


Update on Subsequent Entry Biologics
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Update on Subsequent Entry Biologics

- ***BACKGROUND***
- ***THE MARCH 27, 2009 GUIDANCES***
- ***UNANSWERED QUESTIONS***

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Background

- What are SEBs?
- Health Canada consultations
 - January 2008 Guidance
 - Face-to-face consultation June 2008
 - Revised Draft March 27, 2009
- First SEB approval announced April 22, 2009

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Regulatory Requirements

- Basis of authorization – ability to demonstrate “similarity” to suitable biologic
- Full C&M package
- Extensive side by side comparison with reference product
- Reduced clinical and non-clinical data


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Key Issues

- What is Health Canada's authority to issue an NOC to a SEB?
- Will IP protections be applied?
- Will products be interchanged?

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Health Canada Authority

- Health Canada claims to have authority under the NDS regulations
- The ANDS pathway cannot be used
- Claims it is must proceed with issuance regardless of consultations


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IP Protections

- Biologics are listable on Patent Register and Register of Innovative drugs
- Guidance: SEB only approved on basis of direct or indirect comparison to Canadian product
- Interpretation of the regulations will ultimately govern

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Other Guidances

- Revised NOC Regulations Guidance
 - Adds definition of SEB
 - NDS' submitted as SEBs will need to address patents
- Revised Data Protection Guidance
 - A submission for an SEB comparing to an innovative drug will not be accepted for six year period from the innovative drug's NOC.

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Foreign Reference Product

- Particular concern re: IP
- Guidance: sufficient information to explicitly explain the link between the reference drug and the Canadian approved drug
- Use of non-Canadian reference drug will amount to comparison or reference to Canadian product; if patents listed, must be addressed



Interchangeability

- First Draft Guidance spoke to substitutability; March 2009 guidance states: Authorization of an SEB is not a declaration of pharmaceutical and/or therapeutic equivalence to the reference biologic drug
- Substitution is a provincial matter
- Many European countries have rules against substitution, leaving the decision to medical practitioners



Issues on the Horizon

- Litigation is likely over application of the IP regulations
 - Have patents been listed?
 - Will all SEB submissions use a comparison as the basis of their approval?
 - Which products are entitled to data protection?
- Interchangeability issues
- Consistency with EU and US rules

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THANK YOU



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