



IRISH MEDICINES BOARD

Atypical Active Substances

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Website address

- Site contains relevant information under the page heading of '**Inspections - What's New in Inspections**'
- <http://www.emea.europa.eu/Inspections/WhatsNew.html>



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Question re: Atypical Active Substances

- The Notice to Applicants requires the submission of a declaration signed by the Qualified Person that the active substance used is manufactured in accordance with GMP.
- The active substance in my product is widely used, but **not normally as a pharmaceutical active substance**, and I am having some difficulty in confirming compliance.
- What should I do to furnish the required declaration?



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Answer re: Atypical Active Substances

- Full compliance with GMP for finished products and active substances is a **legal obligation for Manufacturing Authorisation holders**.
- It is recognised that for a small number of medicinal products the primary use of the active substance is not in a medicinal product and the producer may therefore not be aiming to meet the specific requirements of pharmaceutical customers that represent an insignificant volume of business.
- **Alternative sources** should normally be sought but in exceptional circumstances the manufacturing authorisation holder should **assess and document** to which extent GMP is complied with and **provide a risk-based justification** for the acceptance of any derogation.



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Answer re: Atypical Active Substances (continued)

- The declaration provided by the Qualified Person should set out in detail the basis for declaring that the standards applied provide the same level of assurance as GMP.
- The EMEA will collect experience with this approach which can be used as a basis for discussion on related amendments to guidelines in the future.



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