



**ECPA's comments on effective authority structures
to ensure quality evaluations of active substances
and zonal product authorisations**

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Introduction

In considering the implementation of the new Authorisation Regulation, and in particular the zonal approach, it is clear that some Member States are better equipped than others to deal with the major workload involved and ensuring a timely evaluation that is in line with the given legislative framework.

The new authorization Regulation requires in Article 75(3) that “Member States shall ensure that competent authorities have a sufficient number of suitable qualified and experienced staff so that the obligations as defined in this Regulation shall be carried out efficiently and effectively.” Given the increasing workload linked to product authorisation and other obligation in the Regulation, industry has concerns that the current structures in place in a number of Member States will not be adequate to ensure efficient evaluations to cope with the current workload, and that they will not have the necessary resources in order to deliver what is required as part of the Regulation.

This document sets out an industry viewpoint on effective authority structures, given the experiences of dealing with a variety of different authorities and structures in the 27 Member States. With the evolution of the zonal process, a number of Member States are expected to review the structures currently in place. Our aim with this document is to provide a number of suggestions that can be considered in such a review.

What efficiencies can be gained in carrying out the evaluation?

One evaluating body in each Member State

While some Member States have one authority that carry out the whole evaluation, others delegate part or all of the evaluation to other Ministries, government’s bodies and external agencies. In the great majority of cases, the evaluation processes are much more efficient when carried out ‘in-house’ by one authority.

The delegation of the work increases the coordination resources required. Most worrying is the fact that a number of delegated authorities are not closely involved in the implementation of the legislation and in a number of cases, the evaluation does not comply with the parameters given in the EU legislation. The assignment of work has however been shown to work effectively – but only when the evaluation is properly managed by relevant experts (or ‘project managers’) in the lead authority.

With the development of the zonal system, having one evaluating body would simplify the coordination and streamline the cooperation between Member State authorities.

- ***One central authority carrying out all the work ensures greater efficiency and coordination.***
- ***Where delegation takes place, a project leader is required to manage the work.***

Clear deadlines to be set out and met

A number of authorities have clear deadlines set out and where the results of their performance in carrying out the evaluation is made public. Such a system is supported by industry as it increases transparency and encourages authorities to look at potential areas of efficiency gains. This will be particularly important in order to ensure that the deadlines for zonal evaluation process are respected.

- ***Support a system which includes clear deadlines and published information on whether the deadlines are being met.***

The role of fees

Fee payment linked to the work carried out

While industry has raised concerns about the level of fees charged for evaluation work, it is accepted that a fee system can ensure that authorities have the resources and independence to carry out the evaluation work within given deadlines. The level of fees should be related to the cost of the work to be carried out.

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Fees to remain within the authority

Paying a fee to a central government budget, as is currently the case in a number of Member States, usually leads to a situation where the actual work carried out is in no way linked to the fee paid. A fee system works most effectively when the fee remains within the managing authority with the fees being reserved to fund the resources required to carry out the work.

- ***Fees should be paid to the authority to ensure that the funds are used to pay for the necessary evaluation resources.***

Making the zonal process work

Clear processes respecting agreements reached at the EU level

The development of clear processes, guidelines and formats which respect the legal timelines, will be essential to ensure the successful evolution of the zonal system. The system cannot be successful if decisions taken at the EU level are not respected. A number of situations currently exist where EU guidance documents are not followed by national authorities and where EU agreed evaluation end-points are not accepted in national evaluations. Further progress is required to ensure that EU level agreements are respected by all authorities, in order to make the zonal and EU system more workable and transparent.

Conclusion

Effective evaluation authorities are essential to ensure the successful implementation of the zonal system being put in place as part of the new authorization Regulation.

The structures in place in a number of Member States should be reviewed in order to improve the national evaluation processes and to maximize the benefits of worksharing that can be gained through the zonal system.