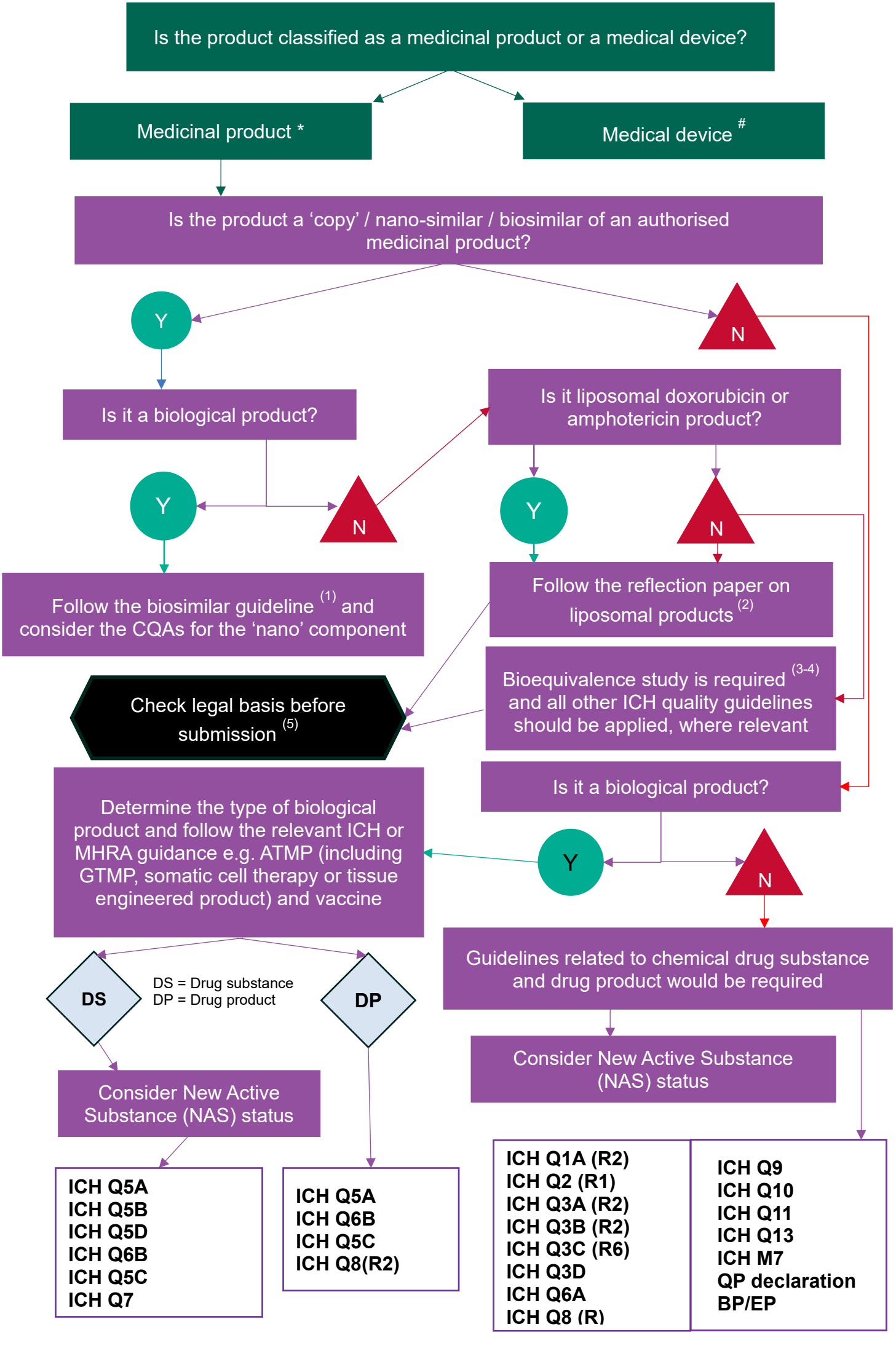
Medicines & Healthcare products
Regulatory Agency

Decision tree for navigating nanotechnology-based products for medical application

February 2025


Is the product classified as a medicinal product or a medical device?
Medicinal product *
Medical device #
Is the product a 'copy' / nano-similar / biosimilar of an authorised medicinal product?
Y
N
Is it a biological product?
Y
N
Follow the biosimilar guideline (1) and consider the CQAs for the 'nano' component
Is it liposomal doxorubicin or amphotericin product?
Y
N
Follow the reflection paper on liposomal products (2)
Bioequivalence study is required (3-4) and all other ICH quality guidelines should be applied, where relevant
Check legal basis before submission (5)
Is it a biological product?
Y
N
Determine the type of biological product and follow the relevant ICH or MHRA guidance e.g. ATMP (including GTMP, somatic cell therapy or tissue engineered product) and vaccine
Guidelines related to chemical drug substance and drug product would be required
DS
DP
DS = Drug substance
DP = Drug product
Consider New Active Substance (NAS) status
Consider New Active Substance (NAS) status
ICH Q5A
ICH Q5B
ICH Q5D
ICH Q6B
ICH Q5C
ICH Q7
ICH Q5A
ICH Q6B
ICH Q5C
ICH Q8(R2)
ICH Q1A (R2)
ICH Q2 (R1)
ICH Q3A (R2)
ICH Q3B (R2)
ICH Q3C (R6)
ICH Q3D
ICH Q6A
ICH Q8 (R)
ICH Q9
ICH Q10
ICH Q11
ICH Q13
ICH M7
QP declaration
BP/EP

References

Note the ICH guidelines recommended for reference above are not meant to be exhaustive. Additional considerations should be made following evaluation of the individual products.

* Reference to Human Medicines Regulation 2012 should be made for the definition of a Medicinal Product.

Reference to Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) should be made for the definition of a Medical Device. Consideration for medical devices is outside the scope of this decision tree.

1. Guidance on the licensing of biosimilar products (https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products)

2. Reflection paper on the data requirements for intravenous liposomal products developed with reference to an innovator liposomal product (EMA/CHMP/806058/2009/Rev. 02)

3. Guideline on the investigation of bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **)

4. Comparator products in Bioequivalence/Therapeutic Equivalence studies (https://www.gov.uk/guidance/comparator-products-in-bioequivalencetherapeutic-equivalence-studies)

5. Types of application (legal basis) (https://www.gov.uk/guidance/types-of-application-legal-basis)