

# Focus Group Session on Contact Lens

9 September 2014

Agnes Goh

Regulatory Specialist

# Overview

- Contact lens listing guidelines
  - SMDR Device Name & Model Information
- Contact lens – Proposed grouping criteria
  - For feedback
- Contact lens labelling requirements
  - Label content
  - Supply of IFU
  - Supply of fitting guides and brochures
- Other Updates

# CONTACT LENS LISTING GUIDELINES



# SMDR Device Name Information

- <Product owner name><Brand name as per label>

# SMDR Model Information

## Scenario 1: **Common identifier** available for a range of dioptries

Name as per Device Label	Identifier	Brief description of item
<p>&lt;Name per label&gt;, &lt;dioptre range&gt;, &lt;other parameters e.g. cylinder power, if applicable&gt;, &lt;range of pack size&gt;</p>	<p>&lt;Common identifier&gt; &lt;individual colour, if applicable&gt;</p>	<p>&lt;replacement schedule&gt; &lt;material&gt;</p>
<p><i>MAGIC COLOR Xtra (-6.00D to -0.25D, +0.25D to +6.00D) (pack of 6, 12)</i></p>	<p><i>Z150 (Starry yellow)</i></p>	<p><i>daily disposable, Nelfilcon A</i></p>
<p><i>MAGIC COLOR Xtra (-6.00D to -0.25D, +0.25D to +6.00D) (pack of 6, 12)</i></p>	<p><i>Z250 (Deep purple)</i></p>	<p><i>daily disposable, Nelfilcon A</i></p>

# SMDR Model Information

**Scenario 2: No unique identifier** i.e. only brand name  
***Clear Contact Lens***

Name as per Device Label	Identifier	Brief description of item
<p><b>&lt;Name per label&gt;, &lt;diopetre range&gt;, &lt;other parameters e.g. cylinder power, if applicable&gt;, &lt;range of pack size&gt;</b></p>	<p><b>&lt;Name per label&gt; &lt;individual colour, if applicable&gt;</b></p>	<p><b>&lt;replacement schedule&gt; &lt;material&gt;</b></p>
<p><i>MAGIC Xtra (-6.00D to -0.25D, +0.25D to +6.00D) (pack of 6, 12)</i></p>	<p><i>MAGIC Xtra</i></p>	<p><i>daily disposable, Nelfilcon A</i></p>

# SMDR Model Information

Scenario 2: **No unique identifier** i.e. only brand name

## Colour Contact Lens

Name as per Device Label	Identifier	Brief description of item
<p>&lt;Name per label&gt;, &lt;diopetre range&gt;, &lt;other parameters e.g. cylinder power, if applicable&gt;, &lt;range of pack size&gt;</p>	<p>&lt;Name per label&gt; &lt;individual colour, if applicable&gt;</p>	<p>&lt;replacement schedule&gt; &lt;material&gt;</p>
<p><i>MAGIC COLOR Xtra (-6.00D to -0.25D, +0.25D to +6.00D) (pack of 6, 12)</i></p>	<p><i>MAGIC COLOR Xtra (Maxi black)</i></p>	<p><i>daily disposable, Nelfilcon A</i></p>
<p><i>MAGIC COLOR Xtra (-6.00D to -0.25D, +0.25D to +6.00D) (pack of 6, 12)</i></p>	<p><i>MAGIC COLOR Xtra (Skylight blue)</i></p>	<p><i>daily disposable, Nelfilcon A</i></p>

# Model Information for Contact Lens

- Annex 2 list of configurations for SMDR device listing information to be prepared based on slides 8,9,10 during product registration for contact lens
- If there are packaging configuration for trial lens from the manufacturer, applicant to include these in the Annex2 list of configurations
- SMDR listing of models will be based on above

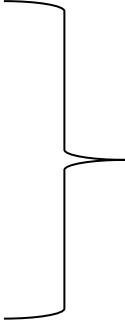
*Model information (Annex 2 list of configurations and listing) is applicable for pending and new applications moving forward only.*

# Contact Lens Proposed Grouping Criteria

# Grouping

## Permissible variants

- Dioptre
- UV protection
- Tinting
- Colour



GN-12 Guidance on Grouping  
of Medical Devices for Product  
Registration

## Proposed inclusions for contact lens:

- Wearing schedule (daily wear, extended wear)

*Note: Listing of devices on SMDR may differ from grouping*

# Grouping

The following are the proposed non-permissible variables for contact lens grouping:

- Different replacement schedule
  - Daily, weekly, monthly etc.
- Material
- Intended use e.g. toric vs. non-toric,

# Grouping Criteria for Contact Lens - Timelines

- Proposed grouping criteria on slides 13 and 14 are open for feedback
- Email your feedback by 1 October 2014 via email to [hsa\\_md\\_info@hsa.gov.sg](mailto:hsa_md_info@hsa.gov.sg) with subject of the email as:  
Contact Lens Grouping Feedback
  - *An excel template for feedback will be uploaded on the website with this presentation slides by 12 Sep 2014*
- Final grouping criteria will be emailed to stakeholders by HSA

*Final Grouping criteria will be applicable for **new** applications submitted from 1 January 2015.*

# Contact Lens Labelling Requirements

# Contact Lens Labelling Requirements


- Labelling Requirements
- Supply of IFU
- Supply of Fitting Guides and Brochures

# Labelling Requirements


<p><b>Rationale</b></p>	<p>To provide clarity on the intended use of the contact lens</p>
<p><b>Requirements</b></p>	<p>Following information to be stated on the <b>IFU</b> <u>and/or labels</u>:</p> <ul style="list-style-type: none"> <li>• Replacement Schedule (e.g. daily disposable, monthly disposable)</li> <li>• Wearing Schedule (i.e. daily wear and/or extended wear)</li> <li>• Intended Use             <ul style="list-style-type: none"> <li>• For vision correction e.g. myopia, hyperopia, astigmatism, presbyopia</li> <li>• Aphakic, non-aphakic</li> <li>• Non-diseased eyes</li> </ul> </li> </ul>

# Example 1

Sample device label:





## MAGIC COLOR Xtra Monthly Disposable Soft Contact Lens




Contents: Six (6) soft contact lenses (43% balafilcon A, 57% water) in buffered saline

For daily wear

LOT

BC	DIA	PWR
Left <input style="width: 40px; height: 20px;" type="text"/>	Right <input style="width: 40px; height: 20px;" type="text"/>	

STERILE




**Monthly Disposable** (replacement schedule)



**For daily wear** (wearing schedule)




Device Proprietary / Brand Name:  
[PRODUCT OWNER][BRAND NAME]



**HSA MAGIC COLOR Xtra Monthly Disposable Soft Contact Lens**

# Example 1

## Sample Instructions for use:

-  for daily wear (**wearing schedule**)
-  to correct visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia.  
  
The lens may be worn by persons who exhibit refractive astigmatism of .50 dioptres or less where the astigmatism does not interfere with visual acuity. (**intended use**)
-  to be discarded and replaced with a new lens every month.  
  
(**replacement schedule**)

HSA

**MAGIC COLOR Xtra Monthly Disposable Soft Contact Lens**

## Instructions for Use

- **Product description**
- **Intended use / indications**

Indicated for daily wear to correct visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia.


The lens may be worn by persons who exhibit refractive astigmatism of .50 dioptres or less where the astigmatism does not interfere with visual acuity.

It is recommended that the lenses be discarded and replaced with a new lens every month. However, eye care practitioners are encouraged to determine an appropriate lens replacement schedule based upon the response of the patient.


- **Directions for use**
- **Lens care directions**
- **Important**
- **Warnings and precautions**

# Example 2

Sample device label:



## MAGIC COLOR Xtra Soft Contact Lens




Contents: Six (6) monthly disposable soft contact lenses (43% balafilcon A, 57% water) in buffered saline

LOT

BC


DIA


PWR



Left

Right



STERILE 



**Monthly Disposable** (replacement schedule)


Device Proprietary / Brand Name:  
[PRODUCT OWNER][BRAND NAME]





**HSA MAGIC COLOR Xtra Soft Contact Lens**

# Example 2

## Sample Instructions for use:

 for daily wear (**wearing schedule**)

 intended use not clear

 replaced every month.  
(**replacement schedule**)

**HSA**

**MAGIC COLOR Xtra Soft  
Contact Lens**

### Instructions for Use

- **Product description**

Contact lens are available as a spherical lens design. Contact Lenses contain visibility blue tint from edge to edge and contain a benzophenone UV absorbing monomer which is used to block UV radiation.

The device is designed for daily wear and the lens is to be cleaned, rinsed and disinfected each time it is removed from the eye and replaced every month.

- **Directions for use**
- **Lens care directions**
- **Important**
- **Warnings and precautions**

# Contact Lens Labelling Requirements

- Labelling Requirements
- **Supply of IFU**
- Supply of Fitting Guides and Brochures

# Supply of IFU

- Regulations 42 of First schedule of health Products (Medical Devices) Regulations 2010

## **General information to be provided with medical devices**

42.—(1) The following information shall be provided with a medical device, having regard to the training and knowledge of potential users of the medical device:

- (a) information identifying the medical device;
- (b) information identifying the product owner of the medical device;
- (c) information explaining how to use the medical device safely.

# Supply of IFU

- Regulations 43 of First schedule of health Products (Medical Devices) Regulations 2010

## Location of information to be provided with medical devices

43.—(1) Unless it is impracticable or inappropriate to do so, the information required to be provided with a medical device shall be provided on the medical device itself.

(2) If it is not practicable to comply with sub-paragraph (1) in relation to the provision of the information, the information shall be provided —

(a) on the packaging used for the medical device; or

(b) in the case of medical devices that are packaged together because individual packaging of the medical devices for supply is not practicable, on the outer packaging used for the medical devices.

(3) If it is not practicable to comply with sub-paragraph (1) or (2) in relation to the provision of the information required under paragraph 44, the information shall be provided on a leaflet supplied with the medical device.

(4) If it is not practicable to comply with sub-paragraph (1) or (2) in relation to the provision of the information required under paragraph 45, the information shall be provided in a printed document or using other appropriate media.

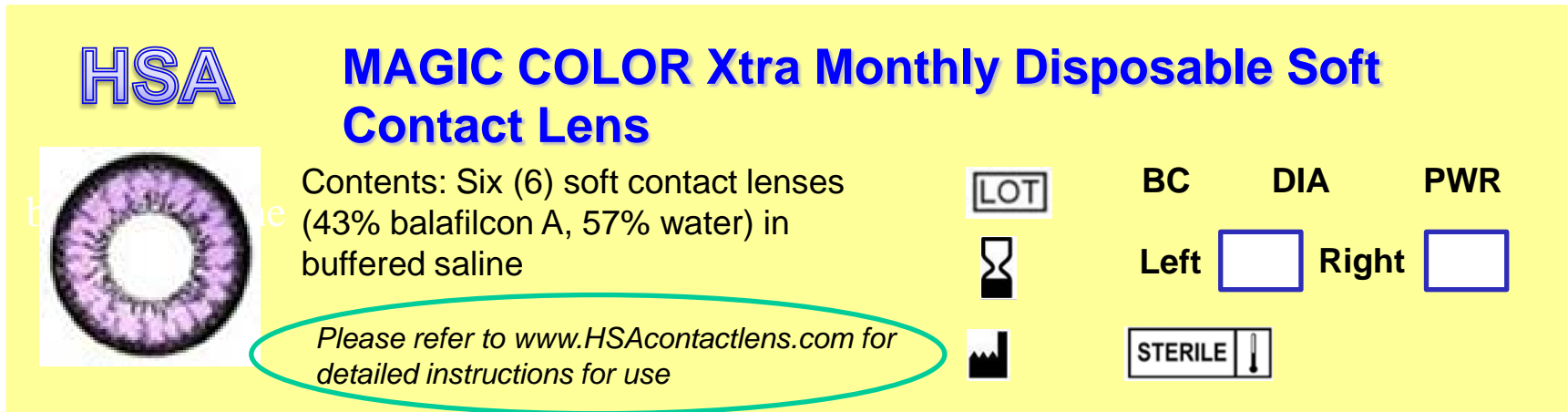
# Supply of IFU

Type of IFU	Requirements
<b>Option 1:</b> Hard copy	<ul style="list-style-type: none"> <li>• IFU to be packaged with contact lens</li> </ul>
<b>Option 2:</b> Soft copy (e-IFU)	<ul style="list-style-type: none"> <li>• Website link to be printed on the label and displayed in such a manner that alerts the user to its purpose.</li> <li>• E-IFU is to be accessible and available for viewing by the public</li> <li>• Only approved version of IFU is to be uploaded on the website.</li> <li>• Registrant shall undertake responsibility to supply the information in printed form to the user, patient and/or other relevant parties upon request.</li> </ul>

Note:

- Company to inform MDB as part of pre-market submission the supply format of IFU
- Company to notify MDB via a change notification should there be any changes to the hard or soft copy (e-IFU).

Sample device label:



**HSA** **MAGIC COLOR Xtra Monthly Disposable Soft Contact Lens**

Contents: Six (6) soft contact lenses (43% balafilcon A, 57% water) in buffered saline

Please refer to [www.HSAcontactlens.com](http://www.HSAcontactlens.com) for detailed instructions for use

LOT

BC DIA PWR

Left  Right

STERILE

✓ Please refer to [www.HSAcontactlens.com](http://www.HSAcontactlens.com) for detailed instructions for use

✓   [www.HSAcontactlens.com](http://www.HSAcontactlens.com)

✓ Please refer to [www.HSAcontactlens.com](http://www.HSAcontactlens.com) for more information

✗ [www.HSAcontactlens.com](http://www.HSAcontactlens.com)  
 (Note: not clear; does not alert the user to the purpose of the weblink)

# Contact Lens Labelling Requirements

- Labelling Requirements
- Supply of IFU
- Supply of Fitting Guides and Brochures

# Supply of Fitting Guides and Brochures

- Not mandatory to be submitted during pre-market application, however evaluator may request for such documents for reference purposes
- **Duty of Registrants** to ensure that fitting guides and brochures are aligned with the approved intended use

# Implementation Approach for Labelling Requirements

- All **pending and new contact lens registration** applications, to comply with the labelling guidelines
  - Companies that need additional time to compliance for pending applications can inform evaluators and timeline to be worked out accordingly.
- For **SMDR registered contact lens**, to incorporate these updates to the next upcoming labelling revision for the device and can be submitted in the CN for those labelling revisions.

# OTHER UPDATES



# UDI Update to Labels

- Labelling changes to registered MDs to **solely** incorporate UDI information into the labels,
  - Require a Notification CN (No fees or TAT apply)
  - UDI and non-UDI versions of the labels allowed to co-exist in Singapore market
  - All other information on the labels to be aligned to what is approved by HSA

# UDI Update to Labels

- Labelling changes to registered MDs to incorporate **UDI information** into the approved labels,
  - where bundled with other Notification labelling changes as specified in GN-21 Guidance(Section 5, Table 1)
    - Require a Notification CN (No fees or TAT apply)
    - Two versions of the labels allowed to co-exist in market
    - All other information on the labels to be aligned to what is approved by HSA

# Thank you for your attention!



Further feedback/enquiries:  
[HSA\\_MD\\_Info@hsa.gov.sg](mailto:HSA_MD_Info@hsa.gov.sg)