The Hemp Trades Association UK Ltd t/a
Cannabis Trades Association
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Submitted to Medicines and Medical Devices Act 2021 – Stakeholder Call For Evidence

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https://consult.defra.gov.uk/vmd-policy-development-and-delivery-office/mmd-act-2021-stakeholder-survey/consultation/subpage.2025-08-18.4648131426/

Section 1 – Respondent Information

1Which best applies to you:

I am responding on behalf of an organisation

If responding on behalf of an organisation, please indicate the geographical area(s) your organisation covers.

England, Wales, Scotland,

Northern Ireland

Name of organisation (If applicable)

Name of organisation:

The Hemp Trades Association UK Ltd t/a/ The Cannabis Trades Association

What are the main activities or industry sector of your organisation?

Trade association for businesses involved in the Hemp & Cannabis Sector

Section 2 – Operation of the Regulations

How well do you think the current legislation protects animal health and welfare?

Somewhat effectively – there are noticeable gaps or areas for improvement

Please briefly explain your answer and, where possible provide examples to support your view.:

The legislation provides strong safeguards against unsafe medicines but is disproportionately restrictive when applied to non-medicinal wellbeing products such as CBD supplements. The 2018 VMD statement classified all CBD as medicinal, yet since then controlled clinical trials in dogs (osteoarthritis, epilepsy adjunct) and toxicology data show CBD is well tolerated at conservative doses. Meanwhile, the FSA has created an effective human CBD framework with ADI and THC limits. By not permitting a regulated wellbeing category for animals, the law drives owners to grey-market imports, undermining welfare. A tiered model - licensed medicines for treatment, regulated wellbeing products for support - would better protect animal health.

In your experience on, a scale of 1 to 10, how effectively do the regulations work in practice? This refers to the clarity, enforceability, consistency, and practical impact of the regulations in achieving their intended outcomes. (1 = Not at all effective, 10 = Extremely effective)

5

Please briefly explain your answer to the above question and, where possible, provide examples to support your view:

The regulations are strong in principle but inconsistently effective. Clarity and enforceability are undermined by outdated positions and ambiguous borderline decisions. For example:

- Owners already buy CBD online without quality assurance, creating enforcement gaps.
- Vets avoid advising on CBD for wellbeing due to VMR constraints, leaving owners without professional guidance.
- Divergence between VMD and FSA creates regulatory duplication.
- International comparators (FDA, Switzerland) manage CBD wellbeing products more flexibly.

The framework achieves protection in theory but fails in practice where rigid rules push owners and businesses to unregulated channels.

Have you encountered any issues, blockers, or areas of ambiguity when using the regulations?

Yes

If yes, please provide specific examples:

- The blanket 2018 CBD position creates uncertainty, ignoring new evidence.
- Lack of clear criteria for differentiating wellbeing products from veterinary medicines.
- Vets face professional risk for offering harm-reduction advice on CBD.
- Duplicated oversight between regulators (FSA vs VMD) increases burden.

Are there any particular areas of the regulation which you consider impose unnecessary or excessive regulatory burdens?

Yes

If yes, please provide specific examples :

The requirement that all CBD is treated as a veterinary medicine is disproportionate. Licensing costs are prohibitive for SMEs, despite low-risk use at conservative wellbeing doses.

Without a regulated supplement pathway, businesses cannot innovate, and owners turn to unregulated sources.

Do you think the policy objectives of the outlined legislation could be achieved with less regulation?

Yes

Please briefly explain your answer:

A two-tier system could protect welfare more effectively:

1. Licensed veterinary medicines for treatment of disease.
2. Regulated wellbeing/nutraceutical products with GMP standards, batch CoAs, conservative CBD/THC limits, labelling, and adverse event reporting.

This mirrors the FSA's human CBD framework and would reduce burdens while improving safety.

How do UK regulations compare with those of other regulators or international comparators (e.g., EU, FDA)?

The UK is more restrictive than comparators.

- US (FDA): CBD pet supplements tolerated under enforcement discretion with NASC standards.
- EU: Some member states allow CBD nutraceuticals for pets where no medical claims are made.
- Switzerland: Pragmatic, safety-based model without arbitrary ADIs.

UK rigidity discourages veterinary engagement and drives grey-market use. A proportionate model would align better with international best practice.

Section 3 – Structure of the Legislation

On a scale of 1 to 10, how clear, well-structured, and easy to navigate do you find the legislation? (1 = Not at all clear or easy to navigate, 10 = Extremely clear, well-structured, and easy to navigate)

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Are there any overlapping, duplicative, or outdated provisions?

Yes

If yes, please provide specific examples where possible:

- Divergence between FSA oversight (human CBD) and VMD oversight (animal CBD).
- Overlaps between medicines law, feed law, and supplements.
- Outdated 2018 CBD position, treated as binding despite new evidence.
- Parallel adverse event reporting regimes with no harmonisation for supplements.
- The VMR is comprehensive but highly legalistic, with key positions (e.g., CBD) buried in external statements rather than codified. SMEs and cross-sector businesses find it inaccessible.

Do the regulations provide the appropriate balance of flexibility to respond to new technologies or emerging animal health issues, and robust regulatory oversight?

Disagree

Do you think the current balance between what is set out in legislation versus what is provided in supporting guidance is appropriate?

No – too much is in guidance that should be in legislation

Please briefly explain your answer and, where possible, provide examples to support your view.:

Important borderline rules (e.g., CBD thresholds) are set out only in statements, lacking transparency or parliamentary scrutiny. These should be embedded in law, with guidance used to explain application.

Do you have any further views regarding the structure of the legislation?

- Consolidate and simplify provisions with plain-language notes.
- Create a dedicated nutraceutical/wellbeing section for emerging products.
- Align cross-regulator rules (FSA, MHRA, DEFRA).
- Provide digital, interactive legislation with case studies for SMEs.

What is your view on the extent to which the legislation should be changed? (Please select the option that best reflects your view)

Significant changes – the legislation would benefit from major changes and restructuring

What impact, if any, would large scale changes to the legislation have on you or your organisation?

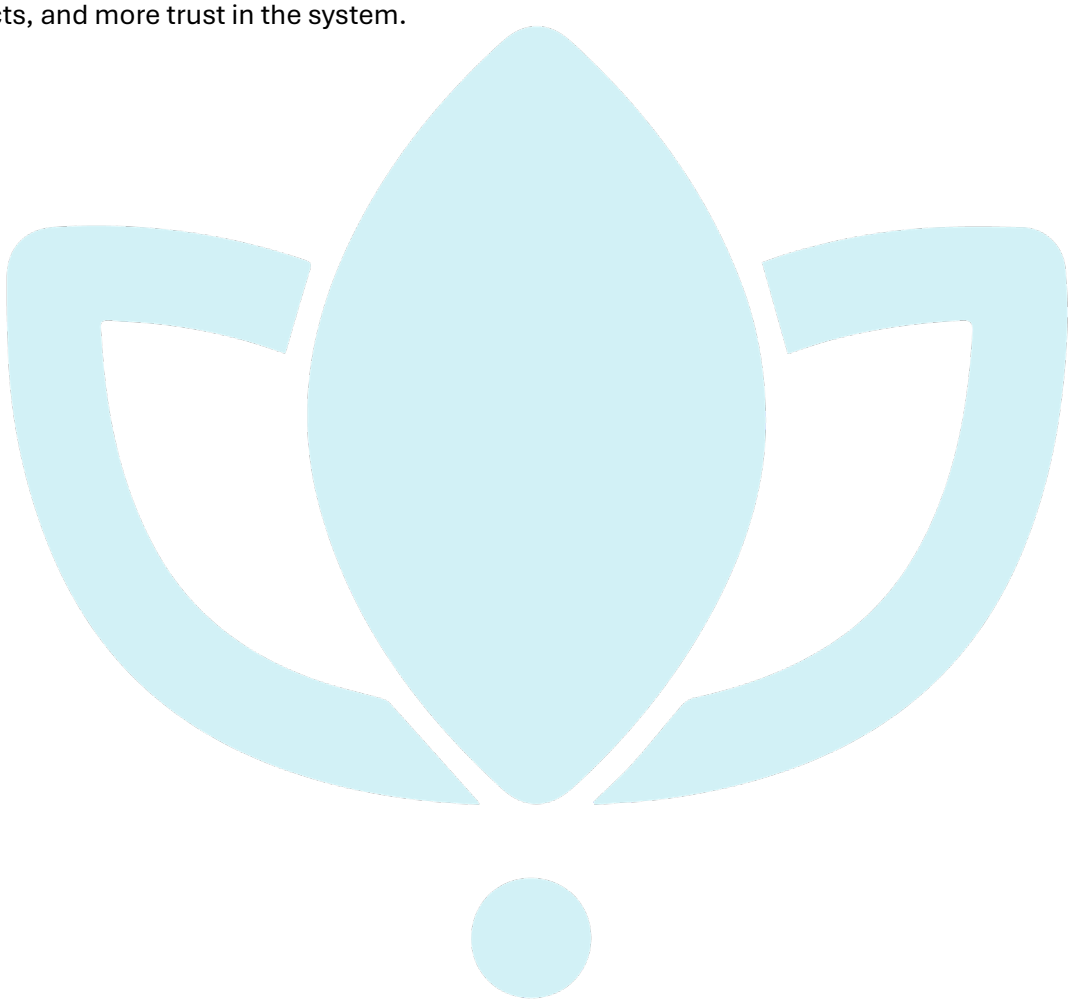
Very positive impact

In your opinion, would the benefits of restructuring outweigh any potential downsides?

Yes

Please briefly explain your answer :

Short-term transition costs would be outweighed by long-term benefits: clearer rules, better enforcement, safer products, and more trust in the system.



Section 4 – New Regulations Made Under the MMD Act

Have you had experience of interacting with the amended VMR?

Yes

If yes, regarding the new regulations:

Somewhat effectively

Have you encountered any issues or concerns in their implementation?:

Positives: Strengthened enforcement powers; flexibility in principle; alignment with post-Brexit context.

Challenges: No modernisation of CBD position; borderline ambiguity remains; communication inconsistent; SMEs face more complexity without added clarity.

- Continued ambiguity on what constitutes a veterinary medicine.
- Duplication across regulators (FSA vs VMD).
- Lack of proportionate, risk-based pathway for wellbeing supplements.
- Enforcement gaps, as owners still purchase unregulated CBD online.