

How to ensure efficient authorisation & variations procedures for non-prescription medicines ?

How to maximise resources available?

AESGP Member's Meeting

4 February 2009

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Resources issues

- **Experienced in all national competent authorities/Agencies**



- **“Better regulation” principles can help better allocation of scarce resources**

Better Regulation / Legislar mejor



Better Regulation initiative

Goal: Decrease administrative burden to contribute to the strengthening of competitiveness and support growth

‘Less red tape = more growth’

**Not compromising
Public Health,
but improving it!**



Better Regulation initiative

PRACTICAL APPLICATION AT

NATIONAL LEVEL:

EXAMPLES

Belgium

- Improvement of the **IT system**
- Process improvement/simplification:
 - Simplified marketing authorisation system
 - Simplified unique registration number
- **Automatic mailing system** for national minor variations

Finland

- Agency (NAM) has streamlined operations and **focused resources on major issues**
- Rejection of bad quality applications
- **No re-assessment** when concerned MS
- Building **electronic infrastructure** (the project has been delayed due to technical issues and NAM's move)

Germany

- Authorities (BfArM) set up ‘**simplified procedures**’
- Duplicate applications, informed consent, generic, certain extensions & changes (pack size, naming), minor variations
- Increased use of **modern information technology** e.g. sunset clause, notification of changes
- Increased responsibilities for more junior staff
- Pragmatic treatment with **evaluation proportionate to risk** level

Ireland

- **Full review** of all processes and procedures by Agency Board in 2001
- **Organisational changes** + full implementation of **IT** architecture in 2004
- **Renewal and variation backlog cleared end 2005 and backlog for national applications by mid-2006 as planned**
 - In 2003, input = 13,500; output = 8,000
 - In 2006, input = output = 18,000
- **Dialogue** Agency-industry continues

Italy

- Agency (AIFA) pilot project for **electronic uploading/check-in of variations** in the context of e-transparency platform – roll-out awaited
 - **New ‘silent assent’ procedure in place:**
 - Wait = 14+5 days (type IA)
 - Wait = 30+5 days (type IB)
- if no answer from Agency = ok to implement**

Netherlands

- **New business system information and communication infrastructure**
- **New system for allocation slots decentralised procedure (DCP)**
- **New web portal pilot project**
 - **Applicants can trace application in Agency system**
 - **Next: Submissions of applications**
 - **Expected to be rolled out in 2010**
- **PSUR worksharing**

Sweden

- **Simplified** renewal
- **Pragmatic** implementation of ‘**sunset clause**’
- **DCP**: new way of handling slot times
- **Information** on **e-submissions** **timelines** **published**
- **Building** **electronic** infrastructure


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Stakeholders' Information

The use of resources within the European Medicines Regulatory System

The Heads of Medicines Agencies (HMA) is concerned about optimising the use of resources within the European Medicines Regulatory Network (EMRN) and is fully engaged in implementing measures to improve its overall efficiency and coordination within the fields of responsibilities of the National Competent Authorities (NCAs).

Considering the increasing workload in all areas of activity by HMA and with a view to achieving its common mission in promoting public and animal health in Europe, HMA has endorsed the adoption of a public health priority setting agenda based on risk based

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HMA proposals

- Set-up of booking system, **worksharing, exchange of expertise**
- Make mutual recognition/decentralised procedure **work more efficiently**
- Development of common understanding of **risk-based approaches**
- More **efficient** use of **IT systems**, etc.
- Common and coordinated training strategy

Key points

- **National examples illustrate “better regulation” in practice**
- **HMA proposals → promote adoption of similar measures in all other EU countries**
- **Benefit both Authorities and Industry → patients and consumers / Public Health as a whole**