Transitional arrangements

When to switch from the current to the new pharmacovigilance system?

(Florian Schmidt, DG SANCO, D.5)

When does it start?

- **For CAPs: 2 July 2012**
- **For NAPs: 21 July 2012**

…but it is not a revolution, but an evolution with a progressive switch to the new legal and regulatory framework

… some features of the new pharmacovigilance legislation will only be fully functional in some years (Eudravigilance)

What does the July date mean for pending marketing authorisation applications?

- **Basically, nothing!**
- **Applicants are not required to "upgrade" pending marketing authorisation submissions in accordance with new requirements (RMP, PSMF…)**
- **Applicants may however, discuss with competent authorities a switch from the detailed description of the PhV system to a summary description + PSMF, if they wish**

What does the July date mean for pending renewal applications?

- **Basically, nothing!**
- **Applicants are not required to "upgrade" pending renewal submissions in accordance with new requirements (e.g. PSMF, updated evaluation)**
- **Applicants may however, discuss with competent authorities a switch from the detailed description of the PhV system to a summary description + PSMF, if they wish**

What does the July date mean for pending referrals?

- **Basically, nothing!**
- **For referrals for which notification was received before July 2012, the matter is assessed by CHMP, without requiring PRAC and CMD(h) involvement**
- **All referrals for which notifications will be received on or after the date of application of the new provisions will be processed under the new rules**

Pharmacovigilance System Master File

What changes?

- **For all** new **applications: Summary description, instead of DDPS**

*What does it mean for **existing** marketing authorisations?*

- **Progressive switch to summary description + PSMF until July 2015**

When to switch?

- **Renewal or voluntary variation (between 2012-15) or mandatory variation (July 2015)**

Risk management plan

What changes?

- **For all** new **applications: RMP is required**

*What does it mean for **existing** marketing authorisations?*

- **Where granted with a RMP, the marketing authorisation holder shall continue to operate and maintain a RMP**
- **Where granted without RMP, competent authorities may request in justified cases a RMP post-authorisation (Article 104a of Dir. 2001/83 + Article 21 of Reg. 726/2004)**

Post-authorisation safety studies (PASS)

What changes?

- **In accordance with the new provisions competent authorities may impose PASS as a condition to a marketing authorisation**
- **PRAC responsible for PASS oversight (Protocol approval etc.)**

What does it mean for existing PASS?

- **PASS oversight (Article 107n to 107q) not applicable to PASS imposed prior to July 2012**

Periodic safety update reports

What changes?

- **Risk-based approach under the new provisions**
- **Must contain evaluation of risk-benefit balance**

What does it mean for PSUR submissions?

- **From July 2012: PSUR submission not applicable to generics, WEMU, THMP, homeopathics, unless specified in the MA or requested**
- **For centrally authorised products for which PSURs will be submitted on or after 2 July 2012, the PSUR will be processed under the new rules with the involvement of PRAC**

Renewal applications

What changes?

- **Modified submission deadline (9 instead of 6 months)**
- **New data requirements**

What does it mean for a renewal application?

- **As of July 2012 submissions have to comply with new data requirements**
- **The 9-months deadline applies only to products for which the marketing authorisation ceases after 2 April 2013/21 April 2013 (phasing-in)**

Q&A documents

Commission published a Q&A document on its website:

www.ec.europa.eu/health/human-use/index_en.htm

Check for CAPs the website of the European Medicines Agency:

www.ema.europa.eu

Check for NAPs the website of HMA:

www.hma.eu

Any questions?

Thank you

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