

From the European Herbal and Traditional Medicine Practitioners Association (ehpa@globalnet.co.uk) 16 November 2009

EHTPA survey of:

Impact of loss of third party supply to practitioners of herbal/traditional medicine for individual patients after April 1 2011(at full implementation of the Traditional Herbal Medicinal Products Directive)

Companies

Pukka Herbs

The impact on Pukka herbs of the loss of business if it is not possible for those using 12(1) to access third party supplied herbals via Article 5.1 of 2001/83/EC will be a loss of 35 specialist Ayurvedic products, equating to 25% of our turnover involving £500,000 loss of revenue. We will also be forced to remove 7 members of staff as a result of this.

Of course, with the impact of the THMPD and the new EFSA stance on 'botanicals' we will lose a further 25% of our business equating to a loss in revenue of £1m.

Economic impacts like this mean that we will have to restructure our business with resultant loss of jobs and 'follow-on' business within the UK (packaging, transport, printing etc).

The impact on the farmers involved in the projects that we have set up and manage will be substantial. I estimate that 250 families will be made redundant due to lack of work from a drop in demand for the herbal species that we purchase. My use of a third party dispensary totals £12,000 pa.

Woodland Herbs:

We offer a herbal prescribing service for NIMH herbalists. This is something we have offered for the past 5 years and is a gradually increasing part of our business. We focus mainly on prescribed herbal teas as this is an item we have found herbalists cannot stock due to the bulk of the herbs, the expense and the limited shelf life compared to tinctures. We are concerned that the future changes in legislation may impact this service as well as being a proportion of our turnover it is something we see increasing in the future as more herbalists train, qualify and use dried herbs. It is also a worry that herbalists will lose the option to use herbal teas as this is often the lowest cost option for their clients, especially those on a low income.

Proline

Checking our records, I estimate that approximately 10% of our sales are covered by these activities. This would equate to some £160,000.00 p.a.; a volume of sales that we can ill afford to lose, particularly in the current climate. In its own right this would mean a corresponding loss of up to 10% of our workforce.

It is to be noted, however, that this is only a part of the overall picture. The Government and EU have introduced several different but related pieces of legislation concurrently. The Traditional Herbal Medicine Products Directive (THMPD) will have a dramatic negative

effect on our business due to the removal of section 12(2) products in 2011. This accounts for some 20% of our business. It is irrational to suggest that this business will be replaced by licensed THMPD products; this will not happen. While there will be some new work, most formulae containing several herbs simply cannot be registered under the THMPD since the manufacturing quality controls make their production nearly impossible even if 30 years of safe use can be demonstrated. The result of this is that the herbs that are being registered under the THMPD are almost all single-ingredient products, many of which are being registered in multiple applications by various competing companies. This simply creates products of low profitability.

At some point this attrition becomes fatal as we would no longer be able to manage our overhead and regulatory obligations. It remains to be seen if these factors put together are sufficient to create a tipping point at Proline. If indeed this were to be the case then 42 jobs would be lost directly and it is safe to assume that there would be a knock on effect through the supply chain.

Mayway (Chinese herbs)

ANNUAL TURNOVER

PILLS	DRIED HERBS	CP	PRESCRIPTIONS
£300,000	320,000	£320,000	£500,000

PATIENTS	ACUPUNCTURISTS	HERBAL PRACTITIONERS
34,210	680	2,100

This listing is also based on the number of the different groups that we serve on a yearly basis.

As can be seen, the majority of patients have accounts with Mayway and goods are sent directly to them. Practitioners generally give the patients the prescriptions to send in to Mayway. All pills and prescriptions will cease sale after April 2011. It is not clear whether the concentrated powders will be viable. Some of the concentrated powders are sold as third party prescriptions direct to patients. The patients (who use third party prescriptions) and acupuncturists (who use pills) will cease to be customers and only herbal practitioners will remain. This amounts to around 2/3rds of our income lost after 2011 if statutory regulation does not go ahead. This will have a devastating consequence for our business!

Balance Herbs

The impact of this on Balance Healthcare's business will mean a loss of 45% of sales which would mean a loss of 8 jobs.

Panacea

Panacea dispensary is a third party supplier to practitioners for individual patients. This is approximately 20% of Panacea's total turnover and equates to the likely loss of 1 full-time + 4 part-time jobs. The loss of this turnover would have a significant impact on our business and our viability in these difficult economic times.

No 1 Herb Co

Should statutory regulation not go through, the loss to our business will be 100% as our business is entirely third-party supply.

Neals Yard

Anticipate loss of retail sales of dispensed tinctures is approximately £120,000 per annum. Also of consequence is that it would mean our tincture production facility would not be viable and would lose 2 full-time staff.

The Herbal Apothecary

Since 2005 one priority has been the development of a dispensing service. New medical herbalists are qualifying at a much higher rate than ever before. Setting up a new dispensary can be prohibitively expensive. As a consequence we have been offering a dispensing service direct to the patient since early 2006 i.e. the practitioner sends prescriptions direct to our herbalist who will prepare it and despatch it direct to the patient. This is third party supply that would cease after 2011.

This element of our business has grown considerably in the last 3 years and we are now fulfilling in the region of 1500 – 2000 prescriptions per year. This presents employment for one person in our pharmacy.

It is our intention to develop this side of the business further as we are able to offer pharmaceutical manufacturing standards when making products for practitioners and in the dispensing service.

This side of the business will grow significantly over the next 3 year period Our expectation will be 4-fold increase over this time. Obviously all this is dependent on the promised provision of statutory regulation which the DH has been signed up to for a number of years.

Specialist Herbal Supplies (Portslade)

Calculate the loss to Specialist Herbal Supplies of loss of third-party supply about £175,000 a year.

Rutland Herbs

Visits from MHRA officials around 2003 and 2005, encouraged us to take the GMP plunge because I was assured that would effectively guarantee our business after 2011. In terms of improved facilities and operating systems the capital figure to achieve GMP is over quarter of a million. If we lose our practitioner business, it remains doubtful whether I shall live or work long enough to ever recover from the mistake, or worse.

The MHRA have already had £16,226.00 off us in the last three years and the inspectors were talking of putting our fees up to £10,000 per (2 man 3 day) visit last time they were here, just to make us realise that we had to sell huge amounts of *licensed* products to make the whole thing worthwhile. Crazy!

Oxford Medical Supplies Ltd

Our projected Annual Turnover of Herbal Formulas for 2009 will be £91,014.00. We are not a large Company and if we were to lose this amount of revenue it would probably place us in a very difficult financial position especially given the current state of the UK economy. The loss of business if statutory regulation does not go ahead might cause us to have to make staff redundant or in the extreme cease trading. This would result in the loss of 6 jobs. As we are in a rural location the likelihood of our staff finding comparable positions is virtually nil.

Nelsons

We have approx 1800 practitioners on our books. All of these accounts could be affected, to a greater or lesser extent by loss of third part supply. Nelson's pharmacy estimate about 5% of their business and prescriptions would be affected, and a similar figure for our Specials operations and telesales businesses as well.

Maharishi Ayurveda

Sales of Medicines Exempt from licensing in 2008 were £47,000 (these are third-party manufactured) and all of these would cease after 2011 if statutory regulation does not go ahead.

Furthermore because Section 12(1) is the best way for clients to get access to herbal products and because of the probability that evaluation of the safety of food supplement ingredients and/or products will be conducted in such a way as to make it very difficult for suppliers of Ayurvedic products to comply, we consider that all food supplements recommended by practitioners and at least 40% of other food supplement sales are under threat if statutory regulation of herbalists is not carried out. If we add loss of sales of third party manufactured food supplements prescribed by practitioners to patients in a 1-to-1 consultation to the loss of medicines made by third parties, we estimate this to total in all to be about £187,000 pa. This loss would result in loss of about 3-4 jobs from Maharishi Ayurveda Products.

Professional Associations

Register of Chinese Herbal Medicine

Although I don't have precise figures, I estimate that at least 80% of our members are heavily reliant on external dispensaries and that at least 50% could go out of business without access to them. This is probably a conservative estimate since the number of practitioners put out of business might be nearer 60 -70%.

National Institute of Medical Herbalists

530 emails were delivered about preserving access to herbal medicines (3rd party medicines). We had 258 people open the email so just over 50% opened it - this is about 10% up on the usual number that open emails.

47 of those 258 have actually send a reply and of those that responded over **95%** said that they are using a herbal dispensary service. In fact many of them said it was essential to their business. From this it can be seen that the loss of third-party supply is has very serious implications for the viability of our members' practices.

College of Practitioners of Phytotherapy

The majority of members of the College of Practitioners of Phytotherapy (160 members) consider that such a loss would have a hugely negative impact on their ability to operate a

viable business and to meet the health care needs and expectations of their patients. Many members consider that they would lose revenue totalling thousands of pounds (for some above £15,000 p.a.). For many of our members this represents a large percentage loss of income and could threaten the viability of their practices. Some members consider that their loss of revenue could exceed 40% of total annual income. For those members who operate dispensaries in the form of shops the loss of third party products is likely to force them out of business. We are extremely worried about the potential consequences of the loss of third-party products since this could have a devastating effect on our organisation and the wider herbal profession. We feel it is absolutely essential that herbal practitioners achieve statutory regulation in order to protect our ability to use third party products and thereby to meet the needs of patients and maintain our businesses.

The Unified Register of Herbal Practitioners

The average spend of our members who responded to our questionnaire about third-party supply is £6000 pa and we have 69 members so that means that failure to gain statutory regulation will amount to a total loss of revenue across our members of £414,000.

Ayurvedic Practitioners' Association (APA)

Ayurvedic practitioners, like practitioners from other traditional systems of medicine, use a variety of products in their practice. These include dried and cut herbs, oils, pastes and finished products. Amongst these the most commonly form used is the finished product form which is supplied in the main by third-party manufacturers, some based in the U.K. The possible loss of third-party manufactured products would have a major impact on the APA members, affecting almost every member. Furthermore, it is likely to encourage some members of the public to source these products directly, without the expert advice of an Ayurvedic practitioner leading to potential health risks through self-medication.

The impact would not be restricted to loss of turnover for companies and practitioners (approx 1.5 million GBP) involved directly, but also ancillary service providers such as: mailing services, printers, packagers. This would result in increased costs to the Government costs through a rise in unemployment and adversely impact small and medium sized enterprises, which are already under a great deal of financial pressure in the current economic climate.

British Association of Traditional Tibetan Medicine (BATTM)

In essence we have two TTM practitioners and their families who rely on TTM as their source of income. Both their practice and their families will be devastated by the loss of third-party supply as they rely entirely on specials (third-party manufactured herbal products) for their practice. There is one other practitioner who is part time and one other who is just being accredited by us. The impact on their practice of failure to gain statutory regulation will be the same.

As no traditional Tibetan medicine practice will then be possible, the Tara Trust which runs clinics in London and different parts of Scotland anticipates that it will effectively have to close its business completely. Turnover is small approximately £30,000 per year, but it does sustain one TTM practitioner and their family, with two children in their teens. There is no doubt that if statutory regulation is not granted, this will drive the practice of Tibetan medicine underground. This is certainly not in the interest of patients!