



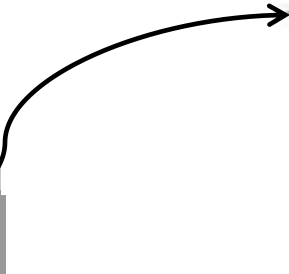
IRISH MEDICINES BOARD

A Practical Guide to Traditional Herbal Medicinal Products

Wholesale Distribution Information Day 28 September 2012

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The Aim...



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Scope of Presentation...

1. Herbal Substances
2. Herbal Preparations
3. Herbal Products
4. The Traditional Herbal Medicinal Product (THMP) Registration Scheme
5. Registered THMPs
6. Current THMP Market Place Controls
7. Homeopathic medicinal products
8. Compliance Recommendations
9. Things to Consider



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1. Herbal Substances & THMPs.... (1)

The materials or substances used to make a THMP include:

- ✓ Whole, fragmented or cut plants;
 - ✓ Plant parts such as roots, stems, barks, leaves, flowers, fruit, & seeds;
 - ✓ Algae, fungi or lichen.
-
- ❖ Any vitamins or minerals present in the formulation must be ancillary to the therapeutic effect provided by the herbal substances.



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1. Herbal Substances & THMPs.... (2)

- Herbal substances considered acceptable for use in THMPs:-

- ✓ <http://www.imb.ie/EN/Human-Medicines/Human-Medicines/Traditional-Herbal-Medicines-Registration-Scheme.aspx>



- May be acceptable for use in Food Supplements but restrictions exist:-
 - ✓ The herbal substance must be appropriate for use in Food Supplements;
 - ✓ Certain chemical constituents must be present at acceptable levels;
 - ✓ No medicinal claims can be made;
 - ✓ Product must comply with Food Legislative Requirements.



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1. Herbal Substances & THMPs.... (3)

- Certain herbal substances are restricted to use only in Herbal Medicinal Products:-
 - Prohibited in THMPs
 - Prohibited in Food Supplements
 - Case-by-Case basis for Cosmetics
- <http://www.imb.ie/EN/Human-Medicines/Human-Medicines/Traditional-Herbal-Medicines-Registration-Scheme.aspx>
- Medicinal Products (Prescription and Control of Supply) Regulations 2003, S.I. 540 of 2003, as amended



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Audience Question

Is echinacea is a herbal substance permitted in food supplements?

A = Yes

B = No



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2. Herbal Preparations... (1)

- Herbal substances can be further processed before being formulated into a finished product in order to minimise variations in the active component(s):-
 - Standardised products
 - Concentrated products
- Products composed of isolated chemical substances are not permitted as THMPs or Herbal Medicines
- Further processing also makes a product more presentable/usable for the consumer



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2. Herbal Preparations... (2)

Method used to make herbal preparations:-

- Decoction
- Extraction
- Infusion
- Fermentation
- Expression
- Fractionation
- Distillation/Purification/
Concentration/Filtration/
Drying

Macerated Plant Material

Solvent Extraction

Extract Filtration

Evaporation to remove extraction solvent

Drying of extraction paste

Dried powder

Encapsulated product



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3. Herbal Products... (1)

- Herbal products are supplied to the consumer in various formats:-

- Dried herbal powders
- Tea leaves / bags
- Capsules or tablets
- Liquid tinctures and extracts
- Creams
- Herbal exudates & juices
- Essential oils



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3. Herbal Products... (2)

- Wholesalers and retailers should know the classification and regulatory status of the herbal products they distribute or sell:-
 - Wholesalers & Retailers should know what ‘Regulatory Box’ a product falls into;
 - Whether it correctly falls into that ‘Regulatory Box’;
 - Whether you can legally distribute or sell the product.



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3. Herbal Products... (3)



Audience Question

Do you know what regulatory boxes the products you distribute fall into?

A = Yes

B = No

C = Unsure



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3. Herbal Products... (4)

- In order to ensure consumer safety and ensure that you meet your regulatory requirements you should know what ‘box’ a product falls into... achieve compliance; fewer deficiencies.
- There is a clear delineation between THMPs and other herbal products based on the herbal substance used and this can be used to determine whether a product falls into the THMP ‘box’.
- However, we know that it is not always that straight forward because of the similarities that can exist between products. There are several reasons for this.



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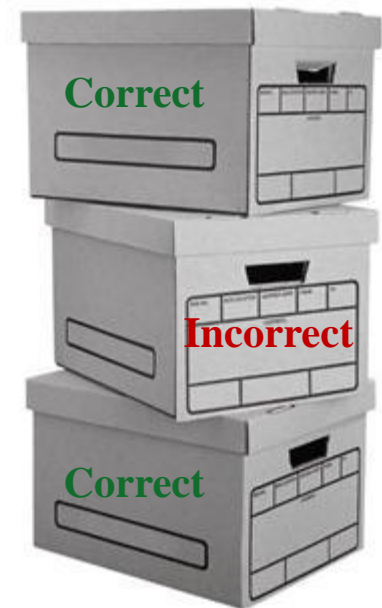
3. Herbal Products... (5)

- Often these similarities can overlap to the extent that it is difficult for wholesalers and retailers to determine whether the correct system of regulation has been applied to the product... especially if no system of product assessment is in place.
- This can lead to wholesalers placing a product into the incorrect 'box'.
- In order to prevent this the product needs to be examined carefully to determine which box it falls into.



3. Herbal Products... (6)

- How to place herbal products into the correct 'box':-
 - ✓ Legal definitions
 - ✓ The product descriptions
 - ✓ Product characteristics
 - ✓ Typical product functions



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3. Herbal Products... (7)

Product Descriptions

- Description of herbal products that are classified as food supplements:-

- ✓ Does not fulfil the definition of a medicine;
- ✓ Contain no herbal substances that are not acceptable in food supplements or prohibited from being included in food supplements;
- ✓ Certain chemical constituents must be present at acceptable levels e.g. Anthraquinone/Aloin is absent or negligible in Aloe vera;
- ✓ Meet the Food Legislation Requirements;
- Must be notified to Food Safety Authority of Ireland (FSAI).



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3. Herbal Products... (8)

- Description of herbal products that are classified as THMPs:-



- ✓ Contains a herbal substance that is acceptable for use in a THMP;
 - ✓ Makes medicinal claims... the claims made should not be for conditions that require medical intervention or monitoring;
 - ✓ The product can demonstrate traditional use;
 - ✓ The product is presented for oral, external or use by inhalation;
 - ✓ The product is not a herbal medicine or 'full' medicinal product.
-
- ❖ Registered THMPs carry a TR number in the format TR0000/000/000
 - ❖ Some are general sale; Some are pharmacy only



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3. Herbal Products... (9)

- Description of herbal products that are classified as Herbal Medicines:-



- ✓ Contains a herbal substance listed in the prohibited list; see slide 6; list is not exhaustive;
- ✓ Contains a herbal substance listed in the Medicinal Products (Prescription & Control of Supply) Regulations 2003, S.I. 540 of 2003, as amended;
- ✓ Contains no isolated chemical substances.



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3. Herbal Products... (10)

- Product characteristics:-



- What is the active substance or substances used in the product? Are they on any lists? Are they used in THMPs or Herbal Medicines? Are they acceptable for use in Food Supplements?
- What concentrations are they used at? Are they high or low compared to other similar products or compared to an authorised medicinal product or registered THMP?
- What other ingredients (excipients) are used in the product and at what concentrations are they used? Are they prohibited for use in Cosmetics or Food Supplements?



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3. Herbal Products... (11)

- What is the product to be used for i.e. what is its primary function? Does it function comply with the definition of a medicinal product? A medical device? A cosmetic product? A food supplement? A biocidal product?
- What is the mode of action in operation that gives the product its function? Is the action physical or chemical? pharmacological? metabolic? Or immunological? Is information about the product's mode of action available in the literature provided or on a website?
- What claims does the product labelling make, are they medicinal, cosmetic, biocidal, or health claims permitted on foods? What claims are made on the literature and other promotional items such as websites that are associated with the product?
- What is the product's labelled usage instructions and how is the product to be used? Is it to be ingested? Inhaled? Or applied to the skin?



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3. Herbal Products... (12)

Typical functions of food supplement	Typical functions of a medicinal product	Typical functions of a medical device	Typical functions of a cosmetic	Typical functions of a biocidal product
<p>Supplement the diet; concentrated source of nutrients; Adequate intake may reduce the risk of X; Intake supports the body e.g. circulation, heart, immune system; Supports healthy cholesterol levels; Supports a healthy digestive system</p>	<p>Cure; Restore; Correct; Modify; Strengthen; Prevent; Maintain; Protect; Stop; Heal; Control; Treat; Alleviate; Soothe; Helps with; Clears; Anti-inflammatory; Anti-septic; Antibiotic</p>	<p>Restore; Strengthen; Prevent; Maintain; Protect; Stop; Heal; Control; Treat</p>	<p>Clean Protect Perfume Correct body odours Change appearance Keep-in-Good-Condition</p>	<p>Antimicrobial; Antibacterial; Antifungal; Viricidal; Anti-viral; Insecticide; Sanitise; Hygienically clean; Disinfect; Kill; Repel; Deter; Destroy; Prevent/Control the action/spread of; Prevent cross-contamination; Eliminate; Inhibit</p>

Audience Question

The product shown is marketed as:-

A = THMP

B = Cosmetic

C = Homeopathic medicinal product



Audience Question

Is the product shown correctly marketed as a cosmetic?

A = Yes

B = No



4. The THMP registration scheme... (1)



- A herbal product that falls into the classification of being a Traditional Herbal Medicinal Product must register with the regulatory agency in the Member State where the product is being placed for use by the citizens there.
- Before a product is issued with a certificate of traditional use registration it must meet the requisite standards of safety, efficacy and quality.



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4. The THMP registration scheme... (2)

- The registration scheme functions to ensure that these products are safe for consumer use by:-

- ✓ Ensuring their quality;
- ✓ Ensuring that the correct herb is used;
- ✓ Ensuring users are aware of side effects and interactions with other medicines;
- ✓ Post-marketing monitoring;
- ✓ Ensuring they are not adulterated.



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4. The THMP registration scheme... (3)

Detailed guidance materials available on IMB's website:-

- <http://www.imb.ie/EN/Publications/Medicines/Human-Medicines/Herbal-Medicines/Guidance-on-the-Traditional-Herbal-Medicinal-Products-Registration-Scheme.aspx?page=1&year=0&categoryid=&letter=&q=>
1. Guide to Traditional Herbal Medicinal Products Registration Scheme
 2. Herbal Substances considered to be acceptable as Traditional Herbal Medicinal Products
 3. Herbal Substances not permitted in Traditional Herbal Medicinal Products
 4. Industry Q& A
 5. Consumer Q& A



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5. Registered THMPs... (1)

- THMPs registered with IMB are issued with a TR (Traditional Registration) number and this appears as a number in the format TR0000/000/000 on the product's packaging.
 - Registered THMPs can be found on the IMB website by inserting the letters TR into the licence number box when in the advanced search facility.
 - Registered THMPs that are for general sale will appear on the general sales list. Some THMPs will be for sale through pharmacies only.
- ❖ Reference: IMB Newsletter Number 42

6. Current THMP Market Place Controls... (1)

THMP that has been registered with IMB

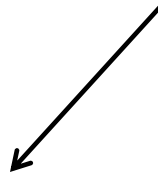
Registered THMP
TR0000/000/000



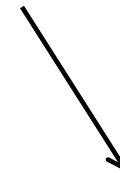
Listed on IMB's website



THMP can be supplied and sold in accordance with the conditions of the certificate of traditional use registration



General Sales



Pharmacy Only



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6. Current THMP Market Place Controls... (2)

THMP that is the subject of an application to register with IMB

THMP that is the **subject** of an **application** to register which was submitted before **31 December 2011** and was **on the market** before **23 July 2007**.



THMP can be **supplied** by **wholesalers** and **sold** by **retailers**.
Product can be **replenished** by both.



Upon issuance of the **certificate of traditional use registration** only product in the **approved packaging** bearing a TR number can be **sourced**



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6. Current THMP Market Place Controls... (3)

THMP that is the subject of an application to register with IMB

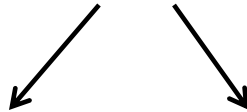
THMP is the subject of an application to register which was submitted before 31 December 2011 but was not on the market before 23 July 2007.



THMP stock on the market before 30 April 2011



Yes



Wholesalers

Retailers



Permitted to run-down product until 31 December 2011. No replenishment.

Run-down to expiry date of product. No replenishment.



No



THMP should not have been placed on the market. No run-down; No replenishment.



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6. Current THMP Market Place Controls... (4)

THMP that is the subject of an application to register with IMB

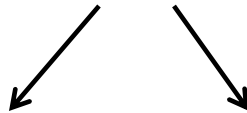
THMP is the subject of an application to register which was submitted after 31 December 2011.



THMP stock on the market before 30 April 2011



Yes



Wholesalers

Retailers



Permitted to run-down product until 31 December 2011. No replenishment.

Run-down to expiry date of product. No replenishment.



No



THMP should not have been placed on the market. No run-down; No replenishment.



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6. Current THMP Market Place Controls... (5)

No application to Register submitted

THMP that is not the subject of an application to register with IMB



THMP stock on the market before 30 April 2011



Yes

No



Wholesalers

Retailers



Permitted to run-down product until 31 December 2011. No replenishment.

Run-down to expiry date of product. No replenishment.

THMP should not have been placed on the market. No run-down; No replenishment.



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Audience Question

A THMP that was first placed on the market here in February 2007 and for which an application to register with IMB was received on October 2011; can this THMP be supplied post 31 December 2011?

A = Yes

B = No

Can the product be replenished?

A = Yes

B = No

7. Homeopathic medicinal products... (1)

- Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles.
- In order to place a homeopathic medicinal product onto the market it must have a marketing authorisation or certificate of registration from the IMB.



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7. Homeopathic medicinal products... (2)

- A homeopathic medicinal product must be marketed in 1 of 3 ways:-
 - ✓ Registration under the Simplified Registration Scheme (SRS) and assigned a HOR number;
 - ✓ Authorisation under the National Rules Scheme (NRS) and assigned a HOA number;
 - ✓ Authorisation under a full product authorisation and assigned a PA number.



7. Homeopathic medicinal products... (3)

Homeopathic Medicinal Product
Requiring a PA



Cannot be supplied or sold until the
product authorisation has been granted



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7. Homeopathic medicinal products... (4)

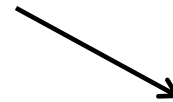
SRS Homeopathic Medicinal Product



Registered HOR product



Wholesalers



Retailers



HOR must be **supplied** in the approved packaging i.e. bear a HOR number as of 1 January 2012

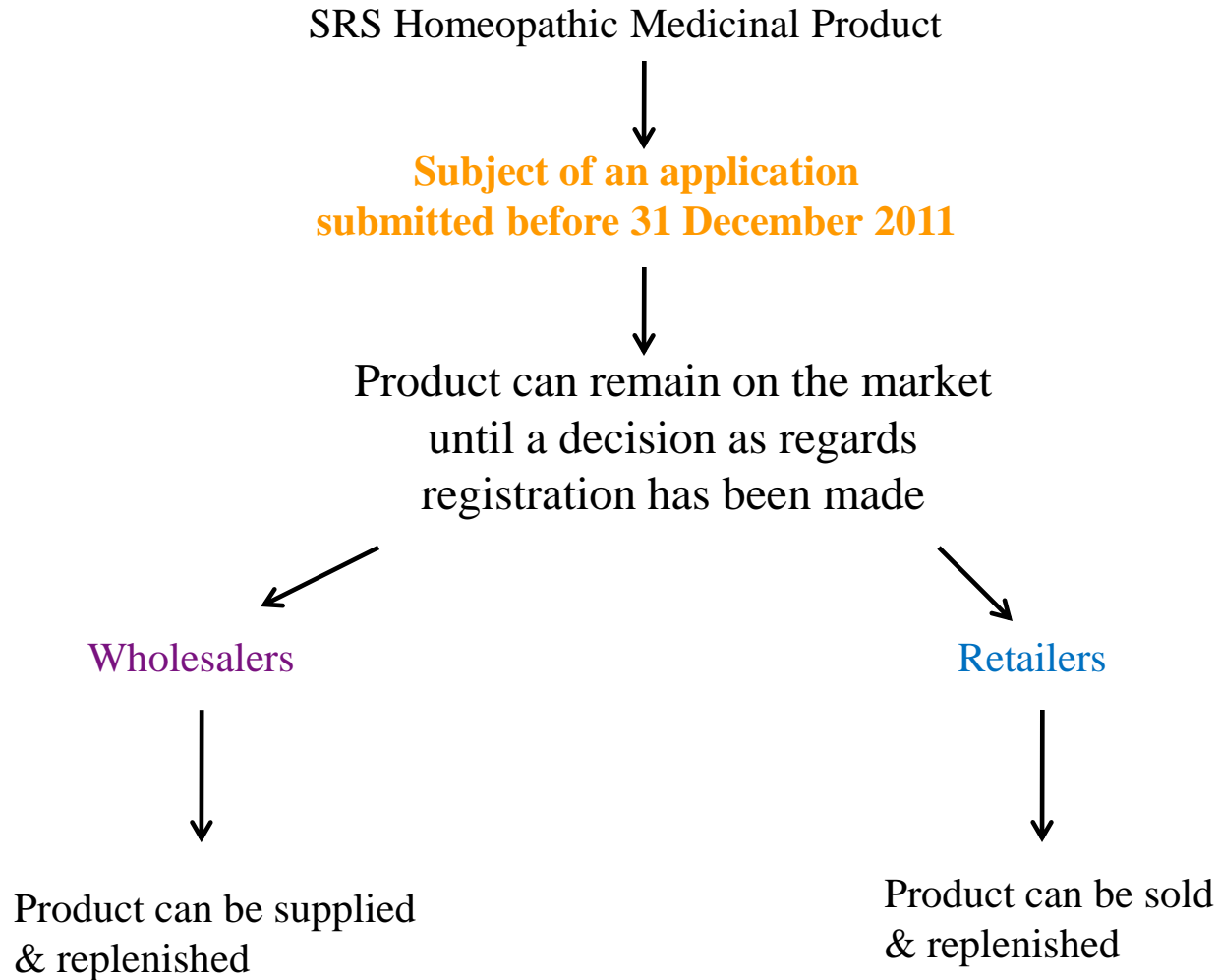


HOR must be **sourced** in the approved packaging i.e. bear a HOR number as of 1 January 2012



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7. Homeopathic medicinal products... (5)



7. Homeopathic medicinal products... (6)

SRS Homeopathic Medicinal Product

↓
Unregistered

↓
Product stock on market
before 30 April 2011

Yes

No

Wholesalers

Retailers

↓
Permitted to run-down stock
until 31 December 2011.
No replenishment.

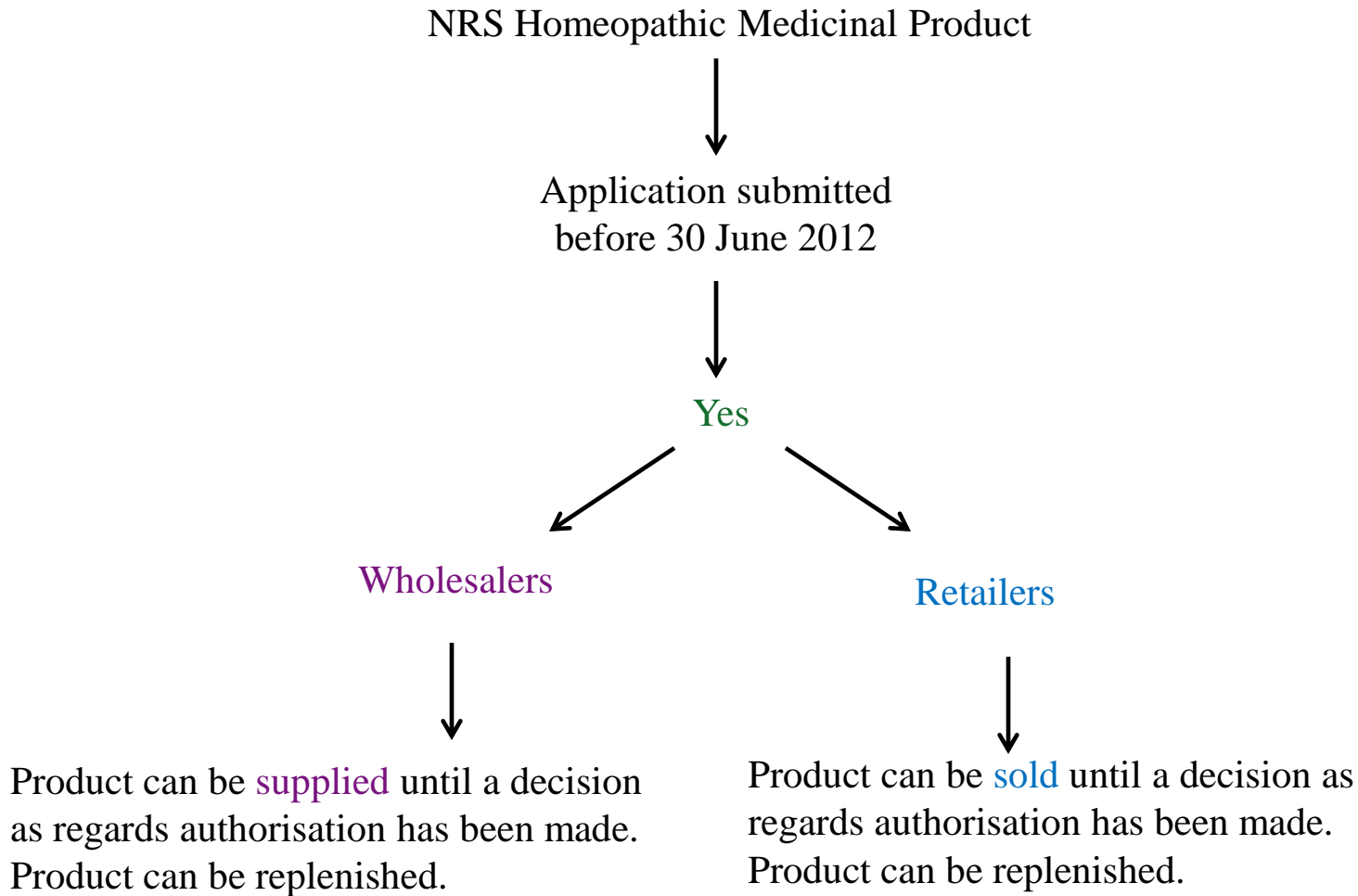
↓
Run-down to the expiry
date of the product.
No replenishment.

↓
Product should not have been
placed on the market. No run-
down; No replenishment.

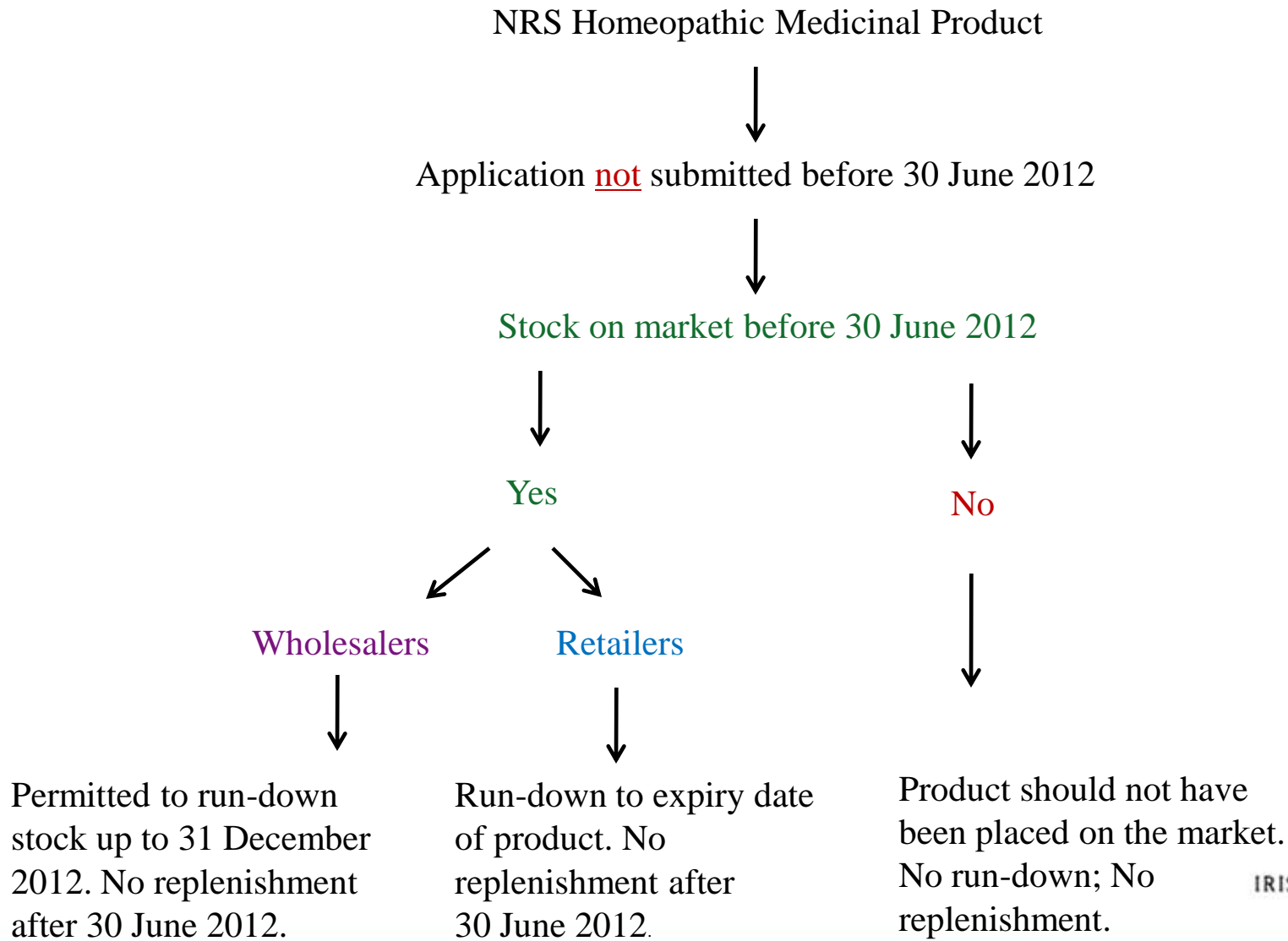


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7. Homeopathic medicinal products... (7)



7. Homeopathic medicinal products... (8)



8. Compliance Recommendations... (1)

- Wholesalers should have procedures in place that allow them to:-
 - ✓ Determine if a [herbal] product can be placed on the market here;
 - ✓ Determine what ‘regulatory box’ the [herbal] product falls into and records to assess the categorisation of products;
 - ✓ Determine whether the [herbal] product is for general sale or for retail through pharmacies only.



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8. Compliance Recommendations... (2)

- Develop the knowledge and training of staff involved in product classification/new product set-up;
 - Keep up to date with guidance provided by IMB in the area of product classification; guidance is available on IMB's website at <http://www.imb.ie/EN/Medicines/Classification-of-Medicines.aspx>;
 - Determine the impact of regulatory changes on product classification and supply e.g. Updates to the THMP and prohibited lists; Council Directive 2011/84/EC on hydrogen peroxide levels in tooth-whitening products.
-
- Do not rely solely on your direct supplier
 - Verify any information provided... supplier evidence



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9. Things to Consider... (1)

- Each product you supply is governed by legislative requirements;
- Do you know what regulatory system applies to the products you supply? i.e. medicinal products, medical devices, food, cosmetics, biocides;
- Just because a product doesn't have an authorisation number issued by IMB or the European Medicines Agency (EMA) doesn't mean it is not a medicine... examine the ingredients and label claims.



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Audience Question

Please indicate whether you now have a clearer understanding of the requirements in place for the supply of THMPs:-

A = Yes, I do

B = No, I don't



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Audience Question

Are you now in a better position to assign the products you distribute into the appropriate regulatory box?

A = Yes

B = No



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Thank you for your time & attention
Any Questions?

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