

Our Ref: 7/2012

2<sup>nd</sup> May 2012

## **CONSULTATION DOCUMENT ON THE AMENDMENT TO SUBSIDIARY LEGISLATION 458.14 (CONTROL OF ADVERTISING OF MEDICINALS REGULATIONS) AND SUBSIDIARY LEGISLATION 31.24 (ORAL RETINOID MEDICINAL PREPARATIONS REGULATIONS)**

### Objectives and Scope

#### **Subsidiary Legislation 458.14 (Control of Advertising of Medicinals Regulations)**

Subsidiary Legislation 458.14 (Control of Advertising of Medicinals Regulations) available on <http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11254&l=1> contains the practice prior to 2005 through which any person who advertises or allows to be advertised any medicinal preparation or remedy, shall ensure that the permit number of the Department of Health appears on every advertisement. the practice was superceded through a 2005 Legal Notice available on the following URL: <http://www.doi.gov.mt/EN/legalnotices/2005/11/LN380.pdf>. It is proposed that SL 458.14 is repealed.

#### **Subsidiary Legislation 31.24 (Oral Retinoid Medicinal Preparations Regulations)**

It is proposed that Subsidiary Legislation 31.24 (Oral Retinoid Medicinal Preparations Regulations) available on <http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=9058&l=1> is also repealed as the authorisation of Oral Retinoids Medicinal Preperations is part of the Marketing Authorisation process.

### Comments

Your comments on the proposed Legal Notices are invited.

Comments are to reach the Medicines Authority in writing or via email [consultations.medicinesauthority@gov.mt](mailto:consultations.medicinesauthority@gov.mt) by the **22<sup>nd</sup> June 2012**.

Should any further information be required kindly contact the Medicines Authority using the following contact details:

Medicines Authority  
203, Level 3,  
Rue D'Argens,  
Gzira GZR 1368  
Malta

Tel no: (+356) 23439151  
Fax no.: (+356) 23439161  
Email: [consultations.medicinesauthority@gov.mt](mailto:consultations.medicinesauthority@gov.mt)

**A.L. ta' l-2012**

**ATT DWAR IL-MEDIĆINI  
(KAP. 458)**

**REGOLAMENTI DWAR  
IL-KONTROLL TAR-REKLAMI TA' MEDICINALI**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 106 ta' l-Att dwar il-Mediċini, il-Ministru tas-Sahħha, l-Anzjani u Kura fil-Komunità għamel dawn ir-regolamenti li ġejjin:–

- |   |                                  |
|---|----------------------------------|
| <b>1.</b> It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2012 li jhassru r-Regolamenti dwar il-kontroll tar-reklami ta' mediċinali. | Titlu                            |
| <b>2.</b> Ir-Regolamenti dwar il-kontroll tar-reklami ta' mediċinali, huma b'dawn imħassra.   | Iħassar<br>A.L. 85<br>ta' l-1991 |

**L.N. of 2012**

**MEDICINES ACT  
(CAP. 458)**

**CONTROL OF ADVERTISING OF MEDICINALS  
REGULATIONS**

BY virtue of the powers conferred by article 106 of the Medicines Act, the Minister for Health, the Elderly and Community Care, has made the following regulation:—

- 1.** The title of these regulations is the Control of Advertising of Medicinals Regulations (Repeal), 2011.
- 2.** The Control of Advertising of Medicinals Regulations, 2012 are hereby repealed.

Title

Repeals  
L.N. 85  
of 1991.

**A.L. ta' l-2012**

**L-Ordinanza dwar il-Professjoni Medika u  
l-Professjonijiet li għandhom x'jaqsmu magħha  
(KAP. 31)**

**REGOLAMENTI DWAR PREPARATI  
MEDIĆINALI ORAL RETINOID**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 40A ta' L-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x'jaqsmu magħha, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità għamel dawn ir-regolamenti li ġejjin:–

- |   |                                   |
|---|-----------------------------------|
| <b>1.</b> It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2012 li jhassru r-Regolamenti dwar Preparati Medicinali Oral Retinoid. | Titlu                             |
| <b>2.</b> Ir-Regolamenti dwar Preparati Medicinali Oral Retinoid, huma b'dawn imħassra.   | Iħassar<br>A.L. 172<br>ta' l-1993 |

**MEDICAL AND KINDRED PROFESSIONS ORDINANCE  
(CAP. 31)**

**ORAL RETINOID MEDICINAL PREPARATIONS  
REGULATIONS**

BY virtue of the powers conferred by article 40A of the Medical and Kindred Professions Ordinance, the Minister for Health, the Elderly and Community Care, has made the following regulation:—

1. The title of these regulations is the Oral Retinoid Medicinal Preparations Regulations (Repeal), 2011.

Title

2. The Oral Retinoid Medicinal Preparations Regulations, 2012 are hereby repealed.

Repeals L.N. 172  
of 1993