IPRP International Pharmaceutical Regulators Programme

Nanomedicines Working Group

IPRP Nanomedicines Working group - Information sharing and mapping (as of January 2016)

Please fill in your activities in your respective region. Insert links when available.

	Definitions	Current / planned nano guidance	Planned workshops / trainings	Legislation	Classification of nano
ANVISA (Brazil)	There is a set of definitions (nanomaterial and its physical chemicals characteristics) and they will be published for a public consultation until December 2015.	It will be issued after the diagnosis (see "Legislation").	Not applicable	Anvisa will issue a legal requirement soon from which we expect to receive data and information concerning nanomaterials that have already been registered in Brazil. The purpose of this legal requirement is to gather enough information to diagnose the current scenario of Brazil in this matter. Furthermore next steps will include the first national regulation of nanomaterials.	There is a set of definitions (nanomaterial and its physical chemicals characteristics) and they will be published for a public consultation until December 2015.
TFDA (Chinese Taipei)	There is not yet an official definition of nanomedicine yet. Working definition of nanomedicine: artificially designed or manufactured	Current: Regulations for registration of medicinal products	No plan	General: Pharmaceutical Affairs Act is applicable	No specific classification defined yet. However, there are more review experience for liposomal

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	with following criteria: -Nano-size: at least one dimension in the nanoscale range (1~100nm) -Nano-properties: physical or chemical properties or biological effects attributes to its dimensions, even outside the nanoscale range (up to 1 uM)	(1) Annex 3: liposomal new drugs (2) Annex 5: liposomal generic drugs Planned: (1)registration guidance for liposomal medicine (2)registration guidance for liposomal generic medicine			products.
EMA (EU)	Descriptor as agreed with Intl. Nanomedicines WG: • Purposely designed systems for clinical applications • At least one component at nano-scale size (1-1000nm) • Resulting in definable specific properties and characteristics related to the specific nanotechnology application and characteristics for the intended use (route of admin, dose) associated with the expected clinical advantages of the nano-engineering (e.g. preferential organ/tissue distribution)	5 Nano specific guidelines published. See under: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000564.jsp&mid=WC0b01ac05806403e0	Training envisaged on: 1/ generic iron-oxide nano particles and 2/ generic i.v. liposomal formulations	General Medicinal Product legislation is applicable	No specific (e.g. risk-based) classification
FDA (USA)	**No regulatory definition**, but points to consider per FDA finalized guidance "Considering whether an FDA-Regulated Product involves the Application of Nanotechnology.	CDER-specific guidance to be published in 2015 per the Federal Register. Note that	There will be a session on "Current challenges in the characterization of complex drug formulations	n/a	n/a

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	http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm – Whether a material or end product is engineered to have at least one external dimension, or an internal or surface structure, in the nanoscale range (approximately 1 nm to 100 nm); – Whether a material or end product is engineered to exhibit properties or phenomena, including physical or chemical properties or biological effects, that are attributable to its dimension(s), even if these dimensions fall outside the nanoscale range, up to one micrometer (1,000 nm)	several product specific bioequivalence guidances have been published for drug products containing nanomaterials. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm	containing nanomaterials" At the FDA-Sponsored PQRI Conference on Evolving Product Quality On Oct. 5. http://www.pqri.org/Preliminary%20Program.2nd%20FDA.PQRI%20Conference.pdf		
Health Canada (Canada)	Policy Statement on Health Canada's Working Definition for Nanomaterial http://www.hc-sc.gc.ca/sr-	General Guidance: Nanotechnology-Based Health		Health Canada relies on authorities within existing legislative	No specific (e.g. risk-based) classification has been agreed

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	sr/pubs/nano/pol-eng.php **Health Canada's Working Definition of Nanomaterial:** Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be nanomaterial if: a.It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or; b.It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena. For the purposes of this definition: i.The term "nanoscale" means 1 to 100 nanometres, inclusive; ii.The term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and, iii.The term "manufactured" includes engineering processes and the control of matter.	Products and Food: http://www.hc-sc.gc.ca/dhp-mps/nano-eng.php		and regulatory frameworks, which require the assessment of potential risks and benefits of products to the health and safety of Canadians before they can be authorised for sale.	
HSA (Singapore)	HSA currently does not have a specific definition of nanomedicine.	No specific guidelines available.	None planned.	Existing legislative & regulatory framework are applicable.	No specific (e.g. risk-based) classification

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MHLW, PMDA (Japan)	No definitions In the reflection paper on block copolymer micelles, there is a sentence as follows: "As block copolymer micelle products are of nano-scale size, contain more than one component, and are purposely designed for specific clinical applications they may be considered as nanomedicines."	<u>Current guideline</u> Reflection paper on block copolymer micelles (http://www.nihs.go.jp/drug/section4/nanomedicine_e/nano_e.html) <u>Planned guidelines</u> -Guideline on liposome drug product -Reflection paper on nucleic acid (siRNA)-loaded nanotechnology-based drug product	Not planned at the moment	General Medicinal Product legislation is applicable	No specific classification has been agreed
Swissmedic (Switzerland)	Nanoparticles: The particles have at least one nanoscale dimension (1-1000nm) plus a function and/or mode of action based on nanotechnology characteristics. ("positive flag" in FO Application for authorisation / variation and FO Application for clinical trials)	No specific quidelines available	Not planned at the moment	General therapeutic products legislation is applicable	No specific classification has been agreed

Disclaimer:

This document reflects the views of subject matter experts participating in the IPRP Nanomedicines Working Group (NWG) and should not be construed to represent the official views of any given regulatory authority participating in the IPRP.