Access this article online

Quick Response Code:

Website: https://journals.lww.com/ijar

DOI: 10.4103/ijar.ijar_171_24

When regulation ignores evidence: The case of Denmark's *Ashwagandha* ban and the Technical University of Denmark's misguided risk assessment

Antonio Morandi

ABSTRACT:

The recent ban on *Ashwagandha* (*Withania somnifera* (L.) Dunal) supplements in Denmark, based on a risk assessment by the Technical University of Denmark (DTU), exemplifies the challenges in regulating traditional herbal medicines within modern frameworks. This article critically examines the DTU report, highlighting methodological flaws including overreliance on animal studies and selective literature review. The report's disregard for *Ashwagandha's* long history of traditional use and mischaracterization of its effects, particularly alleged abortifacient properties, contradicts a growing body of scientific evidence supporting its safety and efficacy. The current research demonstrating *Ashwagandha's* benefits in stress reduction, sleep improvement, and cognitive function further underscores the disparity between scientific findings and the DTU's conclusions. The ban's implications extend beyond Denmark, raising questions about regulatory consistency and proportionality in evaluating herbal products globally. The Indian Ministry of Ayush's critique emphasizes the need for a more comprehensive, evidence-based approach for assessing traditional medicines. This controversy may catalyze the development of integrated evaluation methods, such as the Collaborative Medicine and Science framework, bridging diverse knowledge systems in regulatory decision-making. The case underscores the necessity for a global health paradigm that harmonizes traditional and modern medical approaches, ensuring public safety while preserving access to beneficial traditional remedies.

Keywords:

Ashwagandha, Ayurveda, Collaborative Medicine and Science, Denmark, Technical University of Denmark, Evidence-based assessment, Global health policy, Herbal regulation, Regulatory decision-making, Traditional medicine

INTRODUCTION

The recent Danish ban on *Ashwagandha* (*Withania somnifera* (L.) Dunal) supplements, based on the results of a risk assessment prepared by the Technical University of Denmark (DTU),[1] shows a rather stark example of the challenges that regulatory decision-making in the area of traditional herbal medicine is facing. The situation is so severe that it leaves no option but to examine this DTU report in light of the current research findings and explore its broader implications for herbal supplement regulation and integration of the traditional and modern medical systems.

METHODOLOGICAL FLAWS IN THE DANISH TECHNICAL UNIVERSITY REPORT

Upon close examination, the DTU report presents so many methodological flaws that cast significant doubts on its conclusions. The most important one is an overreliance on animal studies and *in vitro* experiments,

Ayurvedic Point, Institute and School of Ayurveda, Milan, Italy

Address for correspondence:
Dr. Antonio Morandi, Ayurvedic Point, C.so Sempione 63, Milan - 20149, Italy.
E-mail: dr.morandi@ayurvedicpoint.it

Received: 23-07-2024
Revised: 21-08-2024
Accepted: 26-08-2024
Published: 30-09-2024

How to cite this article: Morandi A. When regulation ignores evidence: The case of Denmark's *Ashwagandha* ban and the Technical University of Denmark's misguided risk assessment. Int J Ayurveda Res 2024;5:144-7.

which used doses often far in excess of typical human consumption. While such studies undoubtedly provide valuable mechanistic insights, their direct extrapolation to human outcomes without due consideration of dose–response relationships and interspecies differences is scientifically questionable at best.[2,3]

Furthermore, the literature review in the report itself comes across as selectively biased. Studies highlighting potential risks have been favored, while substantial research on the safety and efficacy of *Ashwagandha* in human trials has been dealt with in a very cursory manner. This imbalance misses the comprehensive and nuanced representation of the herb's risk–benefit profile.

MISREPRESENTATION OF *ASHWAGANDHA'S* EFFECTS

Perhaps most concerning is, in this report, the seeming disregard for *Ashwagandha's* long history of traditional use in Ayurveda. The fact that the traditional use of herbs like *Ashwagandha* has been sustained over centuries with diverse populations is in itself solid evidence of safety and efficacy. The longevity of these practices, further refined through generations by empirical observation, offers a form of long-term and large-scale assurance regarding safety that even modern clinical trials struggle to match. The fact that *Ashwagandha* has been in continuous use in Ayurvedic medicine for thousands of years is a testament not only to its safety but also to its considerable therapeutic value. These traditional sources of wisdom combined with the rigorous discipline of modern scientific study create an excellent foundation for grasping herb's benefits and appropriate uses. The credibility of DTU's analysis is further eroded by the misinterpreted information from the American Herbal Pharmacopoeia, as pointed out by Patwardhan *et al*.[4]

A particularly staggering misrepresentation in the DTU report concerns the alleged abortifacient activity of *Ashwagandha*. This is opposite to the evidence of centuries of traditional use and stands in stark opposition to contemporary research findings. Ayurveda regards *Ashwagandha.* as promoting fertility and healthy pregnancies;[5] if it had abortifacient properties, this would be a paradoxical practice. Modern scientific studies strongly verify this age-old wisdom. Several studies have shown the potential of *Ashwagandha.* to enhance male fertility. A recent systematic review[6] reported that *Ashwagandha.* supplementation improved sperm concentration, motility, and semen volume in men with oligospermia. Furthermore, a randomized, double-blind, placebo-controlled pilot study[7] reported that *Ashwagandha* root extract improved sperm count and motility in infertile men. In women, far from being abortifacient, *Ashwagandha* has shown potential benefits in reproductive health. Another study[8] reported that *Ashwagandha* root extract increased sexual function in healthy women. Although studies on direct pregnancy outcomes are limited due to obvious ethical issues, the general evidence indicates a protective effect on reproduction and not a harmful one. The DTU's portrayal of *Ashwagandha* as potentially abortifacient stems from a flawed analysis. It overemphasizes limited animal studies and isolated case reports when neglecting crucial factors such as dosage and preparation methods. Moreover, it disregards the substantial body of evidence that contradicts this claim. This is a wrong conclusion that warns against the pitfalls of picking and choosing data, when demonstrating the need for a totality of evidence evaluation that includes both traditional knowledge and modern scientific research.

CURRENT RESEARCH ON *ASHWAGANDHA*: EVIDENCE CONTRADICTING THE DANISH TECHNICAL UNIVERSITY REPORT

In marked contrast to the DTU conclusions, new research continues to emerge supporting and fleshing out our understanding of *Ashwagandha's* possible health benefits. A recent systematic review with meta-analysis[9] reported that *Ashwagandha* supplementation is related to significant decreases in stress and anxiety compared with placebo across several randomized controlled trials. In the context of sleep health,[10] in a randomized, double-blind, placebo-controlled study, *Ashwagandha* root extract improved sleep quality and sleep onset latency in adults with insomnia.

Supplementation with *Ashwagandha* has also shown to have positive effects on cognitive function, an area of growing interest in an aging global population. According to one of the systematic review, these enhancements include executive function, attention, and reaction time.[11] It has also been shown to improve physical performance, in another study in which enhanced muscular strength and recovery in recreationally active men was observed.[12]

Of particular relevance to the DTU's concerns about endocrine effects, a study[13] showed that *Ashwagandha* root extract improved thyroid function in patients with subclinical hypothyroidism, suggesting a potential therapeutic role rather than the harm implied by the DTU report.

These findings, at the same time, indicate one severe deficiency in the DTU report: its failure to adequately consider the potential public health implications of banning a widely used supplement with demonstrated

health benefits. By removing legal access to the herb, the Danish authorities will deprive their population of a safe and effective natural remedy and push some consumers toward other, much less regulated or even dangerous alternatives.

REGULATORY INCONSISTENCIES AND PROPORTIONALITY

Furthermore, the DTU approach does not contextualize risks associated with *Ashwagandha* against other commonly consumed substances. Widespread foods such as caffeine and alcohol pose well-documented health risks,[14,15] yet they are widely available. This disproportionate risk assessment and management put into question the consistency and fairness of the regulatory approach.

It is also well worth noting that the DTU report fails to give due consideration to differences in *Ashwagandha* preparations and their potential implications for safety profiles. The failure to conduct a rigorous dose–response analysis further restricts the utility of the report for establishing appropriate safe dosage levels or contextualizing risks at typical supplemental doses.

TOWARD AN INTEGRATIVE APPROACH: THE NEED FOR A COMMON FRAMEWORK

With the numerous flaws and biases previously discussed, a DTU report is far from being a suitable basis for making regulatory decisions. However, there is an even more profound challenge: the inherent limitation of assessing traditional remedies based solely on the parameters of modern biomedicine. This approach excludes epistemological differences between two medical systems, often leading to incomplete or misguided conclusions. This underlines to an even greater degree the need for establishing interdisciplinary methodologies that can bridge diverse knowledge systems, thereby allowing a more holistic and culture-nuanced assessment of Traditional Medicine (TM) within a modern context. This example of *Ashwagandha* shed light on an even more significant global health issue: the integration of TM systems into modern biomedicine. There is a pressing need for a common conceptual framework that enables different medical systems to communicate effectively.[16,17]

In this context, the concept of Collaborative Medicine and Science (Co. M. S.) has been recently advanced. Its objective is to provide a dialog between traditional and modern systems without challenging their integrity. In the case of *Ashwagandha*, such an approach could have led to a more nuanced and comprehensive risk assessment that considered both traditional use and modern scientific evidence in a balanced manner.

This process involves reformulating traditional concepts to resonate with contemporary science without reducing them to fit the biomedical paradigm. For *Ashwagandha*, this means exploring parallels between its role as an adaptogen and modern stress physiology and neuroendocrine function concepts.

We also need models that capture the holistic nature of TM. For *Ashwagandha*, this could involve a framework synthesizing its effects on stress, sleep, cognition, and endocrine function. Such a system-based approach aligns with personalized medicine trends, benefiting both traditional and modern practitioners.

Finally, we must consider adapting traditional knowledge to diverse global contexts when preserving its core principles. This is crucial for regulatory decisions like the Danish *Ashwagandha* ban, requiring examination of the herb's effects and safety profile, which might vary across different populations and environments.

These elements could serve as the foundation for a more comprehensive and nuanced approach to evaluating and integrating TM within modern health-care systems. We can work toward a more inclusive and effective global health paradigm by embracing this multifaceted perspective.

CONCLUSION AND FUTURE DIRECTIONS

Regulatory caution certainly has its place, but it must be balanced with scientific rigor and proportionality. The Danish ban on *Ashwagandha*, based on the flawed DTU report, is a disproportionate application of the precautionary principle incongruent with the current body of scientific data and evidence. This ban now establishes a questionable precedent, one that could stifle innovation in the area of natural products when simultaneously limiting consumers' choices, with no apparent commensurate public health benefit related to it.

In an attempt to accord legitimacy to TM, regulatory authorities should achieve a more balanced approach that considers the totality of evidence contribution emanating from traditional use, human clinical data, and postmarket surveillance. They should also engage in more transparent processes, including peer review of risk assessments and consultation with diverse stakeholders. The Co. M. S. framework presents an up-and-coming model for this, ensuring genuinely open dialog between the traditional and modern medical systems.

As the body of research on *Ashwagandha* continues to grow, regulatory decisions must evolve along with our scientific understanding. The case of the Danish *Ashwagandha* ban serves as a stark reminder of the need for ongoing dialog between researchers, regulators, and practitioners to ensure that public health policies are grounded in the best available evidence.

The Indian Ministry of Ayush has taken a strong stance against the DTU report and its subsequent impact.[18] In a media statement, the Secretary of the Ministry of Ayush pointed out that the report *"lacks comprehensive evaluation of ashwagandha's diverse properties related to function and safety"* and emphasized that *"substantial new evidence on ashwagandha's safety and efficacy has been published since 2020 (over 400 papers and safety dossiers)."*

Our analysis aligns with the Ministry's critique, highlighting the report's lack of scientific rigor and its potential role as a nontariff barrier. This situation underscores the need for a more robust, evidence-based approach to evaluating traditional herbal products in a global context.

In fact, the controversy surrounding the Danish ban on *Ashwagandha* presents an opportunity to initiate a new policy framework. This framework should provide greater clarity in assessing medicinal herbs and their products, bridging the gap between traditional knowledge and modern scientific understanding.

This controversy could serve as a catalyst for developing a more integrated approach for evaluating traditional herbal products. By leveraging frameworks like Co. M. S., which bridges diverse knowledge systems, it will be possible to create more comprehensive and culturally sensitive assessment methods. Such an approach could not only ensure public safety but also preserve access to potentially beneficial traditional remedies, contributing to a more inclusive and effective global health paradigm.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Technical University of Denmark (DTU). Risk Assessment of the Root of *Withania somnifera*. Lyngby, Denmark: DTU Food Institute; 2020.
2. Van Eersel GG, Koppenol-Gonzalez GV, Reiss J. Extrapolation of experimental results through analogical reasoning from latent classes. Philos Sci 2019;86:219-35.
3. Tandon N, Yadav SS**.** Safety and clinical effectiveness of *Withania somnifera* (Linn.) Dunal root in human ailments. J Ethnopharmacol 2020;255:112768.
4. Patwardhan B, Chaturvedi S, Tillu G, Deshpande S, Hegde BM. Danish ban on *Ashwagandha***:** Truth, evidence, ethics, and regulations. J Ayurveda Integr Med 2024;15:101028. [doi: 10.1016/j.jaim.2024.101028].
5. Kulkarni SK, Dhir A. *Withania somnifera*: An Indian ginseng. Prog Neuropsychopharmacol Biol Psychiatry 2008;32:1093-105.
6. Nasimi Doost Azgomi R, Zomorrodi A, Nazemyieh H, Fazljou SM, Sadeghi Bazargani H, Nejatbakhsh F, *et al.* Effects of *Withania somnifera* on reproductive system: A systematic review of the available evidence. Biomed Res Int 2018;2018:4076430. [doi: 10.1155/2018/4076430]. Erratum in: Biomed Res Int 2019;2019:7591541. [doi: 10.1155/2019/7591541].
7. Ambiye VR, Langade D, Dongre S, Aptikar P, Kulkarni M, Dongre A. Clinical evaluation of the spermatogenic activity of the root extract of *Ashwagandha* (*Withania somnifera*) in oligospermic males: A pilot study. Evid Based Complement Alternat Med 2013;2013:571420.
8. Dongre S, Langade D, Bhattacharyya S. Efficacy and safety of *Ashwagandha* (*Withania somnifera*) root extract in improving sexual function in women: A pilot study. Biomed Res Int 2015;2015:284154.
9. Lopresti AL, Smith SJ, Malvi H, Kodgule R. An investigation into the stress-relieving and pharmacological actions of an *Ashwagandha* (*Withania somnifera*) extract: A randomized, double-blind, placebo-controlled study. Medicine (Baltimore) 2019;98:e17186.
10. Langade D, Thakare V, Kanchi S, Kelgane S. Clinical evaluation of the pharmacological impact of *Ashwagandha* root extract on sleep in healthy volunteers and insomnia patients: A double-blind, randomized, parallel-group, placebo-controlled study. J Ethnopharmacol 2021;264:113276.
11. Ng QX, Loke W, Foo NX, Tan WJ, Chan HW, Lim DY, *et al*. A systematic review of the clinical use of *Withania somnifera* (*Ashwagandha*) to ameliorate cognitive dysfunction. Phytother Res 2020;34:583-90.
12. Bonilla DA, Moreno Y, Gho C, Petro JL, Odriozola-Martínez A, Kreider RB. Effects of *Ashwagandha* (*Withania somnifera*) on physical performance: Systematic review and Bayesian meta-analysis. J Funct Morphol Kinesiol 2021;6:20.
13. Sharma AK, Basu I, Singh S. Efficacy and safety of *Ashwagandha* root extract in subclinical hypothyroid patients: A double-blind, randomized placebo-controlled trial. J Altern Complement Med 2018;24:243-8.
14. Poole R, Kennedy OJ, Roderick P, Fallowfield JA, Hayes PC, Parkes J. Coffee consumption and health: Umbrella review of meta-analyses of multiple health outcomes. BMJ 2017;359:j5024.
15. Wood AM, Kaptoge S, Butterworth AS, Willeit P, Warnakula S, Bolton T, *et al.* Risk thresholds for alcohol consumption: Combined analysis of individual-participant data for 599 912 current drinkers in 83 prospective studies. Lancet 2018;391:1513-23.
16. Morandi A. The challenges of a new path of Research in Ayurveda. Ann Ayurvedic Med 2018;7:9-13.
17. Morandi A. One medicine: The need for a common conceptual framework. J Res Ayurvedic Sci 2023;7:181-2.
18. Ministry of AYUSH. Response to Denmark's Ban on *Ashwagandha* Based on Flawed Report; 2024. Available from: https://x.com/moayush/status/1810279299976396830?lang=bn. [Last accessed on 2024 Jul 22].