Danish ban on *Ashwagandha:* Truth, evidence, ethics, and regulations

Introduction

"There are two ways to be deceived: One consists in believing in what is not true, and the other in refusing to believe what is true." - Soren Kierke- gaard, Danish philosopher.

The ban on *Ashwagandha* by Denmark invites scientific scrutiny as this decision may have far reaching consequences. Therefore, as a scientific journal, it is our duty to take its due cognizance.

Ashwagandha, botanically classified as *Withania somnifera (L.) Dunal*, Family-Solanaceae, is also known as Indian ginseng or winter cherry. *Ashwagandha* roots have been used for centuries in Asian cultures and Indian traditional medicine systems, including Ayurveda, Siddha, Unani, and Sowa Rigpa. It is widely known for its health benefits and has attracted more attention during the COVID-19 pandemic. It is readily available as a dietary supplement in many countries.

It is recognized in several pharmacopoeia and authoritative compendiums worldwide, such as the Ayurvedic Pharmacopoeia of India, Indian Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, American Herbal Pharmacopoeia (AHP), Japanese Pharmacopoeia, Pharmacopoeia the People's Republic of China, and the World Health Organization's (WHO) Monographs. Despite its widespread global recognition, the Danish Veterinary and Food Administration (DVFA) decided to ban *Ashwagandha* based on a 2020 report by the Technology University of Denmark (DTU).

Concerns with the Technology University of Denmark Report

The DTU report has several technical, scientific, and ethical pitfalls. This report does not seem to be peer-reviewed, and the credentials of the authors, funding sources, and conflict of interests are not disclosed. The English version of the DTU report is a bit unusual. The reasoning is hardly convincing; in fact, it contradicts itself at several points. The DTU report on *Ashwagandha* discusses its ingredients, general toxicity, and effects on sex hormones and reproduction, metabolism, immune system, and central nervous system. Unfortunately, the report refers to a few articles from predatory journals in its sketchy literature review. Although the mandate from DVFA is on *Ashwagandha* roots, it draws conclusions from studies on whole plants, stems, leaves, and fruits/berries that are clearly irrelevant to this case. In general, the DTU report is far from a critical review or analysis and inconsistent with the methodology commonly practiced in food and pharmaceutical sciences, making it substandard and misleading.

It is not clear what prompted the DVFA to commission this report to the DTU. The report lacks systematic evidence synthesis to support the decision to ban *Ashwagandha*. Some of the serious gaps in the DTU report have been critically discussed in the context of the chemistry and biological effects of *Ashwagandha*.[1] In general, the conclusions drawn by the DTU report are far from the truth, rather closer to deception.

The DTU report has not considered several clinical studies, including those demonstrating female fertility promotion and the absence of mutagenicity or genotoxicity.[2] A 2018 systematic review has reported that *Ashwagandha* roots enhance spermatogenesis and improve sperm-related indices.[3] The DTU report cites an ethnobotanical survey and preclinical animal studies to claim abortifacient effects in humans.[4] However, the ethnobotanical survey has been challenged and disproved by subsequent research reporting no evidence of maternal or fetal toxicity, even from high doses of *Ashwagandha* root extract.[5] Furthermore, traditional use, clinical studies, and Pharmacovigilance data do not support these claims regarding abortifacient effects. Agreeably, a few sporadic reports have raised concerns about possible adverse events related to the liver, thyroid, and gastrointestinal system. However, no conclusive causal relation with *Ashwagandha* has been established.[6,7] In addition, several studies have reported no observed adverse effect level for *Ashwagandha* roots, even at high doses. *Ashwagandha* is traditionally used only as root powder 3–5 g per day or equivalent aqueous or hydroethanolic extracts.

Despite numerous studies showing the feto-maternal safety of *Ashwagandha* root, it is not known why the DTU report has cited poorly conducted studies, that too on methanol and other solvent extracts, and ignored scholarly scientific literature. Claims regarding hormonal, reproductive, immunological, and neurological risks pointed out in the DTU report are similarly flawed.

Danish Veterinary and Food Administration's Ban on *Ashwagandha*

The DVFA's official website states: "Do not eat *Ashwagandha* or supplements containing *Ashwagandha* because its root has negative effects on sex hormones and reproduction for both men and women. In addition, the plant can affect the metabolism, the immune system, and the central nervous system." Having researched and used *Ashwagandha* for over three decades, we find that the statement is far from truth.

The DTU report fails on the scientific and ethical aspects. Regulatory agencies, especially in the food and drug domains, typically have stringent procedures for approving substances/products for health benefits. The DVFA should have followed a similar stringent procedure for banning *Ashwagandha*. However, this is not the case.

Flawed Report, Flawed Decisions

The primary reference for the DTU report's conclusion regarding abortifacient effects is the WHO monograph on selected medicinal plants on *Ashwagandha* (2009) which in turn refers to the AHP *Ashwagandha* root monograph and therapeutic compendium (2000). However, this reference chain perpetuates citation distortion. The report does not correctly interpret the AHP monograph and support abortifacient effect; rather, it highlights *Ashwagandha's* traditional use to prevent miscarriage and stabilize pregnancies. The AHP editor has issued a clarification that defeats the DTU report's foundation.[8]

The American Herbal Products Association's Botanical Safety Handbook (BSH) affirmed the reproductive safety of *Ashwagandha* in 2022 and reclassified its safety Class from 2d to 1 based on new studies. BSH Class 1 signifies that a plant is considered safe when used appropriately. It is generally well tolerated and suitable for use in herbal products or remedies.

The DTU report and its findings are contradictory to the scientific literature that has emerged over the past few decades. PubMed search for *Ashwagandha* yields over 1100 papers published during 2013–2024 (as of June 2024), which indicates growing interest in Ashwagandha and its health and well-being potential. It must be noted that no clinical trials in the last 10 years have reported any serious adverse events associated with *Ashwagandha* roots. More than 500 scientific papers have been published on the safety and activity of *Ashwagandha* since the DTU report of 2020. This new body of evidence shows that the DTU report is redundant and irrational and calls for its update.

International Perspectives

Outlooks on the safety and use of *Ashwagandha* vary globally. For instance, *Ashwagandha* root use is permitted as a food or dietary supplement in the United States of America and the United Kingdom. The American National Center for Complementary and Integrative Health of the National Institutes of Health informs of the safety of *Ashwagandha* for short-term use. The Medicines and Healthcare Products Regulatory Agency of the UK has permitted the ongoing APRIL Trial, which is a randomized, placebo-controlled trial using *Ashwagandha* led by researchers at the London School of Hygiene and Tropical Medicine, UK, and the All India Institute of Ayurveda, India. About 320 medicines listed in the Australian Register of Therapeutic Goods include *Ashwagandha*.

Several European and Scandinavian countries also have taken a balanced approach. For instance, Poland allows the use of *Ashwagandha* roots but not leaves or other parts. It further specifies that the content of withanoloides should be <10 mg in the daily portion of the product. Germany has expressed concerns about *Ashwagandha,* probably based on the DTU report; however, it continues to be available there. Sweden permits local authorities to make decisions on such matters rather than depriving people of its health benefits. These decisions are rational, scientific, and in the public interest. However, Denmark seems to have overlooked these facts.

We are afraid that the DTU report might influence the decisions of some countries in this regard. It is necessary to undertake a systematic situation analysis on the status of Ashwagandha in different countries. In this context, the Ministry of AYUSH, Government of India, has released an Ashwagandha Safety Dossier 2024. This dossier synthesizes data and presents robust scientific evidence on the safety and efficacy of *Ashwagandha* roots.

Risk-benefit Analysis

The DTU report is titled "Risk assessment of the root of *Withania somnifera*." A "risk assessment" approach is typically used for environmental or occupational hazards, whereas for pharmacological purposes, a "safety assessment" that includes toxicity and "risk–benefit analysis" is more appropriate. *Ashwagandha* is known as Rasayana, which means beneficial for rejuvenation, immunomodulation, and longevity. Substantial scientific evidence supports the benefits of *Ashwagandha* in inflammation, stress, cancer, neurodegeneration, musculoskeletal diseases, and healthy aging.[9,10]

The DTU report entirely ignores the "benefit" component, raising serious questions about its conclusions. Most drugs have some adverse effects but are used based on risk–benefit assessments. For example, toxic drugs like Taxol are used in cancer treatment because their benefits outweigh the risks. Proper health advice along with essential information consisting of precautions, contraindications, and dosage of *Ashwagandha* will help maximize its therapeutic benefits. Banning *Ashwagandha* roots based on the data on the toxicity of leaves or berries is akin to banning apples because their seeds contain amygdalin, which is a precursor to cyanide.

Responsible Regulatory Mechanisms

There is no denying that regulators must be careful about the safety and quality of any product for human consumption. However, for this purpose, robust mechanisms are necessary. Decision-making must be based on scientific evidence and not influenced by political, economic, or other factors. The DVFA is a responsible regulatory agency from a progressive country like Denmark. The DVFA decision could have cascading consequences, potentially extending beyond the ambit of science and regulation into geopolitics or economics.

The case of the ban on *Ashwagandha* underscores the importance of transparency in evidence-based regulations. A prestigious institution like DTU should have exercised greater caution in preparing this report, given its potential impact on public health. The DVFA should reconsider the ban in light of the extensive scientific literature supporting the safety and efficacy of *Ashwagandha* roots.

This incidence invokes the value of truth in *Kierkegaardian* words of wisdom! India's rich heritage of traditional medicine offers the potential for planetary well-being in the spirit of *Vasudhaiva Kutumbakam*, the world as one family. Scientific exploration, guided by ethics and international collaboration, should serve a higher purpose – a world where advancements promote solidarity, and harmony. As the Vedas teach us, "*Sarve Santu Niramaya-Sarve Bhavantu Sukhinah"* – let everyone be free from illness and find peace and happiness. This is the true purpose of science. The scientific community shall collaborate in the pursuit of a healthier and happier world.

Author contributions

BP conceptualized and wrote the first draft with SC. BP, GT, SC together revised the draft with inputs from SD to BMH. All authors reviewed and approved the final draft.

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The authors did not use generative AI for drafting the manuscript.

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