

## **Armour Thyroid (USP) and combined thyroxine/ tri-iodothyronine as Thyroid Hormone Replacement**

### **A Statement from the British Thyroid Association Executive Committee**

**November 2007**

#### Part 1. Use of Armour Thyroid

A. Armour Thyroid contains both thyroxine (T4) and tri-iodothyronine (T3) extracted from the thyroid gland of pigs. One grain, about 60 mg, of desiccated pig thyroid extract contains about 38mcg of T4 and 9mcg of T3, a ratio of around 4 to 1. The normal concentration of these hormones in the human thyroid is, however, at a ratio of 14 to 1. In other words, Armour thyroid extract contains excessive amounts of T3 relative to T4 when used to replace thyroid hormone in man. Moreover, as pig thyroid contains other substances apart from T4 and T3, Armour Thyroid is not a pure preparation of thyroid hormones. Historically, extracts of animal thyroid glands were the only way to treat thyroid underactivity, but since the 1950s pure synthetic thyroid hormones have been available in tablet form (thyroxine sodium [T4] and liothyronine [T3]).

B. The concentration of thyroid hormones in Armour Thyroid USP is regulated by the manufacturer to United States Food and Drug Administration (FDA) standards. Despite this, there have been significant problems with the stability of Armour Thyroid in recent years, prompting a massive recall of tablets.<sup>1</sup> Because of these stability problems with Armour Thyroid, there is potential for fluctuations in thyroid hormone levels in the blood of patients treated with Armour Thyroid. These fluctuations may be unpredictable and have adverse effects on patients' health.

C. There is no evidence to favour the prescription of Armour Thyroid in the treatment of hypothyroidism over the prescription of thyroxine sodium, as supplied in the United Kingdom. There has never been a direct comparison of these two treatments. The BTA committee cannot recommend a treatment with possible side-effects, when a safe and equally well-established treatment exists.

D. Armour Thyroid is not on the British National Formulary and is not a licensed therapy in the UK. Mr. G. Matthews, the Pharmaceutical Assessor of the Medicines and Health Care Products Regulatory Agency, in a letter sent to BTA dated 19 October 2005, has clarified that "The regulations on medicine allow doctors to prescribe an unlicensed medicine for a patient to meet