EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP V and RMP Template Rev 2 – Update on implementation

11th industry stakeholder platform, 02 June 2017

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An agency of the European Union

GVP V and RMP Template Rev 2 published on March 2017

EMA guideline on good pharmacovigilance practices: Module V – Risk management systems (Rev. 2)	(English only)	adopted	25/06/2012	30/03/2017	31/03/2017

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000360.jsp&mid=WC0b01ac058067a113

Guidance on the format of the risk management plan (RMP) in the EU – in integrated format (Rev. 2)	(English only)	adopted	30/03/2017		31/03/2017
Guidance on format of the risk-management plan in the European Union – in integrated format (Rev. 1)	(English only)	adopted	08/11/2012	21/08/2013	22/08/2013

Transitional arrangements

Rev 1 Template RMPs accepted:

- 6 months from publication i.e. 30 September 2017:
  - Initial MA applications
  - D121 responses
- 12 months for all other submissions, i.e. 31 March 2018:
  - D181 responses
  - D91 responses for initial MA applications with accelerated assessment
  - All post-authorisation submissions

After these dates there will be no exceptions: RMP using Rev 1 -> outstanding issue: to update the RMP

Consider using early the Rev 2 of the RMP Template (e.g. long or parallel procedures)

Further guidance in preparation

- Pre-submission and post-authorisation procedural guidance (PAG & PSG) to be updated
  - Including more guidance on RMP submission and assessment in parallel procedures
- RMP Q&A on scientific/content
  - Including frequently asked questions from applicants
  - Including lessons learned from monitoring the RMP submission quality (active project)
- EMA internal training is ongoing
  - Contact your Risk Management Specialist for product-related queries
- Training of PRAC and CHMP assessors planned

Assessment report templates to be updated

- include additional guidance based on last 5 years of experience
- RMP assessment process improvements under discussion
- reflect Rev 2 of the RMP Template
- update the EPAR publication process and templates

Restart of RMP summaries publishing

- Pilot phase ended last year, recommendations included in the updated Rev 2 RMP Template
- Summary uses only data available and assessed in the RMP
- Not in lay language
- Prepared by the applicant and approved with the RMP assessment
- Ready at the time of the Opinion
- RMP summaries for RMP using Rev2 Template will be published for all procedures: initial applications and post-authorisation updates
- In time, all active products will have public RMP Summaries

News and press releases
Events
What's new
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Therapeutic areas: latest updates
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UK's withdrawal from EU

New advanced therapy to repair cartilage defects in the knee

Press release

19/05/2017

New advanced therapy to repair cartilage defects in the knee

Spherox recommended for marketing authorisation

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for a new advanced therapy medicinal product (ATMP) to treat adult patients who have symptomatic articular cartilage defects in the femoral condyle (the ball-shaped end of the thigh bone in the knee) and the patella (knee cap), where the size of the affected area is no larger than 10 cm^2.

Damage to the articular cartilage of the knee is a common orthopaedic problem which often occurs in young, active people. It can result from direct trauma, repetitive injuries, fractures, or degenerative and inflammatory conditions. People with this type of damage experience recurrent pain and swelling of the joint, locking of the knee and may be impaired in their ability to walk or participate in sports. To restore functionality of their knee, patients often opt for surgery which aims to fill the cartilage loss.

Spherox is an ATMP composed of spheroids, i.e. spherical aggregates of chondrocytes (cells that are found in healthy cartilage). In this therapy, a small piece of cartilage is

Related information

Spherox: Pending EC de

Related content

Meeting highlights from Committee for Medicinal for Human Use (CHMP) 2017 (19/05/2017)

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Future interaction with Industry

- EMA will organise trainings for the Industry or participate in existing fora (subject to resource availability)
  - Next: DIA Workshop on Benefit-Risk Strategy – Prague – 15 and 16 June
  - Other events are being planned
- Contact
  - AskEMA form
  - Contact details also on next page

Any questions?

Further information

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