

SNOMED CT Drug Content Analysis Project

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asnomedct



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- 1. Welcome
- 2. Update on work done
- 3. Points for discussion process
- 4. Points for discussion content
- Adding the content to the International Edition

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- 6. Next therapeutic area
- 7. Next meeting

https://confluence.ihtsdotools.org/display

/USRG/Drug+Content+Analysis+Project



Welcome





Rules of engagement

- Managing our discussions courteously
- Please mute your microphone when not speaking
- Please save questions till after presentations
- Post questions in the chat as the meeting progresses





Update on work done





DCAP to date

- The previous meetings
 - At the Lisbon SNOMED meeting
 - November teleconference
- Confluence work instructions
 - Updated as a result of feedback from the November teleconference
- Anti-infectives spreadsheet
 - Prepared by Norway
 - Work from Ireland, UK and India...so far



MP and MPF (so far)

- 87 rows of content
- 1 contributor (UK) so far in addition to Norway

A	Have this concept in national extension or MPD; support its inclusion	SNOME Internation
В	Have very similar concept in national extension or MPD; support its inclusion	
С	Do not have this concept in national extension or MPD; support its inclusion	
D	Do not support inclusion	

Decision	Α	В	С	D	blank
UK	27		31		29

	Notes on decision	Product References provided	Comments
UK	5	42	0

CD (so far)

- 139 rows of content
- 2 contributors (UK & India) so far in addition to Norway

A	Have this concept in national extension or MPD; support its inclusion	SN Inte
в	Have very similar concept in national extension or MPD; support its inclusion	
С	Do not have this concept in national extension or MPD; support its inclusion	
D	Do not support inclusion	

Decision	Α	В	С	D	blank
Ireland	47	11	79	1	1
India	16	7	73	43	0

	Notes on decision	Product References provided	Comments
Ireland	19	38	31
India	51	20	24



Points for discussion process





Who chose which classes



- MP/MPF: UK
- CD: Ireland, India
- How did it go?
 - Were there any elements in the file that might be redundant? Any that were insufficient/absent? Suggestions as to improve workflow?
- Was the amount of work about right or too much?
- Any situations where we had more references than needed....
 - So far does not seem to have happened
 - Thoughts as to how to handle? Are we satisfied with two, or should we have a "more is more" type of approach?

Those who have requested access....what are your plans....?



Points for discussion content Just a couple of examples





Unlicensed products

- National extensions have unlicensed product information
 - This is because unlicensed products **are** used in patient care
- Our editorial guidance requires us to have *authorised/authoritative* product information
 - This is because we need to be confident about all the attributes especially for Clinical Drugs
- If a medicine is unlicensed in one country....it might be licensed elsewhere?
- Could/should we consider an MPF if there is sufficient support?
 - What "evidence" would be acceptable?
 - Mitomycin ocular; vancomycin ocular

Publiced.gov
Advanced
S
Review > Expert Opin Drug Saf. 2007 Jan/6(1):27-32. doi: 10.1517/14740338.6.1.27.

Uses and complications of mitomycin C in ophthalmology



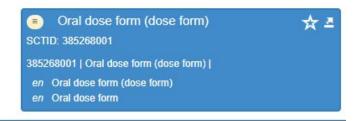
Brand name



Concentrate dose forms



- Concentrate dose forms are now included in the international content
 - <u>https://confluence.ihtsdotools.org/display/USRG/DEUSG+Meeting+-+Decemb</u>
 <u>er+15th+2022</u>
- Concentrate dose forms **may** be used for authoring of CDs
- What should we do about CDs that have been authored before it was possible to properly define a concentrate dose form?



Children (39)

- Concentrate for conventional release oral or rectal solution (dose form)
- Concentrate for conventional release oral solution (dose form)
- Concentrate for conventional release oral suspension (dose form)

Concentrate dose forms

- "RCDs are found as "concentrate for solution for infusion" still "solution for injection"
 - 781818004 |Product containing precisely ciclosporin 50 milligram/1 milliliter conventional release solution for infusion (clinical drug)|is covering the concept at international level as broader term. More granular CDs with "concentrate for solution for infusion" may be mapped in national extensions.

1. Name of the medicinal product		
SANDIMMUN [®] Concentrate for Solution for Infusion 50mg/ml.		
2. Qualitative and quantitative composition		It's about avoiding
The concentrate for solution for infusion contains 50 mg/ml. Each ampoule of 5 ml contains 250 mg of ciclosporin.	of 1 ml contains 50 mg of ciclosporin. Each ampoule of	the risk of
Excipients with known effect:		anaphylaxis
Ethanol: 278 mg/ml. Sandimmun 50 mg/ml concentrate for solution for infus ethanol).	ion contains around 34% v/v ethanol (27.8% m/v	
Macrogolglycerol ricinoleate/ Polyoxyl 35 castor oil: 650 mg/ml		
For the full list of excipients, see section 6.1.		
	6.6 Special precautions for disposal and other h	andling
3. Pharmaceutical form	The concentrate should be diluted 1:20 to 1:100 with	normal saline or 5% glucose, and given as a slow intravenous infusion over
Concentrate for solution for infusion	approximately 2 to 6 hours. Diluted infusion solutions	must be discarded after 24 hours.

Clear, brown-yellow oleaginous concentrate.

Pegylated and Liposomal Products

- Vyxeos
 - "After reconstitution the solution contains 2.2 mg/mL daunorubicin and 5 mg/mL cytarabine encapsulated in liposomes in a fixed combination in a 1:5 molar ratio"

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- The two substances are **together** inside the liposomes
- Besrimi
 - "We don't have ropeginterfon in Ireland, but for our peginterferons, we express the clinical drug in terms of the interferon with the peginterferon in brackets"
 - 0.5 mL solution contains 500 micrograms of ropeginterferon alfa-2b
 - The strength indicates the quantity of the interferon alpha-2b moiety of ropeginterferon alfa-2b without consideration of the pegylation.

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Overview

The Medicinal Product "containing only" (MP-only) concept is an abstract representation of the active ingredient(s) for a medicinal product. It means that the medicinal product must contain only the active ingredient(s) specified in the FSN but may also contain a modification of the active ingredient(s) specified in the FSN.

Example:

- · Product containing only axitinib (medicinal product)
- · Product containing only abacavir and lamivudine (medicinal product)

Modeling (stated view)

MP-only concepts shall be modeled using the proximal primitive modeling pattern.

Stated parent concept	763158003 Medicinal product (product)
Semantic tag	(medicinal product)
Definition status	900000000073002 [Sufficiently defined by necessary conditions definition status (core metadata concept)]
Attribute: Has active ingredient	 Range: 105590001 Substance (substance) - descendants only, excluding concepts representing structural groupers, dispositions, or combined substances Cardinality: 1* - there is no technical limit on the number of Has active ingredient attributes that may be added to a concept; a practical limit may be imposed at a later date. For content in the International Release, this attribute value should represent the base ingredient, not a modification, unless explicitly identified as an exception. Exceptions: Chemical element with multiple modification (e.g. 422232005 Calcium lactate gluconate (substance)) Chloral hydrate (e.g. 775158004 Product containing only chloral hydrate (medicinal product)) Liposome or lipid complex substance(e.g. 426490000 Vincristine liposome (substance) , 425953004 Amphotericin B lipid complex (substance) , 768664009 Amphotericin B phospholipid complex (substance) , 427544000 Amphotericin B cholesteryl sulfate complex (substance)) Pegylated substance (e.g. 385544005 Pegfilgrastim (substance) , 77065008 Pegvaliase (substance)) Radiopharmaceutical (e.g. 783865003 Product containing only cyanocobalamin (58-Co) (medicinal product)), 783855009 Product containing only sodium iodide (131-l) (medicinal product))) Silver sulfadiazine (e.g. 1234764000 Product containing only benzathine benzylpenicillin (medicinal product))

Thoughts?

- If a substance has an INN, we might "expect" it to have have MP and MPF
- The attribute is "Has active ingredient" without modification
 - So liposomal substances and pegylated substances are considered exceptions

Parents Interferon alfa (substance)			
Peginterferon alfa-2b (substance) SCTID: 395823000	☆≞	Has disposition \rightarrow Antiviral Has disposition \rightarrow Immunomodulator Is modification of \rightarrow Interferon alfa-2b	
395823000 Peginterferon alfa-2b (substance) <i>en</i> Peginterferon alfa-2b (substance) <i>en</i> Peginterferon alfa-2b			

Pegylation (1)

• If a substance has an INN, we might "expect" it to have have MP and MPF

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- The attribute is "Has active ingredient" without modification
 - So liposomal substances and pegylated substances are considered exceptions and have MP and MPF



Pegylation (2)



- At CD, the BoSS is (usually) stated as the unpegylated substance
 - Not least because we don't know the strength of the pegylated substance

Product containing only peginterferon alfa- A Z in parenteral dose form (medicinal product form)	Has manufactured dose form → Parenteral dose form Count of base of active ingredient → 1 Plays role → Antineoplastic therapeutic role
SCTID: 780147001	Has active ingredient → Peginterferon alfa-2b
780147001 Product containing only peginterferon alfa-2b in parenteral dose form (medicinal product form)	
<i>en</i> Product containing only peginterferon alfa-2b in parenteral dose form (medicinal product form) <i>en</i> Peginterferon alfa-2b only product in parenteral dose form	

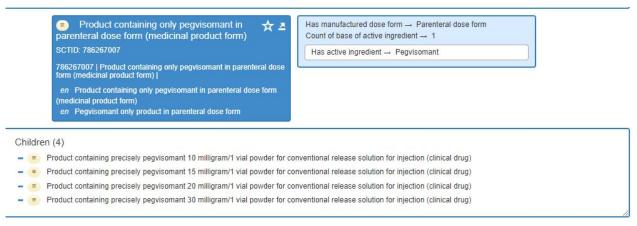
Children (9)

Product containing precisely interferon alfa-2b (as peginterferon alfa-2b) 100 microgram/1 vial powder for conventional release solution for injection (clinical drug)
 Product containing precisely interferon alfa-2b (as peginterferon alfa-2b) 120 microgram/1 pen powder for conventional release solution for injection (clinical drug)
 Product containing precisely interferon alfa-2b (as peginterferon alfa-2b) 120 microgram/1 vial powder for conventional release solution for injection (clinical drug)
 Product containing precisely interferon alfa-2b (as peginterferon alfa-2b) 120 microgram/1 vial powder for conventional release solution for injection (clinical drug)
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 Product containing precisely interferon alfa-2b (as peginterferon alfa-2b) 80 microgram/1 vial powder for conventional release solution for injection (clinical drug)
 Product containing precisely interferon alfa-2b (as peginterferon alfa-2b) 80 microgram/1 vial powder for conventional release solution for injection (clinical drug)
 Product containing precisely interferon alfa-2b (as peginter

Pegylation (3)

- But not always....
 - Sometimes we only know the strength of the pegylated substance
 - There is no unpegylated "visomant"
 - It's a growth hormone analogue protein that has the PEG integral with it

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Similar pattern with pegaptinib, used in AMD - it's an anti-vascular endothelial growth factor aptamer (so a VEGF antagonist) with the PEG as an intrinsic part of the active molecule



Adding the content to the International Edition





Promotion of existing concepts

Required: Minimum 3 countries agree on concepts from collated xls **Options:**

- 1. Retain local ID choosing earliest effective date; must be published in national extension
- 2. Create new International ID
- 3. Unpublished net new concepts to be submitted via CRS as per BAU



Next therapeutic area....





Some Suggestions

- By dose form
 - E.g. all pulmonary products
- By (high level) disposition (of substance)
 - 373272007 | Respiratory system agent (substance) |
 - 373247007 | Cardiovascular agent (substance) |
- We can use ECL to make queries more targeted if needed
- Gastro-intestinal agents



Business Meeting

SNOMED

APRIL 2023 BUSINESS MEETINGS HYBRID CONFERENCE | APRIL 1-11, 2023

In-Person: Andaz Liverpool Street, London, UK

Online: Zoom links will be shared on the What's on this Week calendar

08:30 BST	Registration Desk Open			
09:00-12:30 (Catered break: 10:30-11:00 in Great Eastern Gallery)	Governance Closed - GA only Closed General Assembly (pt.2)	Advisory Group Open to observers Modeling AG Chairs: Peter G Williams &	Working Group Open to all Pathology & Laboratory Medicine Clinical Reference	Working Group Open to observers Drug Content Analysis Project Group
,	Chair: Alex Elias Room: Great Eastern	Yongsheng Gao Room: Fenchurch	Group Chairs: W. Scott Campbell, Thomas Rüdige & James Campbell Room: Bishopsgate	Room: Minories



SNOMED International

• Next meeting -

Thurs. 23rd March 10:00 UTC



THANK YOU



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