many national agencies already tried on their own to cope with the scarcity of resources

- Organisational reengineering : adapting organisational design; revisiting work methods;
- Revamping information systems : workflow, common data bases, full digitalisation of some procedures;
- Developing operational cooperation between different areas of regulation : evaluation, inspection, laboratory control…
- Rethinking operational strategies with a view to prioritising actions on the basis of risk based and public-health-added-value concepts.

But just adding national efforts was not , enough, and a coordinated response from the European network was required

- First discussions in 2007, stimulated in particular by complaints from generic industry about the mouting difficulties of decentralised procedure,
- creation of the resources planning group (Chair: Steve Dean) with initial focus on centralised procedure,
- Setting up of a specific task force on availability of resources at NCA's on MRP/DCP (Chair: Gunnar Alvan, then Martina Cvelbar from August 2008 on),
- launching of a more qualitative reflection on training within the HMA training project team (Chair: Gro Wesenberg)

2008 has been a milestone in that process of devising a common approach of the network on the issues of resources

- Strategic discussion at the July HMA meeting near Paris : first example of plenary + workshop scheme during a HMA meeting,
- Strategic day focused on resources in Saint-Denis on September 5th: in depth discussion between a number of HMA, based on reports of the chairs of the above mentioned groups and a report on the July meeting,
- Approval of the recommendations from the strategic day at second HMA meeting on November 6th and 7th in Paris

Outcome of the recent discussion at HMA level (1)

Common concern on resources confirmed but with some precisions and questions requiring further analysis

- **Shared perception of an increase of the workload in many if not most areas of regulatory activity,**
- **Some perplexity on why volumes are increasing in all authorisation routes, in particular DCP and some national procedures : further discussion with industry needed to explain those evolutions and some future prospects,**
- **Need to avoid overlooking some national specificities : strains on the workforce level more or less strong depending on the structure of financial resources and overall civil service management policies ; differences in public health priorities and expectations .**

Outcome of the recent discussion at HMA level (2)

Main avenues of progress : securing availability of adequate resources

- **Systematically evaluate at an early stage the impact of new legislation and procedures on regulatory activity at NCA level as well as at EMEA level,**
- **Try as creatively as possible to convince outside decision-makers of the need to put additional resources in the system to match new assignments that produce significant increase in workload,**
- **Prepare in advance for meeting quantitative and qualitative challenges, through internal reorganisations and adequate training, requiring enhancement of change management skills.**

Outcome of the recent discussion at HMA level (3)

Main avenues of progress : enhancing efficiency in the use of scarce resources

- **Avoid duplication of assessment within the network,**
- **Developing work-sharing on the basis of existing experiences (PSURs, Paediatrics,…),**
- **Promoted a better use of IT systems and virtual meetings to spare time and energy both within the network and in operational connection with stakeholders.**

Outcome of the recent discussion at HMA level (4)

Main avenues of progress : improving relevance in the use of scarce resources

- **Develop priority setting among all regulatory activities, based on a more systematic assessment of the impact of activities, to focus on areas of most added value,**
- **Share national reflections and tools to foster risk-based methodologies in each area of regulation.**

Outcome of the recent discussion at HMA level (5)

Main avenues of progress : what about MRP/DCP specifically ?

- **Various approaches currently developed at NCA level to avoid duplication of assessment work between RMS and CMS,**
- **Need to harmonise operational tools for handling submissions : harmonised booking system with time slots, hormonised booking form very soon,**
- **Need to devise and implement innovative methods to spare time and make procedures more fluid: harmonise the format of booking time slots, possibly develop bundling similar applications for assessment.**

Outcome of the recent discussion at HMA level (6)

Main avenues of progress : the necessary contribution from industry

- **To further analyse quantitative evolutions and perspectives,**
- **To stick to responsible behaviour in order to facilitate a smooth evaluation process : avoid submitting poor quality dossiers, refrain from double booking or last minute cancellation of submissions, secure proper translations …**

Conclusion

- 2008 has brought a lot of additional light and ideas to address the issue of resources,
- Significant efforts have already been made to tackle the specific problem of MRP / DCP, in particular through on increased involvement of a number of NCA
- But the magnitude of the issue is such that we shall have to be very innovative in combining several types of approaches to devise a lasting and adequate response.