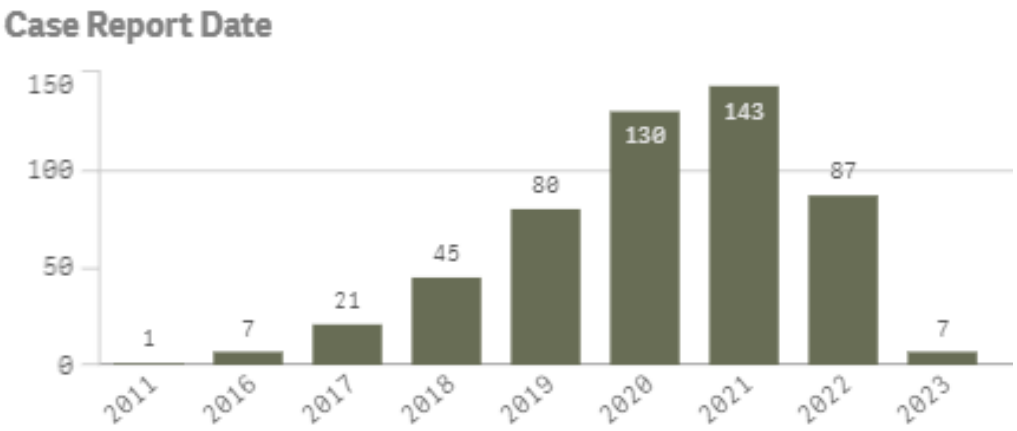
From: s22
To: SKERRITT, John; KAY, Elspeth
Cc: HENDERSON, Nick
Subject: RE: FW: Topic advice from Senator Malcolm Roberts for TGA [SEC=OFFICIAL]
Date: Monday, 13 February 2023 1:23:23 PM
Attachments: image001.png
image002.png
image003.png
image005.png

Hi John,

I have updated the information below (as I also identified a few additional cases) and included some more information on the fatal cases. As these products are unapproved medicines, they are not subjected to our normal pharmacovigilance activities, including individual case review. As such, the fatal cases have not been investigated. However, I have reviewed the cases and the available information does not indicate a link between the product and fatal outcome – the deaths appear related to the underlying health conditions. Here's the revised dot points:

- The DAEN – medicines does not include reports for products accessed via the SAS and AP, except where the adverse event report also includes a suspected general marketed medicine or vaccine. There are currently 16 reports which include a medicinal cannabis product in the DAEN.
- The AEMS data does not always indicate how the product was accessed, as such it is not clear if the reports were accessed legally or via the SAS or AP pathway. However, the reporting pattern is consistent with increased access due to availability of legal access pathways since 2016. (see graph below)
- As of 12 February 2023, the TGA's internal adverse event database (AEMS) contains 521 adverse event reports related to products containing a cannabidiol and/or tetrahydrocannabinol ingredient. In 460 of these reports, the medicinal cannabis product was the sole suspect.
    - The most common reactions were nausea, somnolence (drowsiness), diarrhoea, dizziness, headache and hallucination
    - 178 reports are recorded as serious, and of these:
        - 11 were associated with a fatal outcome
            - all cases were in individuals with complex underlying health conditions and the adverse events appear related to the underlying condition
            - this includes 4 reports for children and in 2 of these the reporter stated they did not consider the medicinal cannabis product was related to the fatal outcome
        - 16 reports were for life-threatening adverse events
        - 77 reports indicate the patient received treatment in hospital for their adverse event
    - 84 of the 521 reports were in children (<18 years of age), of which 40 were classified as serious
        - The medicinal cannabis product was the sole suspected medicine in 62 cases
        - The most common reaction terms in children were somnolence (drowsiness), diarrhoea and abnormal liver function



Kind regards,
s22

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Friday, 10 February 2023 5:44 PM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>
Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22
<s22 @health.gov.au>
Subject: Re: FW: Topic advice from Senator Malcolm Roberts for TGA [SEC=OFFICIAL]

Thanks

Can I have some more info on the fatal reports as we will be asked whether we investigated them

John

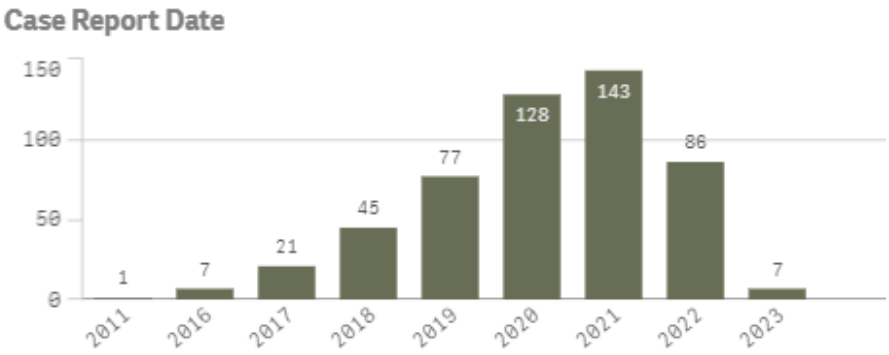
Sent from Workspace ONE Boxer

On 10 February 2023 at 5:07:36 pm AEDT, KAY, Elspeth <Elspeth.Kay@health.gov.au> wrote:

> Hi John, here is some info with thanks to s22 There is little on the DAEN so we have provided some info from AEMS too. Worth noting that AE reporting patterns for medicines supplied under SAS and AP are likely to be different from those for ARTG medicines – it is possible that the apparently low number of AE reports will be misconstrued as evidence of superior safety.
>
> - The DAEN – medicines does not include reports for products accessed via the SAS and AP, except where the adverse event report also includes a suspected general marketed medicine or vaccine. There are currently 16 reports which include a medicinal cannabis product in the DAEN.
> - The AEMS data does not indicate how the product was accessed, as such it is not clear if the reports were accessed legally or via the SAS or AP pathway. However, the reporting pattern is consistent with increased access due to availability of

legal access pathways since 2016. (see graph below)

- As of 9 February 2023, the TGA's internal adverse event database (AEMS) contains 515 adverse event reports related to products containing a cannabidiol and/or tetrahydrocannabinol ingredient. In 454 of these reports, the medicinal cannabis product was the sole suspect.
    - The most common reactions were nausea, somnolence (drowsiness), diarrhoea, dizziness, headache and hallucination
    - 174 reports are recorded as serious, and of these:
        - 10 were associated with a fatal outcome
        - 16 were life-threatening
        - 77 reports indicate the patient received treatment in hospital for their adverse event
    - 80 of the 515 reports were in children (<18 years of age), of which 38 were classified as serious
        - The medicinal cannabis product was the sole suspected medicine in 58 cases
        - The most common reaction terms in children were somnolence (drowsiness), abnormal liver function and diarrhoea



From: KAY, Elspeth <Elspeth.Kay@health.gov.au>
Sent: Friday, 10 February 2023 3:15 PM
To: s22 <s22 @health.gov.au>
Subject: FW: Topic advice from Senator Malcolm Roberts for TGA [SEC=OFFICIAL]

Hi s22 could you please send back some info to John about this – I am not sure if he means DAEN specifically or if he is also wrapping in AEMS, might want to give a sense of how many events in the d/b internally.

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Friday, 10 February 2023 3:07 PM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>
Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Subject: FW: Topic advice from Senator Malcolm Roberts for TGA [SEC=OFFICIAL]

What DAEN info do we have on med cannabis

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care

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(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
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From: s22 <s22 @health.gov.au>
Sent: Friday, 10 February 2023 2:56 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; MURPHY, Brendan <Brendan.Murphy@health.gov.au>
Cc: s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: FW: Topic advice from Senator Malcolm Roberts for TGA [SEC=OFFICIAL]

fyi

From: SENATE-ESTIMATES <SENATE-ESTIMATES@health.gov.au>
Sent: Friday, 10 February 2023 2:35 PM
To: HPRG Parliamentary <hprg.parliamentary@health.gov.au>; s22 <s22 @health.gov.au>; s22 <s22 @health.gov.au>
Cc: SENATE-ESTIMATES <SENATE-ESTIMATES@health.gov.au>; s22 <s22 @health.gov.au>
Subject: Topic advice from Senator Malcolm Roberts for TGA [SEC=OFFICIAL]

Good afternoon,

The Committee has provide advice from Senator Robert's regarding a question he will be putting towards the TGA next Thursday.

Medicinal Cannabis has been legal through the pathways scheme for long enough to have some good data. Can you tell me how many people have been admitted to hospital as a result of harm caused by legally prescribed and legally supplied medicinal cannabis in the last three years or any similar period for which you have data?

Warm Regards
s22

Senate Estimates Team
Cabinet and Parliamentary Coordination
Ministerial and Parliamentary Services Branch
People, Communication and Parliamentary Division | Corporate Operations Group
Australian Government, Department of Health and Aged Care
P: s22 (option #4) | E: senate-estimates@health.gov.au
Location: Scarborough House Level 12.209
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to

land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Community Affairs, Committee (SEN) <Community.Affairs.Sen@aph.gov.au>
Sent: Friday, 10 February 2023 2:31 PM
To: SENATE-ESTIMATES <SENATE-ESTIMATES@health.gov.au>
Cc: Community Affairs, Committee (SEN) <Community.Affairs.Sen@aph.gov.au>
Subject: Topic advice from Senator Malcolm Roberts for TGA

Good afternoon team and happy Friday!

We have received advice from Senator Malcom Robert's that he intends to put the following question to the Therapeutic Goods Administration (TGA) at estimates next week:

- *Medicinal Cannabis has been legal through the pathways scheme for long enough to have some good data.*

Can you tell me how many people have been admitted to hospital as a result of harm caused by legally prescribed and legally supplied medicinal cannabis in the last three years or any similar period for which you have data?

Please let me know if you have any questions.

Kind regards,

s22 | Research Officer
Senate Standing Committees on Community Affairs I Department of the Senate
Phone s22
Parliament House, Canberra ACT 2600
www.aph.gov.au/senate

[SEC=OFFICIAL]