



NHPD Monograph Consultation

Echinacea angustifolia

Echinacea pallida

Echinacea purpurea

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Bad Science Watch

Bad Science Watch is an independent Canadian consumer protection organization dedicated to promoting good science in public policy.

The following was prepared by volunteers over the last several months and represents what we believe to be an honest, fair, and science-based representation of the state of affairs of nosodes on Canada. We are an independent body that is funded by private donations and we do not represent any corporate interests.

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Introduction

On behalf of Canadian consumers and our supporters we would like to submit for your review our comments regarding the proposed monographs for *Echinacea angustifolia*, *Echinacea pallida* and *Echinacea purpurea*. Our concerns are primarily focused on the lack of high quality evidence to support their indications and the potential misinterpretation of what the phrase “traditional use” actually conveys.

Analysis

Systematic reviews and meta-analyses of *Echinacea* have been performed that are relevant to the current monographs under consultation. These reviews all note the wide variety of *Echinacea* preparations with concomitant variations in bioactivity tested in the reported randomized controlled trials (RCT) and available on the market to the general consumer. The majority of the available preparations have not been adequately tested for efficacy (Linde et al 2006).

Linde et al (2006), examined the available evidence from RCT's on *Echinacea* preparations in the prevention and treatment of the common cold. They found some evidence that *Echinacea* preparations made from the aerial parts of *Echinacea purpurea* might be effective on cold symptoms in adults, but noted that not all trials showed this effect, nor even a positive trend. Preparations made from *Echinacea angustifolia* and *Echinacea pallida* lack rigorous trials that would support their use for this indication.

A meta-analysis by Shah et al (2007), also examined the available RCT evidence on *Echinacea* preparations in the prevention and treatment of the common cold and concluded that *Echinacea* was effective for this purpose. However, this analysis included trials that used *Echinacea* preparations in combination with other herbal agents, conducted its analysis on pooled data that grouped together *Echinacea* preparations across species, and also included trials that inoculated participants rather than testing the effects of *Echinacea* on a naturally caught cold (Linde et al excluded all these trials). While taking a more favourable view on the effectiveness of *Echinacea*, the authors nonetheless caution against routine use until rigorous controlled trials examine details such as *Echinacea* preparation, dose, and objectivity of study endpoints. It is entirely possible that when these are conducted the evidence in support of general *Echinacea* use will become less favourable and more in line with conclusions made by Linde et al.

Finally, a meta-analysis was conducted that included only the three trials that tested *Echinacea* on experimentally induced colds. It concluded that *Echinacea* was effective at reducing the incidence of colds, but like the other reviews cautioned that this finding still required independent replication (Schoop 2006).

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The available reviews fail to reach a clear consensus on the efficacy of *Echinacea* in general and on the specific efficacy of each individual *Echinacea* species preparation available. In addition, other authors have called for good quality studies examining the efficacy of standardized *Echinacea* preparations on influenza and other upper respiratory infections (Hudson 2012). The reviews summarized above exclusively looked at the common cold. Also, the evidence in support of the use of *Echinacea* in children with upper respiratory infections has been deemed negative (Koenig and Roehr 2006).

Specific Points

The best evidence does not support routine use of all Echinacea products for all types of upper respiratory infections

All the reviews summarized above focused only on the common cold. They also fail to reach consensus about whether all three species of *Echinacea* in common use are effective for colds. *Echinacea purpurea* has the strongest support, but there is still room for doubt.

The available systematic reviews of evidence in support of Echinacea do not support the use of Echinacea for influenza

Linde et al 2006, Shah et al 2007 and Schoop 2006 did not include studies of individuals suffering from influenza. The proposed indications make no distinction between the common cold and influenza and it is possible that consumers may not realize that there are differences between the two illnesses. There is a risk that consumers may choose an *Echinacea* product to treat more severe respiratory tract infections, instead of seeking out appropriate medical treatment.

The term “upper respiratory tract infections” may cause confusion in consumers.

Since consumers are to be guided by information on the label it is especially important that the general consumer correctly understands the meanings of product indications and instructions. Clarification may be required of what upper respiratory tract infections include and what they do not include. It may not be the case that the general public understands that more severe cold and flu virus infections are not included under the proposed indication. They are far more likely to lump all colds and flus together, regardless of severity, consequently putting themselves at risk. This clarification is especially important since the purpose of these indications is to guide self-selection of products without the involvement of a healthcare practitioner.

The term “traditionally used” may not be fully understood by consumers.

Consumers may misinterpret the phrase “traditional use” as an indication that the scientific evidence that *Echinacea* works is positive and long standing. Consumers may not understand that the indication is meant only to imply a pattern of use. This is problematic because consumers may be seeking out

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Echinacea products because of pre-formed beliefs about its effectiveness influenced by anecdotes and information from the internet. An examination of how the evidence for *Echinacea* is presented on the internet found inconsistencies and concluded that consumers may find it difficult to understand the current state of the evidence (Hart 2009). Since consumers may very well be seeking out *Echinacea* because of information they have read on the internet, they may be even more predisposed to misinterpret what the traditional use claim actually means. This is particularly the case if there is no clarification on the product label of what “traditional use” does not mean.

Consumers may not be aware that not all *Echinacea* products are likely to be effective for the purpose they seek.

In the same vein of patients self-selecting products according to the information available on packaging, it is very likely the case that the general public is unaware that the effectiveness of an *Echinacea* product is somewhat dependent on the particular species of *Echinacea*. Therefore a consumer may inappropriately select a product containing one species of *Echinacea* for a particular indication when it is not approved for this purpose.

Conclusion

While we do not dispute that there is indeed evidence to support the claim that *Echinacea* has been traditionally used for the purposes listed in the monographs, the evidence does not suggest beyond a reasonable doubt that *Echinacea* is effective for the purposes they have historically been used for (Barret, 2008). Therefore we find it problematic that products will be allowed on the market with traditional use claims when many such products lack sufficient evidence of effectiveness. We also wonder whether *Echinacea* products would continue to be licensed for sale with a traditional use claim if in the future the weight of the evidence turns more conclusively negative.

We thank you for the opportunity to share our comments and concerns.

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