

# EXPLANATORY STATEMENT

## THERAPEUTIC GOODS (LISTING) NOTICE 2014 (NO. 1)

*Subsection 9A(5), Therapeutic Goods Act 1989*

### OUTLINE

*Therapeutic Goods (Listing) Notice 2014 (No. 1)* (the Listing Notice) is a notice made by the delegate of the Minister for Health under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act).

The Listing Notice has the effect of requiring that therapeutic goods that contain ‘menaquinone 7’ as a therapeutically active ingredient, subject to certain conditions, be included in the part of the Australian Register of Therapeutic Goods (the Register) for listed goods.

The Listing Notice commenced on the day after it was registered on the Federal Register of Legislative Instruments (FRLI).

### BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (TGA) is responsible for administering the Act.

Unless specifically exempted or authorised under the Act, therapeutic goods are required to be included on the Register before being supplied in, imported into, manufactured in or exported from Australia (sections 19B and 19D of the Act refer). Medicines are either registered or listed on the Register, depending on the ingredients they contain and the therapeutic claims that are being made.

In general, products that contain low risk ingredients are referred to as listed medicines in Australia. Most listed medicines are considered to be of relatively low risk compared to other types of medicines, such as prescription and over-the-counter medicines, as they may only contain ingredients that have been approved by the TGA as being of low risk and may only make limited therapeutic claims.

Part 1 of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations) sets out those therapeutic goods that are required to be included in the part of the Register for listed goods. Part 1 of Schedule 4 does not currently include goods containing ‘menaquinone 7’ as a therapeutically active ingredient.

Subsection 9A(5) of the Act authorises the Minister for Health to publish a notice in the *Commonwealth of Australia Gazette* requiring that specified goods be included in the part of the Register for listed goods. Such notices generally require that goods containing particular ingredients be included in that part of the Register. Once the notice is in effect, persons may apply for the listing on the Register of new therapeutic goods that contain ingredients or substances of the kind set out in the notice.

If Part 1 of Schedule 4 to the Regulations is amended to require goods that are the subject of a subsection 9A(5) notice to be included in the part of the Register for listed goods, the notice ceases to have effect (subsection 9A(6) of the Act).

A person can apply for a new ingredient or substance to be specified in a notice under subsection 9A(5). The TGA evaluates such applications, and the supporting data provided by the applicant, on the basis of safety and quality. The safety-focused element determines whether the ingredient or substance is of sufficiently low risk to allow its inclusion in listed medicines, and the quality-focused element characterises the precise and correct nature of the ingredient or substance.

### **‘Menaquinone 7’**

Vitamin K (both K1 and K2), including ‘menaquinone 7’, is a group of fat-soluble vitamins obtained through dietary intake. ‘Menaquinone 7’ is a common form of vitamin K2 that occurs naturally in bacterially-fermented foods.

‘Menaquinone 7’ has a long history of safe use in food in Japan. Its safety is also supported by long term clinical studies with daily doses of ‘menaquinone 7’ of up to 180 micrograms. As such, the TGA considers ‘menaquinone 7’ suitable for use in listed medicines, subject to conditions relating to the application of appropriate daily doses in adults, children (between 10 to 18 years of age) and young children (less than 10 years of age) - of 180, 90 and 45 micrograms, respectively.

To that end, the delegate of the Minister has determined that therapeutic goods containing ‘menaquinone 7’ as a therapeutically active ingredient to be included in the part of the Register for listed goods, when the preparations are for oral use only.

Draft Compositional Guidelines are prepared by the TGA and are intended to set out the standards and requirements for the specific forms or types of substances for use in listed medicines where there is no monograph in the *British Pharmacopoeia*, *European Pharmacopoeia* or the *United States Pharmacopoeia – National Formulary* in relation to the ingredient or substance in question.

As it has been established that the substance is of appropriate quality to allow its use in listed medicines, the TGA has finalised a draft Compositional Guideline in relation to ‘menaquinone 7’, which will be available on the TGA’s Internet site ([www.tga.gov.au](http://www.tga.gov.au)) for consultation for six weeks following the registration of the Listing Notice on the FRLI. The Compositional Guideline will then be published on the TGA website in its final form.

### **CONSULTATION**

Consultation was not undertaken in relation to the making of the Listing Notice, as the notice is considered to be minor and machinery in nature, with low compliance costs for affected industry. The making of the Notice does not involve any new regulatory steps for industry, but rather provides a basis for products containing this ingredient to access the listing process rather than registration, a significant benefit for sponsors. The Office of Best Practice Regulation (OBPR) has advised that a regulatory impact statement is not required in relation to Listing Notices (OBPR Ref. 14416).

The effect of the Listing Notice is that sponsors wishing to use ‘menaquinone 7’ in the formulation of a medicine can list the medicine on the Register rather than registering that medicine. Applications for new registered medicines are fully evaluated by the TGA for quality, safety and efficacy prior to inclusion on the Register, a process that is considerably more expensive and lengthy than the listing process.

In relation to compatibility with human rights, it is considered that the Listing Notice is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, and a Statement of Compatibility setting that out in further detail is set out below.

## **SUPPLEMENTARY MATERIAL – STATEMENT OF COMPATIBILITY FOR A LEGISLATIVE INSTRUMENT THAT DOES NOT RAISE ANY HUMAN RIGHTS ISSUES**

### **Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

#### **Therapeutic Goods (Listing) Notice 2014 (No. 1) – ‘Menaquinone 7’**

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

#### **Overview of the Bill/Legislative Instrument**

*Therapeutic Goods (Listing) Notice 2014 (No. 1)* (the Notice) is a notice made by the delegate of the Minister for Health under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act). The effect of the Notice is to allow sponsors of orally ingested therapeutic goods containing ‘menaquinone 7’ as a therapeutically active ingredient to list, rather than register, those goods in the Register (registration being a considerably more expensive and lengthy process than listing). Once the Notice has commenced, persons can apply to list goods containing this ingredient on the Register.

#### **Human rights implications**

This legislative instrument does not engage any of the applicable rights or freedoms.

#### **Conclusion**

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

**Professor John Skerritt, delegate of the Minister for Health**