Ordre du jour

Numéro document * :	GT23201351
Date document * :	06/09/2013
N° Enregistrement Audio * :	GT23201354

	GT23 Sécurité non clinique				2013	5
	Séance du *:	17/09/2013	de *:	14:00	à *:	17:30
Responsable du groupe de travail ou commission :	Direction :	DE L'EVALUATION				
	Pôle :	TOXICOLOGIE CLINIQUE ET TOXICOLOGIE NON CLINIQUE				
	Personne en charge :	Dominique MASSET				

Programme de séance

Points	Sujets abordés		Action		
1.	**Introduction**				
1.1	Adoption de l'ordre du jour		Pour adoption		
1.2	Adoption du CR de GT23 Sécurité non clinique - 2013 5		Pour adoption		
2.	**Dossiers thématiques**				
2.1	Prolactin "Reflection paper" sur la pertinence des tumeurs mammaires prolactines dépendantes chez l'animal		Pour discussion		
3.	**Dossiers Produits - Substances (National)**				
3.1			*Sélectionner valeur*		
4.	**Dossiers Produits – Substances (Europe)**				
4.1	Thiocolchicoside		Pour discussion		
5.	**Tour de table**				

Déroulement de la séance

1.	Introduction		
1.1	Adoption de l'ordre du jour	*Sélec. val*	
	Type de dossier :	**2. dossier thématique**	
	Nom du dossier :	The human relevance of prolactin-related mammary tumours in animals	
	Firme concernée :		

Présentation de la problèmatique

Drug substances are tested for their carcinogenic potential according to ICH Guidelines S1A, S1B and S1C. These regulatory safety studies make use of rodent assays. When tumours are found in these animals the relevance for humans needs to be assessed. In case of prolactin-releasing compounds, mammary tumours are a common finding. As such, these tumours have been considered to be rodent-specific. In view of a recently published hypothesis (Philip Harvey (2005, 2012)) based on literature data, there is a need to provide an update on the CHMP's view on this issue.

Questions

Numéro : 1

Les points abordés dans le document sont-ils de nature à répondre à la problématique?

Type de dossier :	
Nom du dossier :	Thiocochicoside Art 31 LOQ
Firme concernée :	

Présentation de la problèmatique

Further to the assessment and discussion of the data previously submitted by the marketing authorisation holders (MAHs) for thiocolchicoside containing medicinal products the CHMP has concerns with regard to the potential genotoxicity of these products for systemic use in human. Furthermore, the CHMP has concerns with regard to the summary of product characteristics (SPC) for thiocolchicoside containing medicinal products for systemic use.

Questions

Numéro : 1

The available data confirmed a clear aneugenic effect of thiocolchicoside metabolite M2. However, the submitted data were not sufficient to establish a NOEL for aneuploidy, thus not excluding the potential presence of a human risk.

a – Which non-clinical studies would SWP recommend to define an effect threshold?

Numéro : 2

In relation to the questions above, what is the SWP position with regards to the risk minimisation measures proposed to address the risk of genotoxicity?