

## Summary of responses Herbal Consultation: Sell Through of Herbal Medicinal Products

Consultation from 09/07/13 to 06/09/13

The consultation sought views on the proposal to end the concession allowing retail businesses and practitioners to “sell through” stocks of unlicensed herbal medicinal products lawfully on the market on 30 April 2011 - the end of the transitional period under the herbal Traditional Herbal Medicinal products Directive 2004/24/EC.

In addition, information was sought on:

- a) What are the products and what are the current levels of stocks remaining to be sold?
- b) given normal turn over of stock when they would anticipate that this stock would be sold through?
- c) what is the demonstrable evidence (in particular systematic stability data) to support stated shelf-life of products beyond December 2013?

In total 54 responses were received. These have been broken down into 6 groups

**Manufacturers/THR Holders:** Bio-Health Ltd, Diapharm UK, Dr Willmar Schwabe GmbH & Co, Healthspan, HRI Herbal Medicine (Jessups), Potters, Schwabe Pharma UK, Bioplanta UK, Diapharm GmbH & Co. KG, Napiers, Organic Herbal Remedies Ltd

**Practitioners – Non TCM:** Registered Nutritional Therapist, Medical Herbalists

**Practitioners – TCM:** Individual TCM Practitioners

**TCM retailers:** Acu-herbs, Acuherbal Chinese Medicine Ltd, AcuHerbs Chinese Medicine Ltd, AcuHeal Chinese Medicine, Dr China, Dr. Sun & Herbs Everwell Chinese Medical Centre, Holistic Health

**Others:** Lay member of IRCHH, Leicester School of Pharmacy, Nightingale collaboration, Patient, Professor of Pharmacology, Regulatory Consultant, Royal College of Physicians

**Umbrella Groups/Trade Associations:** Association of Traditional Chinese Medicine and Acupuncture UK (ATCM), Ayurvedic Trade Association, British Herbal Medicine Association, British Acupuncture Council, General Naturopathic Council, Health Food Manufacturers' Association, Council for Responsible Nutrition (CRN), European Herbal & Traditional Medicine Practitioners Association (EHTPA), Federation of Traditional Chinese Medicine Practitioners Institute (FTCMP), National Association of Health Stores (NAHS), PAGB, The Herbal Forum

## Summary of Reponses

Group	For	Key Messages	Against	Key Messages
<b>Manufacturers - THR Holders</b>	<b>10</b>	<ul style="list-style-type: none"> <li>• Support proposal but concerned how MHRA will ensure 'sell through' is enforced effectively given that cases dealt with on a case by case basis</li> <li>• Do not believe there would be an adverse impact on retail establishments as the period allowed seems to be beyond the normal stock rotation of retailers</li> <li>• The "grace" period has curtailed the ability to fully develop THR licensed products</li> <li>• Surprised at lack of enforcement action by MHRA to date; this has led to a constant flow of products on the market</li> <li>• THR companies have been put at a considerably competitive disadvantage. Sell through favoured the people who were not willing to comply to the legislation</li> <li>• Sell through being abused by manufacturers; expiry dates of 2016 have been found on herbal supplement products, meaning that they were clearly manufactured after the cut off date</li> <li>• Companies now use very small doses of herbs in combination products to claim presence of those products but steer clear of medicinal dose levels</li> <li>• The unlicensed product has huge benefits from the indications allowed on the THR (the</li> </ul>	<b>1</b>	<ul style="list-style-type: none"> <li>• Invested many thousands of pounds in purchasing high quality GMP manufactured stock with a five year shelf life.</li> <li>• If proposal goes ahead, companies will go out of business. There is no evidence of any deterioration over five years</li> <li>• Have sufficient stock of most products to continue selling them until three months before their best before dates.</li> <li>• The latest BB dates are end April 2016.</li> <li>• End the sale through of these products January 2016, allowing customers three months to consume the last products prior to the last BB date</li> </ul>

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		<p>consumer sees this and thinks the low dose product will do the same) and its lower price due to not having to comply with THR regulations</p> <ul style="list-style-type: none"> <li>• Retailers think the law has "no teeth" believe that if a manufacturer or distributor tells them that they are still supplying herbal medicines because they are food supplements on the "Belgian list" that this absolves them from the responsibility of legal supply</li> <li>• Not helped by the lack of clarity in what is a herbal medicine and what is a food supplement. The MHRA have never published a "British list" containing even just those few herbs, for example, St. John's Wort that are clearly not food supplements</li> <li>• Certain herbs should be considered medicinal only, ie St John's Wort, Milk Thistle, Echinacea and Black Cohosh etc and should not be allowed to be sold as a supplement at whatever dosage</li> </ul>		
<b>Practitioners – Non – TCM</b>	<b>1</b>	<ul style="list-style-type: none"> <li>• In favour of the end date, and shelf clearing policy of all unlicensed herbs</li> </ul>	<b>2</b>	<ul style="list-style-type: none"> <li>• Sell by dates will run beyond proposed cut off date, leaving small business with costly stock; tinctures, both singles and formulae have 5 years shelf life</li> <li>• Sold out of several lines but do need to sell what stock left anything short of this would be financially dire and would cause harm to small business</li> </ul>

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				<ul style="list-style-type: none"> <li>• The date of December 31st 2013 was never mentioned and never expected, it was never factored into business plans</li> <li>• Proposal will add to the burden of small healthfood stores</li> </ul>
<b>Practitioners – TCM</b>	<b>0</b>		<b>9</b>	<ul style="list-style-type: none"> <li>• As most practitioners stockpiled prior to April 2011 for up to 5 years, (as most TCM products bear a shelf life of 5 years) after MHRA gave a “green light” for the retail until shelf life ends.</li> <li>• Spent thousands of pounds – there are over 146 of different kinds of herbal products currently in stock; expect to sell through the stock by the end of 2014 or by 2015. Early end of “sell through” of unlicensed herbal medicine products will cause immense waste of stock and financial loss for many TCM practitioners.</li> <li>• Economic downturn has made matters worse with a number of medical centres closing down because they could not afford the rent due to the business decrease. Early end of sell through might make this situation worse.</li> </ul>
<b>TCM retail/practitioner</b>	<b>0</b>		<b>11</b>	<ul style="list-style-type: none"> <li>• Due to the delay of statutory regulation for herbal practitioners, access to unlicensed herbal products under Article 5.1 of EU Directive is blocked.</li> </ul>

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				<p>Practitioners have no other way to use unlicensed herbal products except to use those products purchased legally prior to April 2011</p> <ul style="list-style-type: none"> <li>• Companies imported a large amount of herbal products with five years valid date in 2010. Still quite a few left unsold (in one case value worth around £ 200,000), - plan was to sell these products within its shelf- life -- five years.</li> <li>• Retailing businesses have been under huge pressure for the last couple of years, the sales have been far behind what initially expected when imported these products. If the herbal products are not permitted to be sold at the end of 2013, will suffer from a huge loss</li> </ul>
<p><b>Umbrella Group/Trade Association</b></p>	<p><b>7</b></p>	<ul style="list-style-type: none"> <li>• In most case majority of members in support of proposals, however think more appropriate date would be 30/04/14 to be the final date for products produced before the end of the transitional period to be removed from the market</li> <li>• In the case of certain products which have a bonafide shelf life of more than 3 years, the case can be made for them to remain on the market until shelf-life expiry, subject to conditions</li> <li>• Unlikely to be fully effective without appropriate enforcement action</li> <li>• Ask for further clarifications on the definition</li> </ul>	<p><b>6</b></p>	<p>Mainly practitioner groups</p> <ul style="list-style-type: none"> <li>• Failure to deliver statutory regulation is having a severe impact on the ability to supply their patients with some herbal medicines on which they rely.</li> <li>• Having a serious adverse effect on the financial viability of some herbal practices where there is little or no facility to make up medicines on the herbalists' own premises</li> <li>• When Section 12 (2) was repealed in 2011, there was no time limit set on use of herbal products supplied to practitioners under Section 12 (2)</li> </ul>

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		<p>of and the categories of products and active ingredients (incl. Their concentration) covered by the term 'unlicensed herbal medicines'</p>		<p>before the repeal of this statute</p> <ul style="list-style-type: none"> <li>• Products were purchased by herbalists on the basis that they could be legally prescribed to patients until their sell-by dates expired. In many cases, these sell by dates extend to the end of 2014</li> <li>• Propose that the end of the sell-through period should be 31st December 2014 otherwise will have to bear further unforeseen economic loss due to the inability to prescribe products to patients. In effect, this retrospective legislation will have an unfair financial consequence on those who purchased products in the expectation that they could continue using them until their sell-by dates expired</li> <li>• Based on 198 responses their members survey one TCM organisation said that</li> <li>• Vast majority of our members (88.4%) stockpiled products prior to 2011</li> <li>• Half of members (52.9%) spent over £5000 (wholesale price) on stock</li> <li>• The number of different kinds of herbal products currently in their stock ranges from under 20 to over 150. On average practitioners, have 51 kinds of herbal products currently in their stock</li> <li>• In most cases, the retail value of their current stock is in the range of £10,000 to £20,000.</li> </ul>

Group	For	Key Messages	Against	Key Messages
				<ul style="list-style-type: none"> <li>• Most practitioners can only sell through 10-30% of their current stock by the end of 2013</li> <li>• Most of these products have expire date as end of 2015, with second most common being end of 2014</li> <li>• Only 2.7% (5/186) of practitioners anticipate that they would sell through their stock by the end of 2013. However, 72% (134/186) of practitioners expect to sell through their stock by the end of 2015</li> <li>• Estimated that the monthly business loss for 50% (91/183) of practitioners would be between 21-40%, with another 31% potentially suffering from loss even higher than 40%</li> </ul>
<b>Other</b>	<b>6</b>	<ul style="list-style-type: none"> <li>• Support the removal of products; they should be brought into line with the current THR regulation. The transitional arrangements under Directive 2004/24/EC gave ample time for manufacturers and importers to prepare. Subsequently given a further two years to clear the supply chain. They have had more than sufficient time to comply with the Directive</li> <li>• Current THR products have a rigorous testing regime and any changes to product must be communicated to the MHRA for assessment. It will also help clarify in the public's mind that it is only the THR products that are the higher quality products. Rather</li> </ul>	<b>1</b>	<ul style="list-style-type: none"> <li>• Delay of statutory regulation of herbal practitioners denies our access to unlicensed products</li> <li>• Practitioners have no other way of to use these products accept retail allowed by MHRA</li> </ul>

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		<p>than being confused by a range of possible products</p> <ul style="list-style-type: none"> <li>• Since the date for transitional protection to cease was 30 April 2011, it would seem logical to make the date and sell through cease 3 years later, i.e. 30 April 2014, as legitimate stock with a 3 year shelf life may be still potentially be selling thorough. There should be no exemptions if any products with a shelf life longer than this date</li> <li>• There should be an MHRA plan of enforcement.</li> <li>• The loophole of labelling herbal products as food supplements to avoid medicines legislations should be addressed at the same time</li> </ul>		
Total responses	24		30	