

In line with guidelines from the Register of Chinese Herbal Medicine (RCHM) and the Medicines and Healthcare products Regulatory Agency (MHRA), Su Wen Herbs, licensors of the *Three Treasures* and *Women's Treasure* remedies have produced a yellow card for the report of adverse reactions. I am firmly convinced (and also know from experience) that Chinese herbal remedies that are subject to strict quality controls (as the *Three Treasures* and *Women's Treasure* are) and that are prescribed by properly-qualified practitioners are intrinsically very safe; however, as a profession, it is important to demonstrate to regulatory authorities that we consider the issue of safety to be of paramount importance.

The use of herbal remedies is inevitably linked to possible side-effects or adverse reactions. This is not because they are toxic, but because human metabolism differs widely from person to person and although side-effects are undesirable effects that can be foreseen, individual patients' reactions cannot.

We should distinguish between *side-effects*, *adverse reactions*, '*unspecified reactions*' and *allergic reactions*.

**Side-effects** ~ are predictable. We know, for example, that Yin-nourishing herbs are 'sticky' in nature and have a cloying effect and if they are used continuously for a long time, they may injure the Spleen: this is a possible side-effect and a skilled practitioner should always keep it in mind. Similarly, if we prescribe a Yang tonic we should be aware that its long-term use may injure Yin and cause dryness and we should therefore either discontinue its use at intervals or support the Yin with acupuncture. Likewise, cold herbs that clear Heat and cool the Blood may also damage the Spleen; drying herbs that dry Dampness and resolve Phlegm may injure Yin.

*Such predictable side-effects should not be reported.*

**Adverse Reactions** ~ are undesirable effects that cannot be foreseen and that occur regularly in several patients. They are practically unknown with herbal remedies due to the intrinsic safety of this form of medication (unless, of course, toxic substances are used, or herbs are contaminated by other substances).

*Adverse reactions should be reported using the yellow card.*

**Unspecified 'Reactions'** ~ on the other hand, depend on individual metabolism and cannot be replicated in other patients. For example, if a patient develops a nosebleed following the administration of *Ease the Journey - Yin* (an actual example from practice), this would be an unexplainable, unspecified reaction. It cannot be explained because, even if the diagnosis had been wrong (i.e. the patient was given a Yin instead of a Yang tonic), Yin-nourishing herbs should not cause bleeding.

If an unexpected 'reaction' occurs, the first thing to establish is that it is *truly* a reaction to the herbal remedy. Patients tend to attribute any new or unexpected symptom to any herbal remedy they may be taking; this happens especially with patients who are new to herbal medicine. In my clinical experience, the overwhelming majority of 'reactions' are not related to the herbal remedy but to either acute infections or emotional stress. Thus, unless the reaction is an allergic one (see below), the first approach to take when a patient telephones about a certain reaction is to advise him or her to stop taking the remedy for a few days and then to start it again: if exactly the same reaction occurs again, then it is most probably due to the remedy. In such a case, the remedy should not necessarily be discontinued but one should try to reduce the dosage: if the reaction still occurs then its use should be discontinued.

Whilst some patients are overanxious about taking herbal remedies and may wrongly attribute every little symptom to them, others err in the opposite direction and put up with side-effects in the mistaken belief that these are a 'process of elimination' or a 'healing crisis' (this tends to occur more frequently in patients who have previously received homoeopathic treatment). For example, if we prescribe a Yin tonic and the patient develops daily diarrhoea, this should not be interpreted as a 'process of elimination' or a 'healing crisis', but as a side-effect of the Yin tonic which should therefore be discontinued.

However, as mentioned above, in the overwhelming majority of cases, the reaction does not occur again when the use of the remedy is resumed. Generally speaking, such reactions need not be reported.

**Allergic reactions** are an important exception to the practice of discontinuing a remedy for a few days and then starting it again. If the original reaction was an allergic one, a re-challenge with the same substance could have serious repercussions with the possibility of anaphylaxis. How do we know that an initial reaction was an allergic one? This may be difficult, and sometimes impossible, to establish. However, two particular cases of allergic reactions are easy to diagnose and these are a Type-I asthmatic reaction and an urticarial reaction: if the patient develops severe wheezing and breathlessness or a severe urticarial rash a few hours after taking herbs, these are obviously allergic reactions and the herbs should be stopped immediately and **not be given again**.

Some allergic reactions involve the liver causing a hepatitis-like reaction or cholestatic injury. The possible symptoms of liver failure are loss of appetite, nausea or vomiting, fever, non-colicky upper abdominal pain or right-sided hypochondrial pain, itching, malaise, headache, jaundice, dark urine, pale stools. In the presence of such symptoms we should suspect liver injury (which **may** be allergic) and it would be very unwise to continue the treatment or to re-start it after a period of suspension (in case the original reaction was an allergic one).

**All practitioners should be vigilant and always be alert to the development of symptoms and signs of liver or kidney failure, as indicated below.**

**The possible symptoms of liver failure are:**

- Loss of appetite
- Nausea or vomiting
- Fever
- Non-colicky upper abdominal pain or right-sided hypochondrial pain
- Itching
- Malaise
- Headache
- Jaundice
- A distaste for cigarettes (in smokers)
- Dark urine
- Pale stools

**Of course, it is the combination of three or four of these symptoms that may alert the practitioner to the possibility of a liver disease. If such symptoms and signs occur, the herbal remedy should be discontinued IMMEDIATELY.**

**The possible signs of kidney failure are:**

- Proteinuria
- Oedema
- Scanty urine
- Urine containing red and/or white blood cells
- Loss of appetite
- Nausea, vomiting
- High blood pressure
- Lassitude

**Again, if these symptoms appear after administration of herbs, they should be discontinued IMMEDIATELY.**

*If you stock the remedies, please note that under guidelines of the MHRA, we should write down the batch number of the remedy given on the patient's case sheet. This ensures traceability of each batch.*

**Giovanni Maciocia**

