

Implementation of PDWS Wordings AT = RMS

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CMDh/EMA Sub-group meeting on paediatric Regulation

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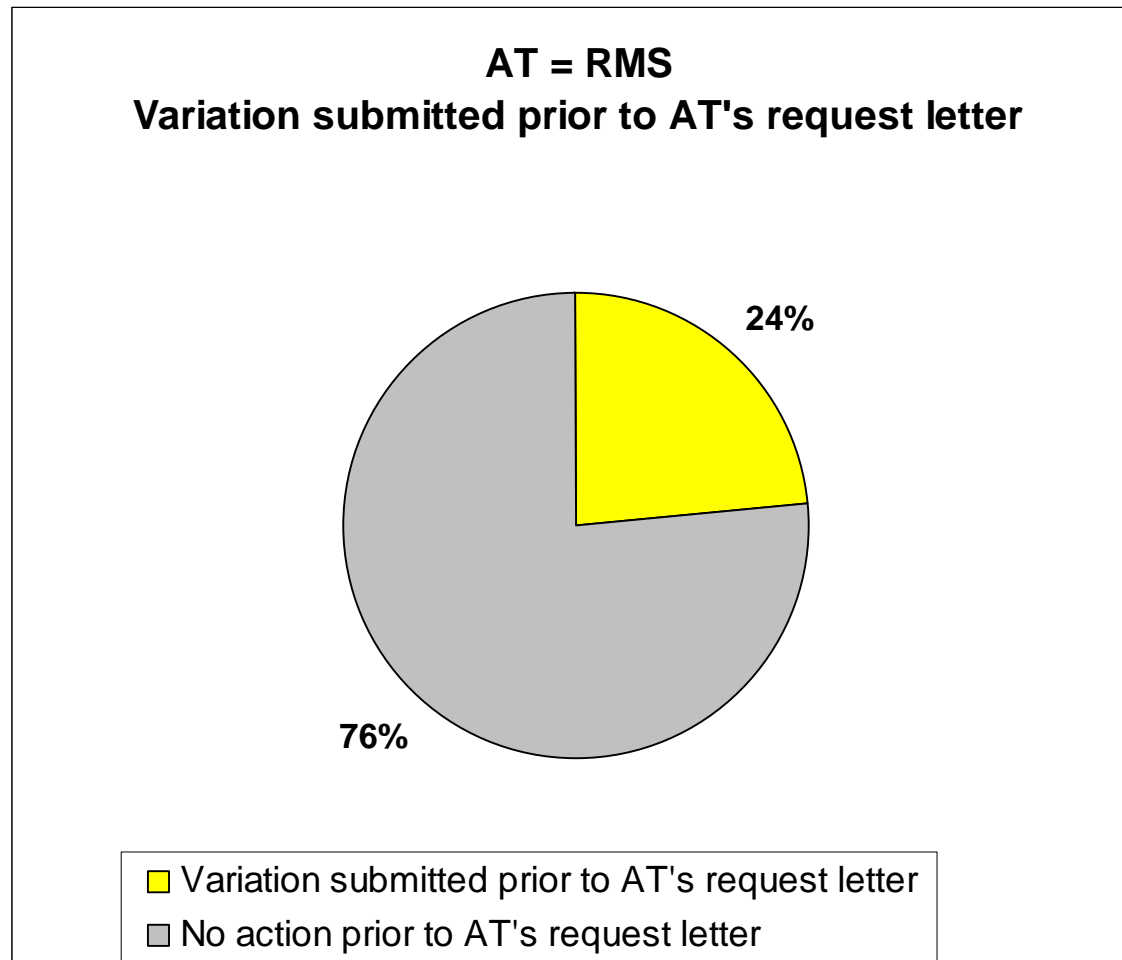
Initial Situation (2011-03-01)



- Number of concerned AT/H-products:
34
- Variations submitted **prior** to AT's request letter:
8 (24 %)
- **No action** initiated by the MAH prior to AT's request letter:
26 (76 %)

→ 26 AT/H-products received a request letter.

Initial Situation in %



Reactions following AT request letter (2011-03-14)



- Number of concerned products:
26
- Variations submitted **following** AT's request letter:
23 (88 %)
- **No reaction** following AT's request letter:
3 (12 %)
 - > because of special cases
 - MAH became insolvent: 1
 - withdrawal is scheduled this year: 2

Reactions following AT request letter in %

