REGULATORY NEWS

see also page 183

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Thyroid extracts: welcome measures… at last!

The recent scandal over thyroid extract-based "slimming aids" has at last prompted the French authorities to take action.

Legislation passed in France in July 1980 banned the use of certain substances in pharmacy compounding (1-3). Two decrees established mechanisms for enforcement in 1982. The first decree banned pharmacy compounding involving substances listed in an annex. This list included: 32 diuretics, 66 psychotropics, 42 appetite suppressants, and thyroid extracts (thyropropic acid, triiodothyroacetic acid, iodinated thyroid hormones, thyroid powder and extracts, thyroxine, and triiodothyronine) (2).

The intention was to end the preparation and prescription of harmful "slimming aids". The rapporteur wrote at the time that "*these abnormal prescriptions (…) are written by a small but growing number of geographically localised heavy prescribers. This growth in prescribing has led certain pharmacies to specialise in these products, at times acting in collusion with high-volume prescribers (…)*" (4). A Ministry of Health press release dated 10 February 1982 clearly stated that: "*the law of 7 July 1980 is aimed at ending aberrant prescriptions by certain physicians who specialise in slimming treatments*" (5).

However, these welcome measures proved very hard to apply. The same was true of the second decree forbidding pharmacists from "unpackaging" drugs in order to use them in compounded products (except for topical products) (3). Various specialists claimed that their freedom to prescribe was being undermined, and many exceptions were allowed, mainly adaptations of products for paediatric use (6).

"Slimming specialists" managed to bypass these regulations for more than two decades. The very same type of prescribers, "slimming specialists", who were initially targeted by this legislation were the first to bypass it, by prescribing appetite suppressants, diuretics, psychotropics and thyroid hormones in the form of separate preparations. Despite the risk of adverse effects associated with these substances, whether taken simultaneously or individually (**a**), a number of pharmacists continued to prepare and sell them. The use of some substances declined, but others quickly took their place. The authorities took little interest in pharmacy compounding, and, in the absence of public scandals, monitoring was relaxed … until the thyroid extract scandal shook Paris earlier this year (7).

Of the 172 people who were found to have used these thyroid preparations, all of which were obtained at the same pharmacy, 18 were hospitalised, one died, and seven required intensive monitoring or intensive care, according to a Ministry of Health report released on 18 May 2006 (7).

Regardless of the exact cause of these complications (dosing errors, use of products of uncertain composition and origin, etc.) several lessons can and must be drawn from this experience. The health authorities and the pharmaceutical profession have reacted rapidly and, so far, responsibly.

Lessons from a major scandal. In May 2006 the Ministry of Health asked the *Haute Autorité de Santé* (French Health Authority) to produce guidelines for healthcare professionals on appropriate management of patients who wish to lose weight (7). The Ministry also promised a wide-ranging debate on the market for "slimming aids" (including non drug measures), with the participation of relevant consumer groups and patient associations. The overriding aim is to stop the public from believing in the benefits of substances that are in reality harmful.

The French regulatory agency sounded the alarm and launched the necessary enquiries. On 17 May 2006, the Agency banned the importation, preparation, prescribing and dispensing of substances containing thyroid powder, thyroid extracts, thyroid hormones or thyroid hormone derivatives (8,9). The Agency reminded health professionals of the serious risks associated with these substances when used by patients with normal thyroid function (risk of hyperthyroidism or even thyrotoxicosis), and pointed out that appropriate pharmaceutical products are available for patients with genuine thyroid disorders (9).

According to the Ministry of Health, regulations and good practice guidelines dealing with pharmacy compounding will be reviewed (7). The French health and welfare inspectorate was already working on a report and proposals on pharmacy compounding (10) before this scandal occurred.

The French Council of Pharmacists reminded its members of their obligations, approved the authorities' initiatives, and requested plaintiff status in the prosecution of the Parisian pharmacy that produced the thyroid preparations. A complaint was also made to the regional disciplinary authority (**b**) (11).

If the announced measures are really implemented, then this distressing affair will at least have ensured that legislation adopted more than 25 years ago is finally enforced.

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a- Taken at high doses and/or for long periods, for inappropriate off-label indications, diuretics can have serious adverse effects, as can thyroid extracts and other substances when taken alone. The use of several of these substances in combination in slimming aids is not the only problem associated with their use in pharmacy compounding.

b- The French National Council of Physicians has barely responded to this scandal, and some physicians may forget this affair too quickly. The French Public Health Code stipulates that pharmacists can refuse to prepare and to dispense a preparation: "When necessary to protect a patient's health, the pharmacist must refuse to dispense a drug. If this drug is prescribed on a written prescription, the pharmacist must immediately inform the prescriber of his or her refusal, and mention it on the prescription."

Selected references from Prescrire's literature search.

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2- "Décret n° 82-200 du 25 février 1982 portant application de l'article L.626 du code de la santé publique relatif à l'usage des substances vénéneuses" *Journal Officiel* 27 February 1982: 695-696.

3- "Décret n° 82-818 du 22 septembre 1982 portant application de l'article L.626 du code de la santé publique relatif à l'usage des substances vénéneuses" *Journal Officiel* 26 September 1982: 2871.

4- Sénat "Rapport fait au nom de la Commission des Affaires sociales sur la proposition de loi de M.Bernard Talon relative à l'innocuité des médicaments et à l'usage des substances vénéneuses, présentée par M. Bernard Talon" Session of 22 May 1980: 16 pages.

5- Ministère de la santé - Direction de la pharmacie et du médicament "Communiqué de presse" 10 February 1982: 2 pages.

6- Prescrire Rédaction "Règles juridiques de prescription et de préparation d'un médicament magistral" *Rev Prescrire* 1988; **8** (76): 295-299.

7- Ministère de la santé et des solidarités "Communiqué de presse" 18 May 2006: 2 pages.

8- Afssaps - Ministère de la santé et des solidarités "Communiqué de presse. Cas de thyréotoxicose" 20 April 2006: 1 page.

9- Afssaps "Décision du 17 mai 2006 portant interdiction d'importation, de préparation, de prescription et de délivrance de préparations magistrales, officinales et hospitalières définies à l'article L.5121-1 du code de la santé publique, y compris les préparations homéopathiques à des dilutions inférieures à la deuxième dilution centésimale hahnemannienne, contenant de la poudre de thyroïde, des extraits de thyroïde, des hormones thyroïdiennes ou des dérivés d'hormones thyroïdiennes": 2 pages. Published in the *Journal Officiel* 13 June 2006.

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11- Parrot J "Pour de bonnes préparations magistrales" *Les Nouvelles Pharmaceutiques* 2006; (319): 1-2.

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