National Medicine Traceability Framework (NMTF)

Analysis
NMTF Consultation Hub Survey Responses

29 November 2021 - 28 February 2022

Australian Government
Department of Health and Aged Care

NMTF background, purpose and approach

Background	The concept of a national medicine traceability framework (NMTF) is being explored by the Department of Health (Health) in response to the 2020-21 Budget Measure: Improving Access to Medicines – development of Unique Identification framework for PBS medicines.
Purpose of this consultation	In November 2021 Health commenced initial consultation with key medicine supply chain stakeholders to help inform the NMTF policy, determine feasible framework designs and implementation approaches, gauge industry appetite and readiness to operate within such a framework, and confirm the expected benefits and impact a framework may have on businesses.
Approach	A cohort of Pharmaceutical Benefits Scheme (PBS) medicines supply chain stakeholders were invited by email in November 2021 to participate in an initial NMTF stakeholder consultation. Invitations advised stakeholders of the opportunity to respond, with the consultation period open for three months till the end of February 2022. Stakeholders were provided with a link to relevant medicine traceability background information, the NMTF consultation paper and the NMTF stakeholder survey hosted on the Department's Consultation Hub.
Responses	38 survey submissions were received by the close of the NMTF initial consultation. An additional 4 written submissions were received by email.

NMTF survey question groups

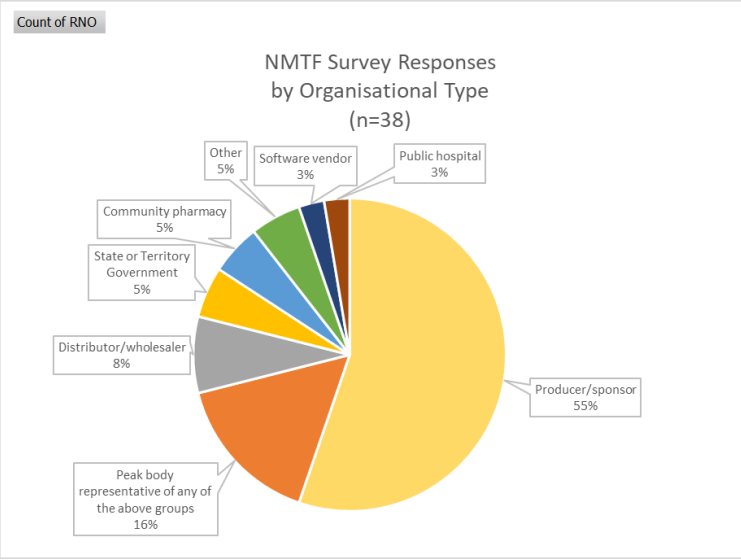
Section	Survey Question Group
1	Target cohort and response demographics
2	Awareness and use of medicine pack serialisation
3	Awareness and use of medicine traceability
4	Business benefits of medicine traceability
5	Public health benefits of medicine traceability
6	Organisational impact of medicine traceability
7	Organisational assistance required
8	Potential business impact
9	Potential regulatory burden
10	Traceability model preferences
11	Capability and capacity to participate
12	Implementation preferences
13	Overall confidence to participate

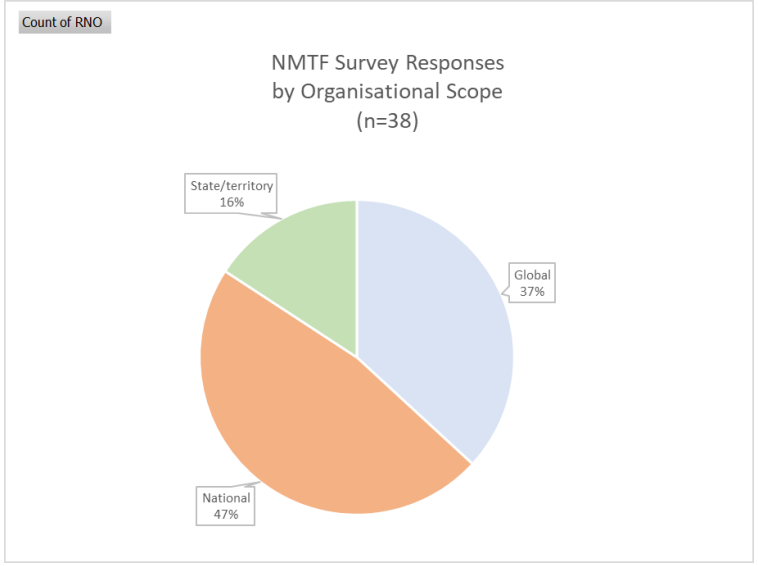
1. Response demographics

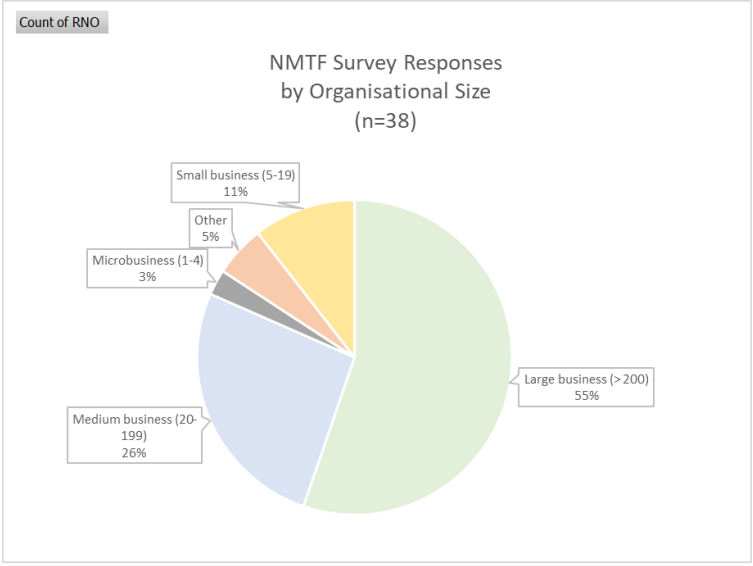
Producer/sponsors represented over half (55%, n=21) of all responses, followed by Peak Bodies (16%, n=6), and Distributor/wholesalers (8%, n=3).

The majority of responses came from National organisations (47%), followed by Global organisations (37%), and State/Territory organisations (16%).

Large businesses (> 200 staff) had the highest representation (55%), followed by Medium businesses (20-199 staff, 26%), and Small businesses (5-19 staff, 11%).







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Q10 - Which of the following categories best describe your organisation's position in the Australian medicine supply chain? - Organisation type
Q11 - Please select the level at which your organisation operates. - Organisation scope
Q12 - Organisation size (i.e. estimated staff numbers) - Business size

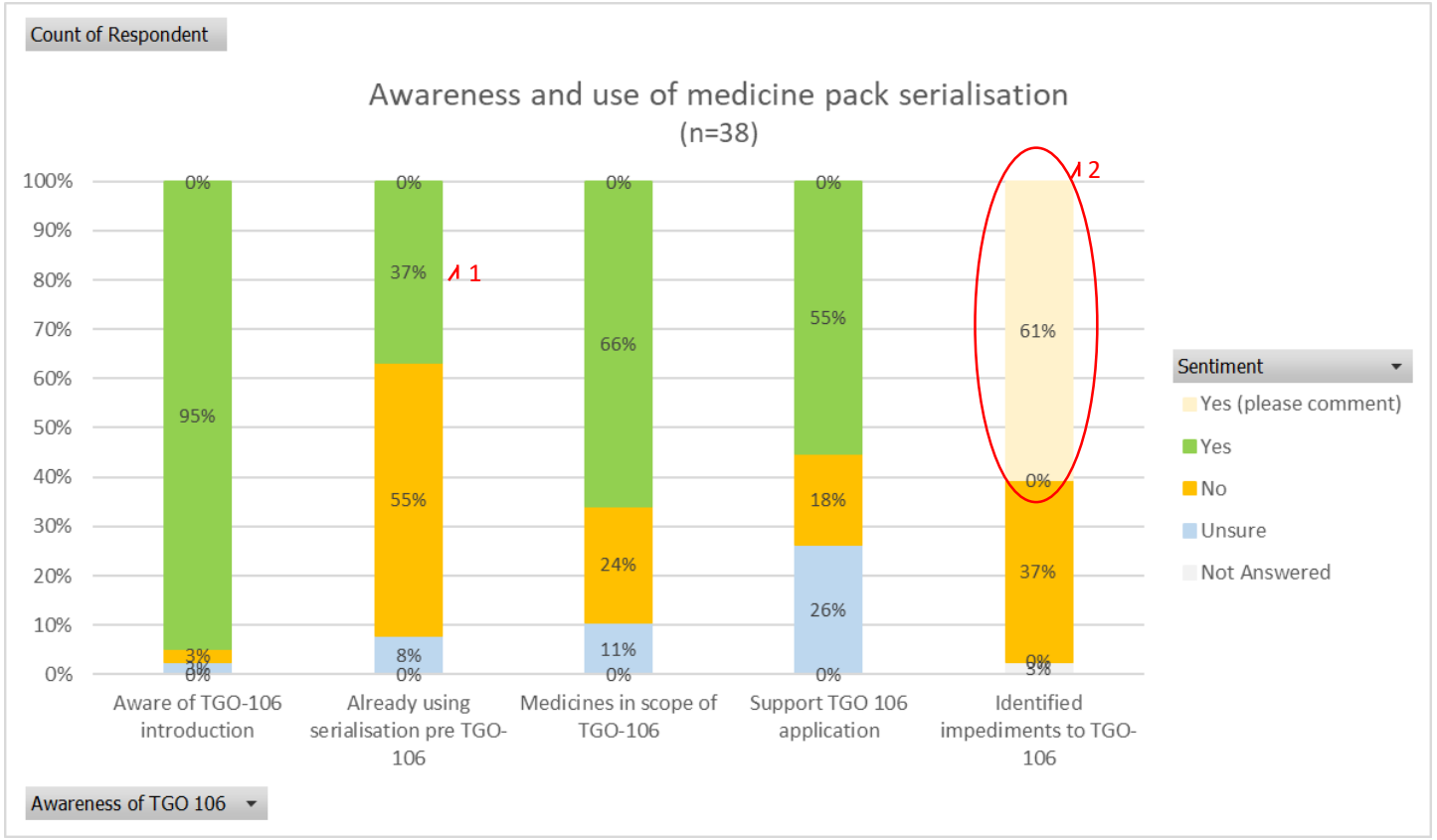
2. Awareness and use of medicine pack serialisation

The five questions regarding serialisation provide an indicator of the level industry awareness of the TGA's TGO-106 2021 2D data matrix medicine pack serialisation standard.

Ninety-five percent of respondents are aware of the TGO-106 standard, with 37 percent of respondents already using some form of medicine pack serialisation prior to the release of TGO-106. [1]

Fifty-five percent of respondents support the application of TGO 106 with 66 percent responding that they have medicines in scope of the standard.

Sixty-one percent of responses identified impediments for implementing the TGO 106 standard. [2]



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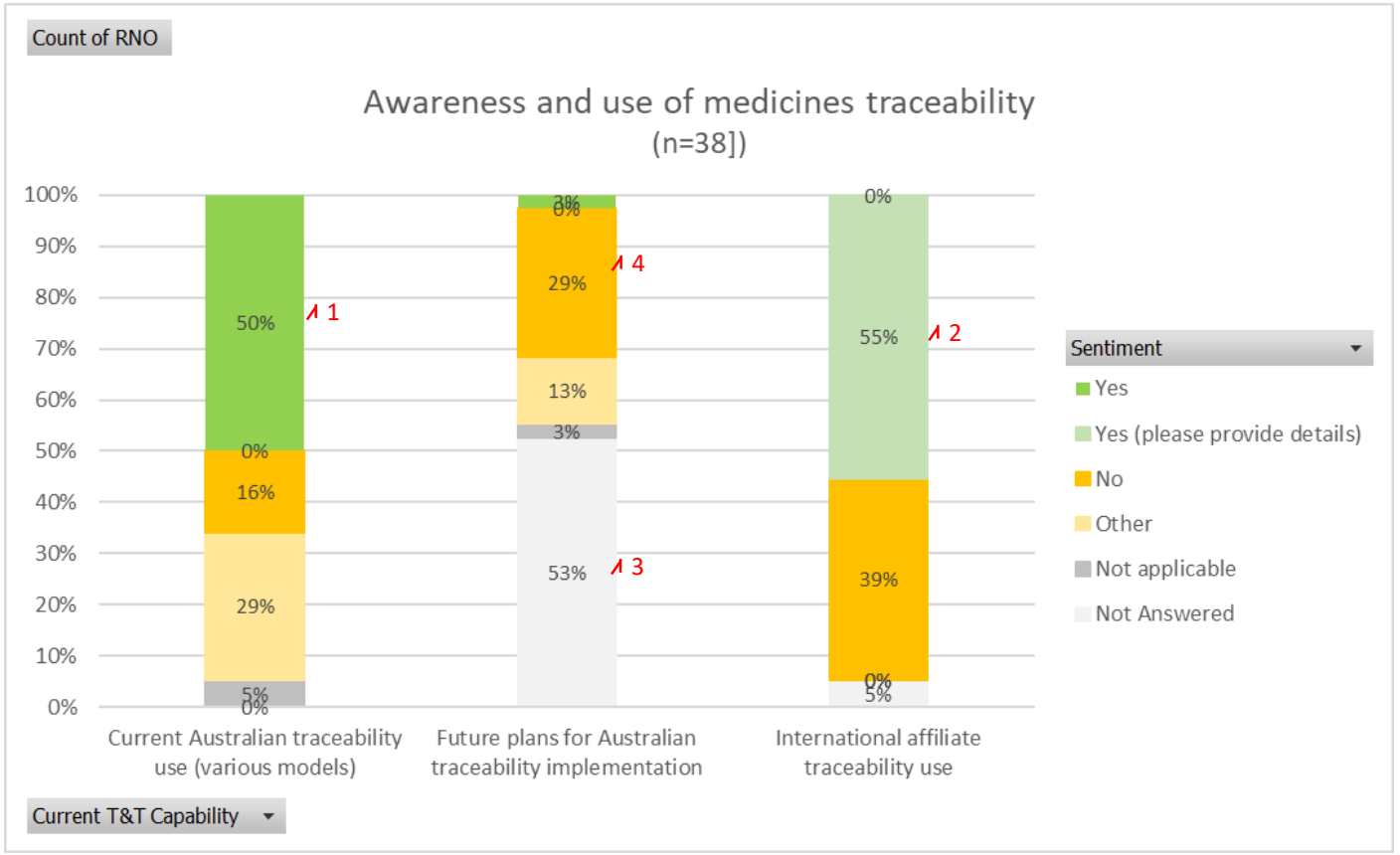
Q15.1 - Your organisation: - Aware of TGO 106 - is aware of the introduction of TGO 106
Q15.2 - Your organisation: - Aware of TGO 106 - has medicines in your inventory within scope for TGO 106
Q15.3 - Your organisation: - Aware of TGO 106 - already used product serialisation codes for medicine product management purposes before the introduction of TGO 106
Q15.4 - Your organisation: - Aware of TGO 106 - supports the use of TGO 106 for your relevant medicine products
Q16.0 - Has your organisation identified any impediment to the adoption of TGO 106?

3. Awareness and use of medicines traceability

The three questions relating to awareness and current use of medicines traceability systems indicate that 50 percent of respondents already utilise some form of medicine traceability within their Australian operations [1], and that 55 percent of responses are affiliated with overseas organisations that are required to participate in medicine track and trace frameworks [2].

The high percentage of 'Not Answered' (53%)[3] and 'No' (29%)[4] responses for 'future traceability plans' is an indicator of the need for further detailed stakeholder engagement on the function and scope of a NMTF.



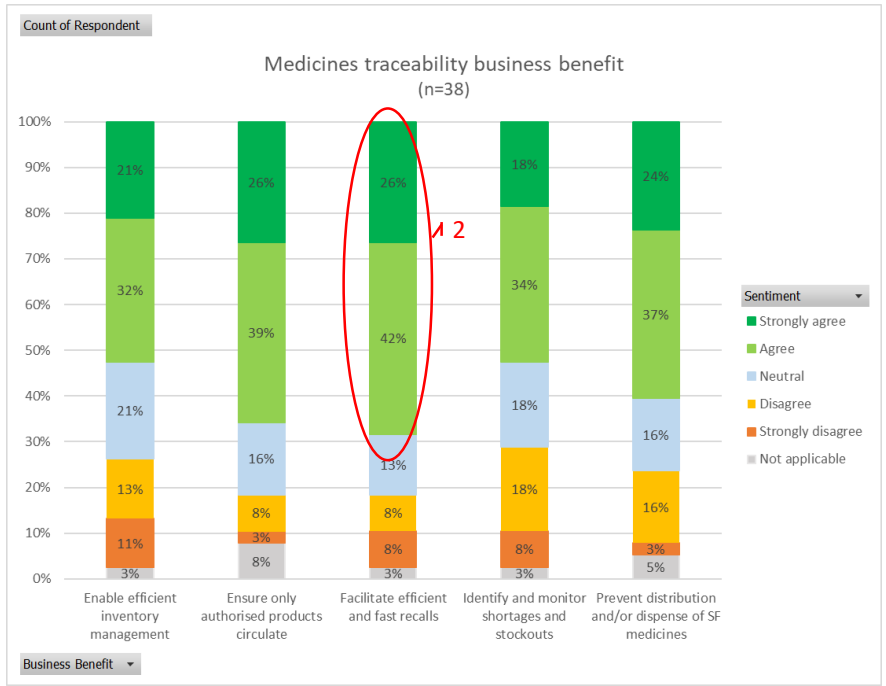
Q17- Does your organisation currently track and trace medicine products as they pass through the supply chain? - Traceability in current management
Q18 - Does your organisation plan to implement a medicine track and trace capability as part of your day to day supply chain management? - Traceability future implementation
Q20 - Does your organisation, or an affiliate of your organisation, participate in medicine traceability systems implemented in other jurisdictions, for instance the European Union's European Medicines Verification System (EMVS) or the United States of America's Drug Supply Chain Security Act (DSCSA)?

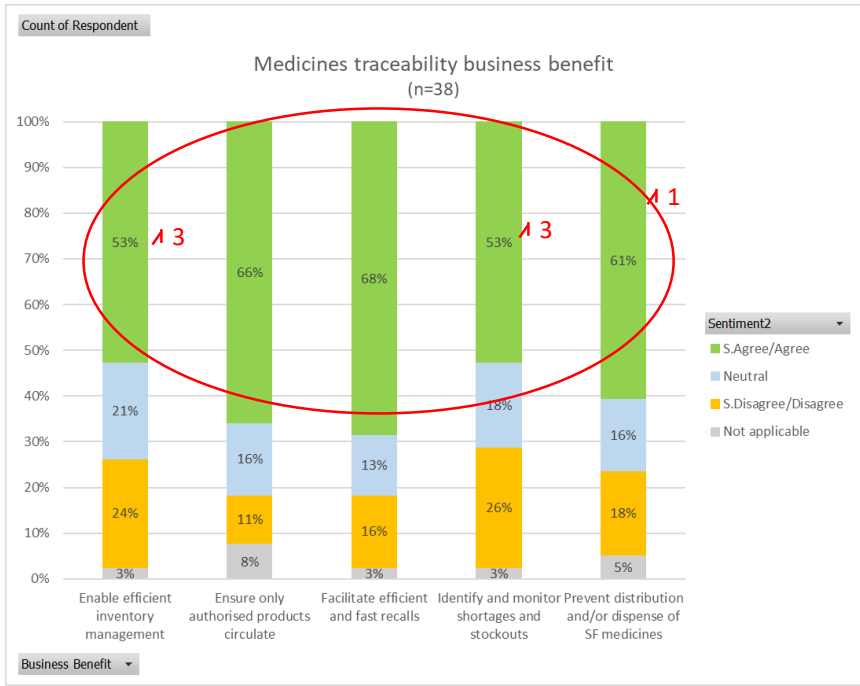
4. Business benefits of medicines traceability

Respondent sentiment is positive across the five questions relating to potential business benefits of an NMTF, with over 50 percent of respondents ‘Agreeing’ or ‘Strongly agreeing’ with each individual benefit type [1].

‘Facilitate efficient and fast recalls’ had the highest ‘Strongly agree’ (26%) and ‘Agree’ (42%) sentiment [2].

Benefit types of ‘Enable efficient inventory management’ (53%) and ‘Identify and monitor shortages’ (53%) shared the lowest positive sentiment [3].





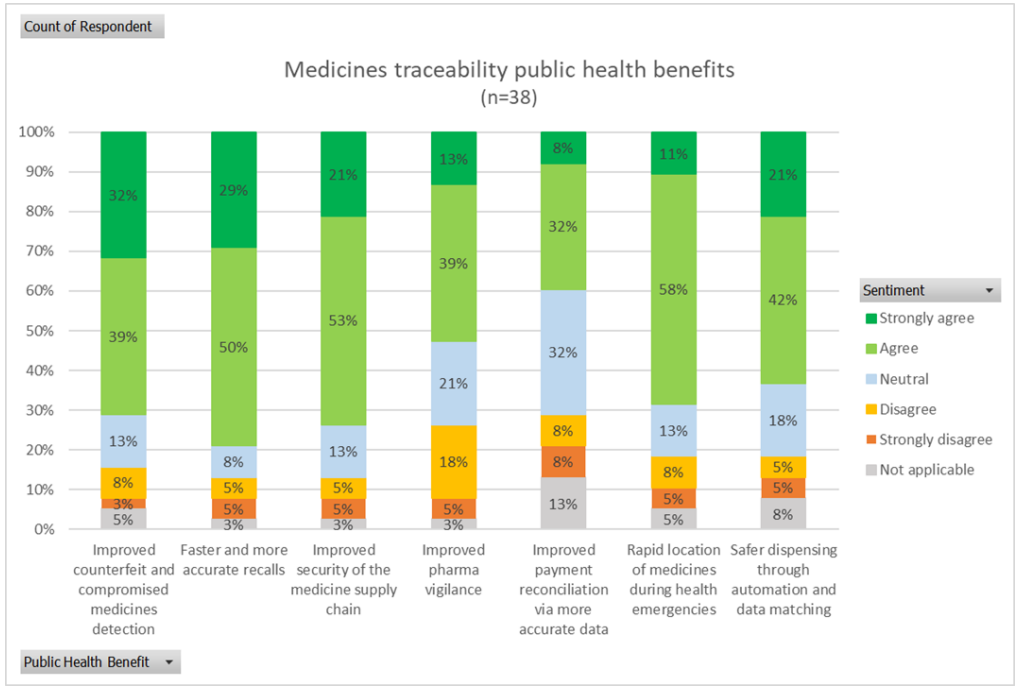
Q21 - An NMTF would benefit your organisation by helping:
Q21.1 - Ensure only authorised products, registered or approved, circulate in the legal supply chain
Q21.2 - Prevent the distribution and/or dispensing of falsified, expired, prohibited or recalled products
Q21.3 - Facilitate efficient and fast market recalls
Q21.4 - Enable efficient inventory management
Q21.5 - Identify shortages and monitor the reasons for shortages and stock outs

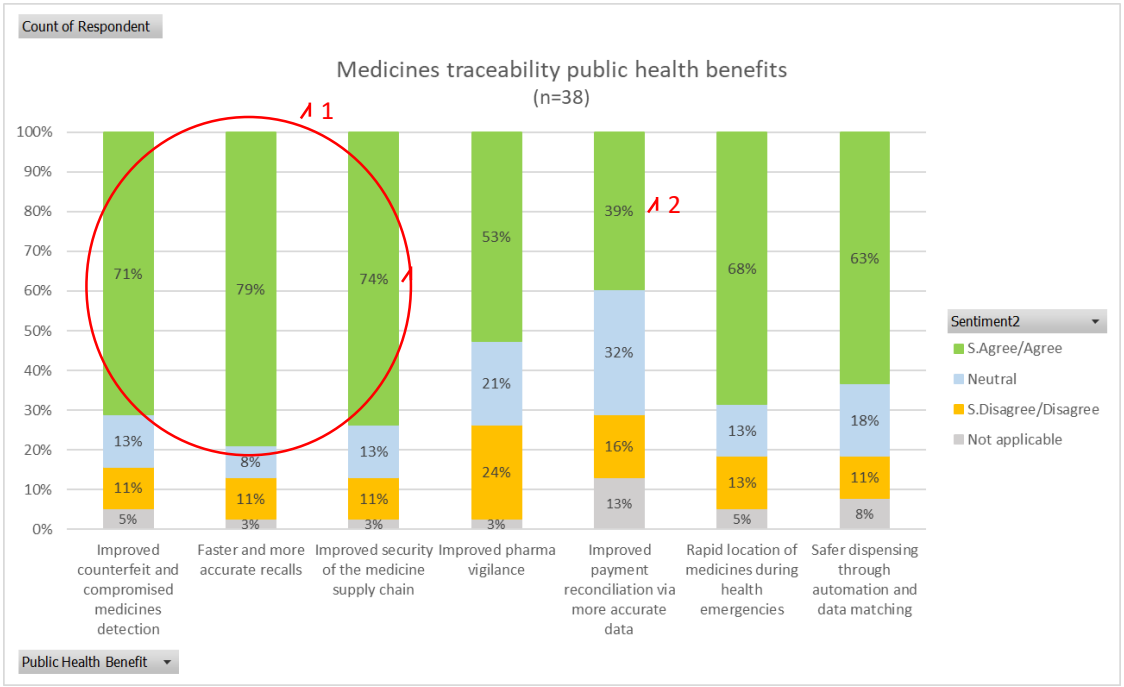
5. Public health benefits of medicines traceability

Respondent sentiment is more than 50 percent positive across six of the seven questions relating to potential public health benefits of a NMTF.

Questions asking about ‘faster and more accurate recalls’ (79%), ‘improved security of the medicines supply chain’ (74%), and ‘improved counterfeit and compromised medicines detection’ (71%) were rated highest of combined ‘Agree’ and ‘Strongly agree’ sentiments [1].

‘Improved payment reconciliation’ received the lowest positive (39%) sentiment and highest ‘Neutral’ (32%) sentiment of all potential public health benefits [2].





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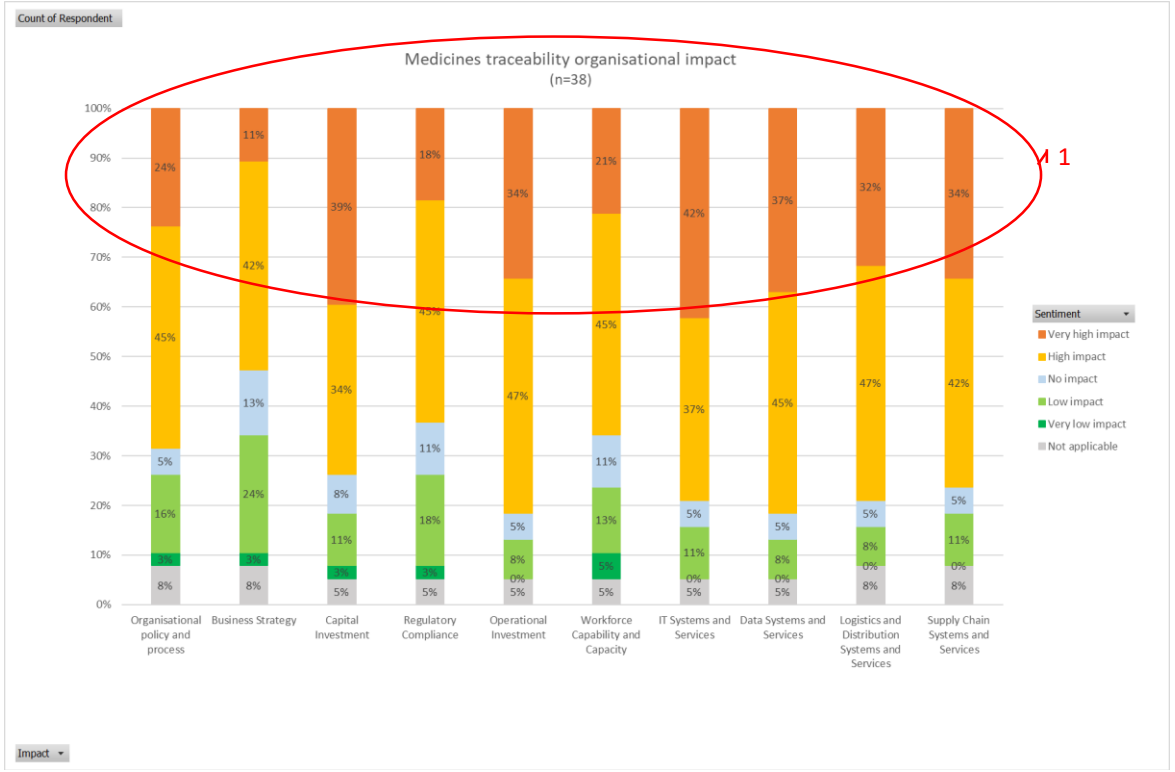
Q22 – An NMTF could benefit public health through:
Q22.1 – Faster and more accurate product recalls as specific locations are known; Q22.2 – Safer dispensing practices through greater automation and data matching
Q22.3 – Improved pharmacovigilance; Q22.4 – Rapid location of medicines within the supply chain, enhancing the ability to respond to health emergencies
Q22.5 - Improved security of the medicines supply chain; Q22.6 - Improved opportunities to identify counterfeit and compromised medicines
Q22.7 - Provision of accurate and secure data that can be used by the supply chain to support payment

6. Organisational impact of medicines traceability

Of the ten questions relating to organisational impact of a NMTF over 50 percent of all respondents rated the organisational impact as either ‘High’ or ‘Very high’, with ratings of ‘Very high impact’ ranging between 11 and 42 percent [1].

‘Operational Investment’ (82%) and ‘Data Systems and Services’ (82%) were ranked the highest areas of ‘high’ and ‘very high’ organisational impact [2].

‘Business Strategy’ (53%), while still significant, was rated as having the lowest organisational impact [3].



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Q23 - Please indicate the expected level of impact your organisation would experience on the following business areas due to the introduction of an NMTF
Q23.1 - Organisational policy and processes; Q23.2 - Business strategy; Q23.3 - Workforce capability and capacity;
Q23.4 - Capital investment; Q23.5 - Operational investment; Q23.6 - Regulatory compliance
Q23.7 - Information technology systems and services; Q23.8 - Data systems and services
Q23.9 - Logistics and distribution systems and services; Q23.10 - Supply chain systems and services

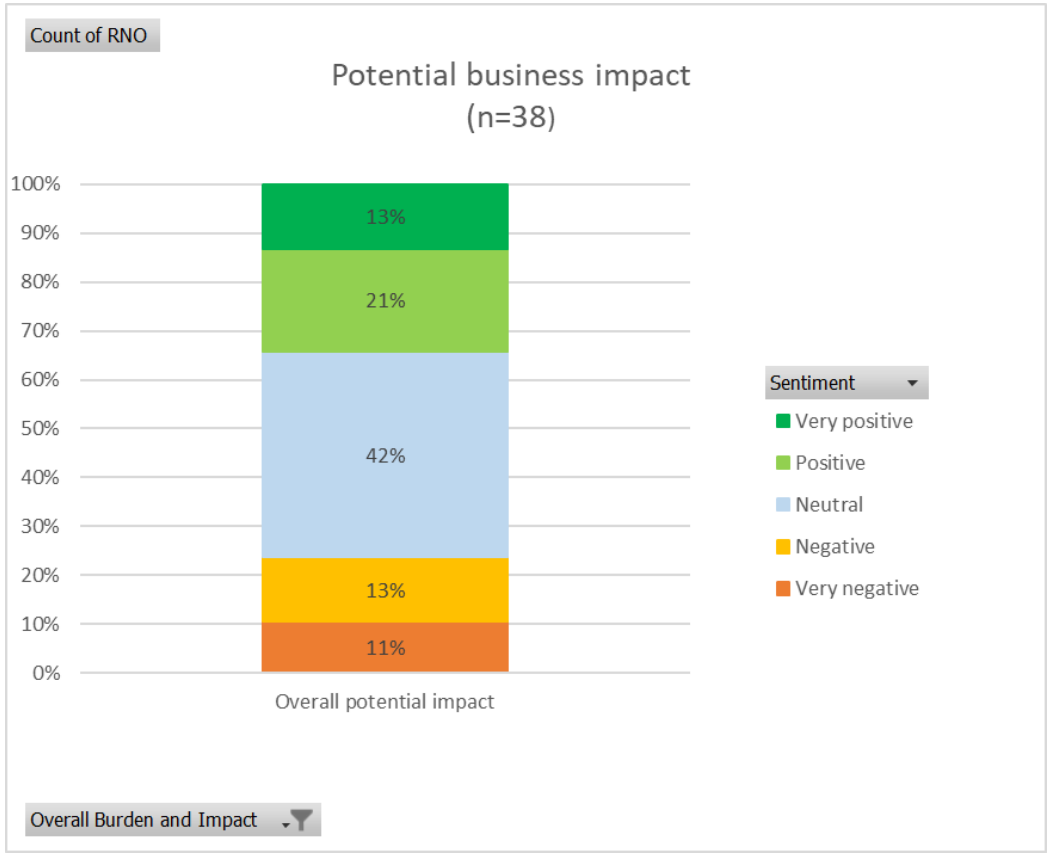
7. Organisational assistance required

Across all five ‘organisational assistance’ questions respondents have indicated a combined ‘Some assistance/High level of assistance’ sentiment of more than 45 percent, with ‘planning and implementation’ (68%) indicated as having the highest requirement for organisation assistance [1].

Q30 – Please indicate the expected level of assistance your organisation would broadly require to plan, initiate, implement and participate in an NMTF
Q30.1 - Planning and implementation assistance; Q30.2 - Workforce capability assistance
Q30.3 - Regulatory assistance; Q30.3 - Financial assistance; Q30.4 - Ongoing operational assistance

8. Potential business impact

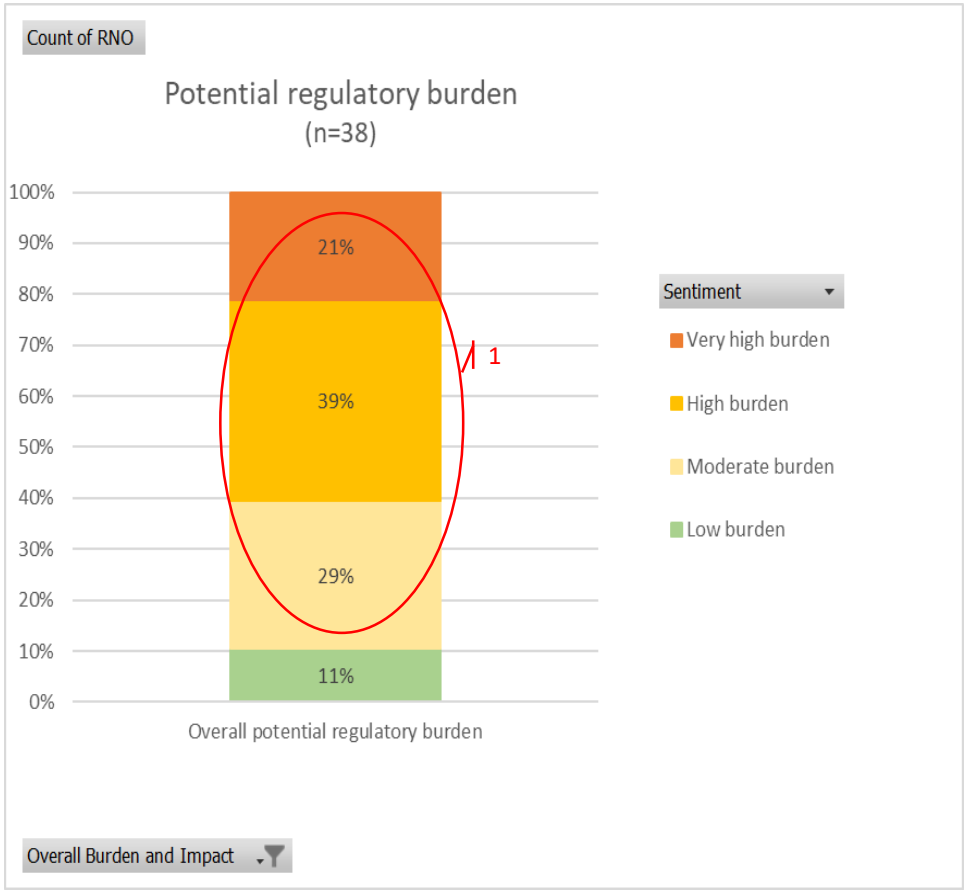
Overall, respondents preferenced a ‘Neutral’ (42%) sentiment over ‘Positive’ (34%) and ‘Negative’ (24%) sentiments regarding the potential business impact of a NMTF.



Q24 - Overall, how does your organisation view the potential impact of an NMTF on your business?

9. Potential regulatory burden

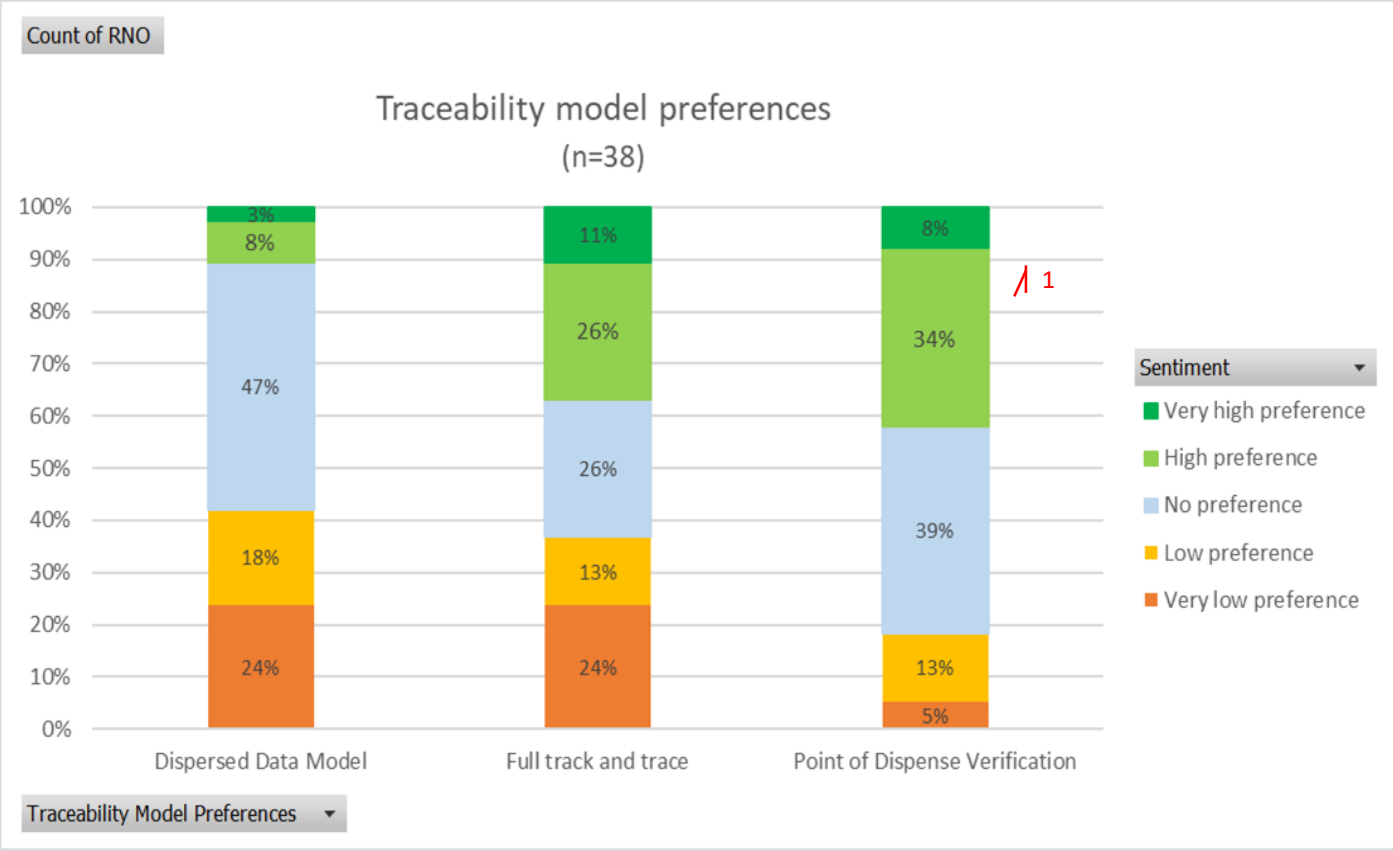
Overall, respondents indicated a combined ‘Moderate/High/Very high’ potential regulatory burden of 89 percent [1].



Q25 - Overall, how does your organisation view the potential regulatory burden of an NMTF on your business?

10. Traceability model preferences

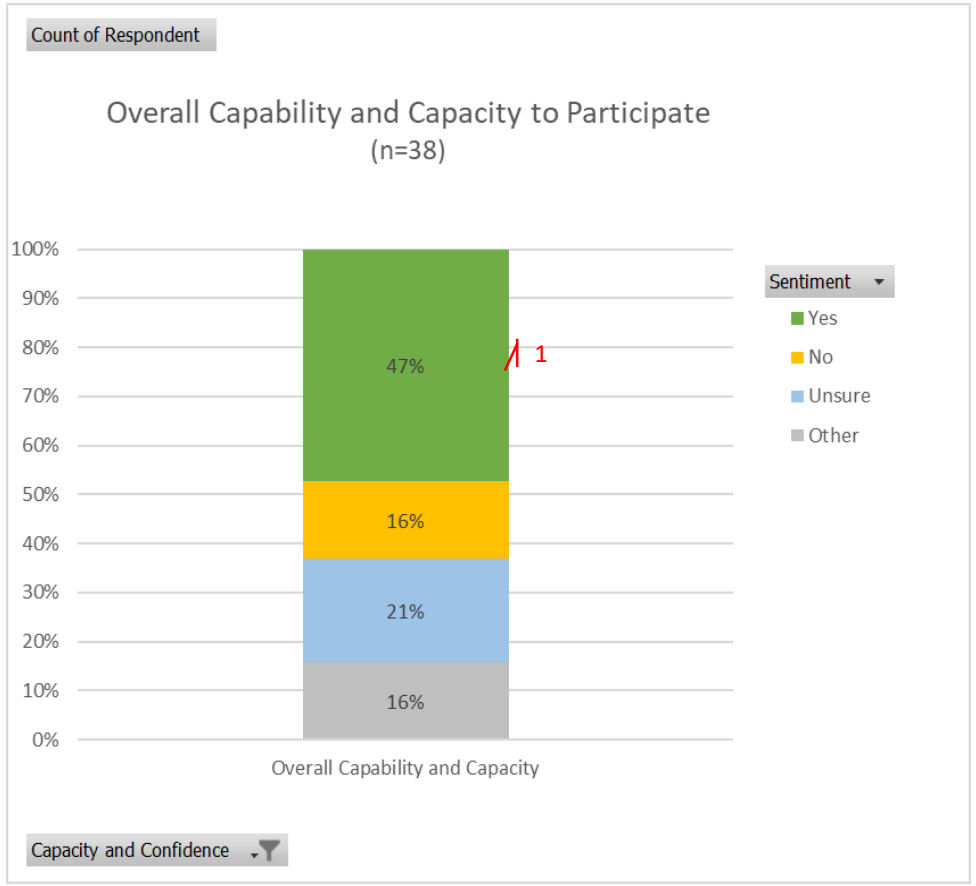
Overall, respondents indicated a combined ‘Very high/High’ preference for the Point of Dispense Verification model (PoDV) (42%) [1], over the Full Track and Trace model (37%) and Dispersed Data model (11%).



Q26 - Does your organisation have a preference for the type of traceability model to be considered for an NMTF?
Q26.1 - Full Track and Trace Model
Q26.2 - Point of Dispense Verification Model
Q26.3 - Dispersed Data Model

11. Capability and capacity to participate

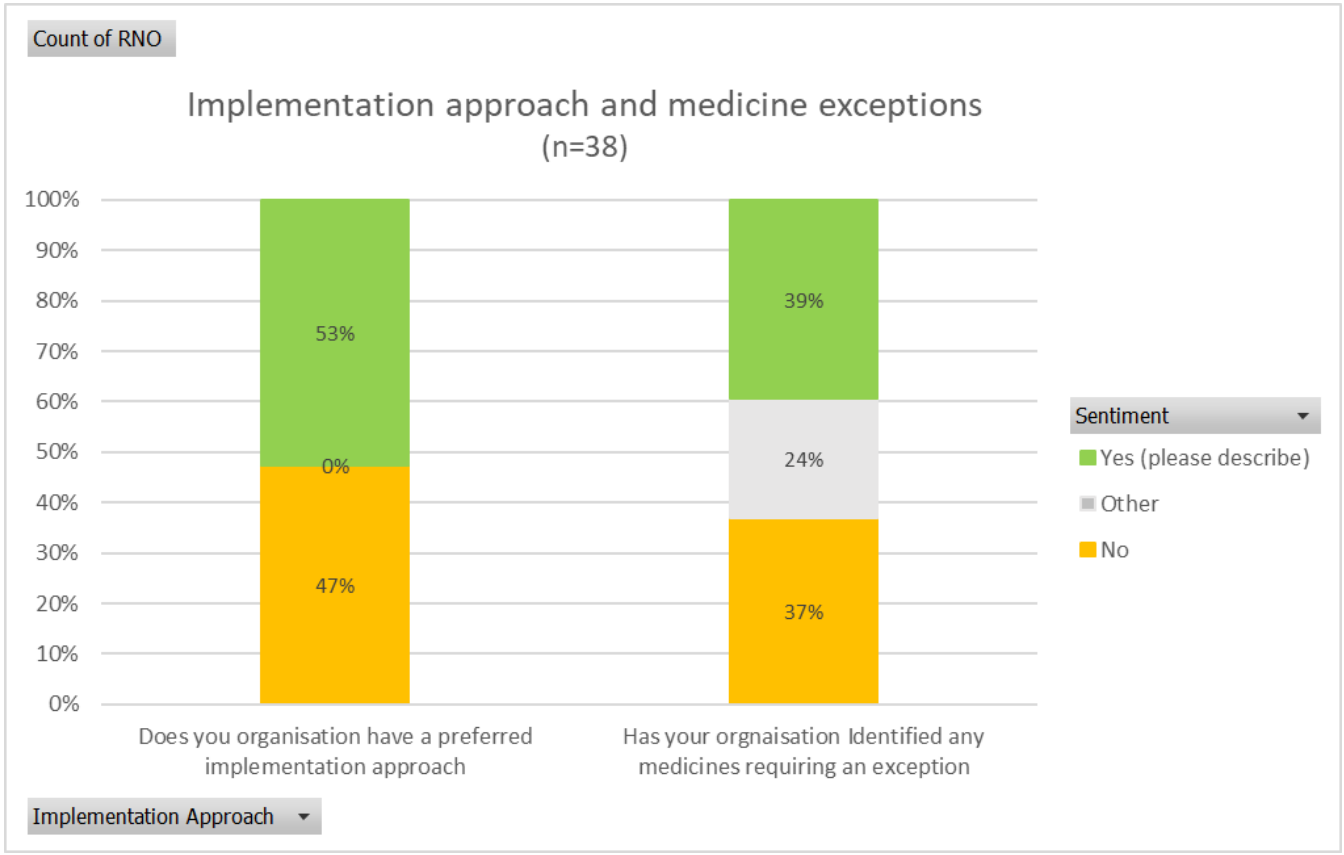
Overall, 47 percent of respondents indicate that their organisation has the capability and capacity to participate in a NMTF [1], with 37 percent indicating they are either ‘unsure’ (21%) or ‘not able’ (16%) to participate.



Q27 - Does your organisation have the capability and capacity to participate in an NMTF for your medicine products?

12. Implementation preferences

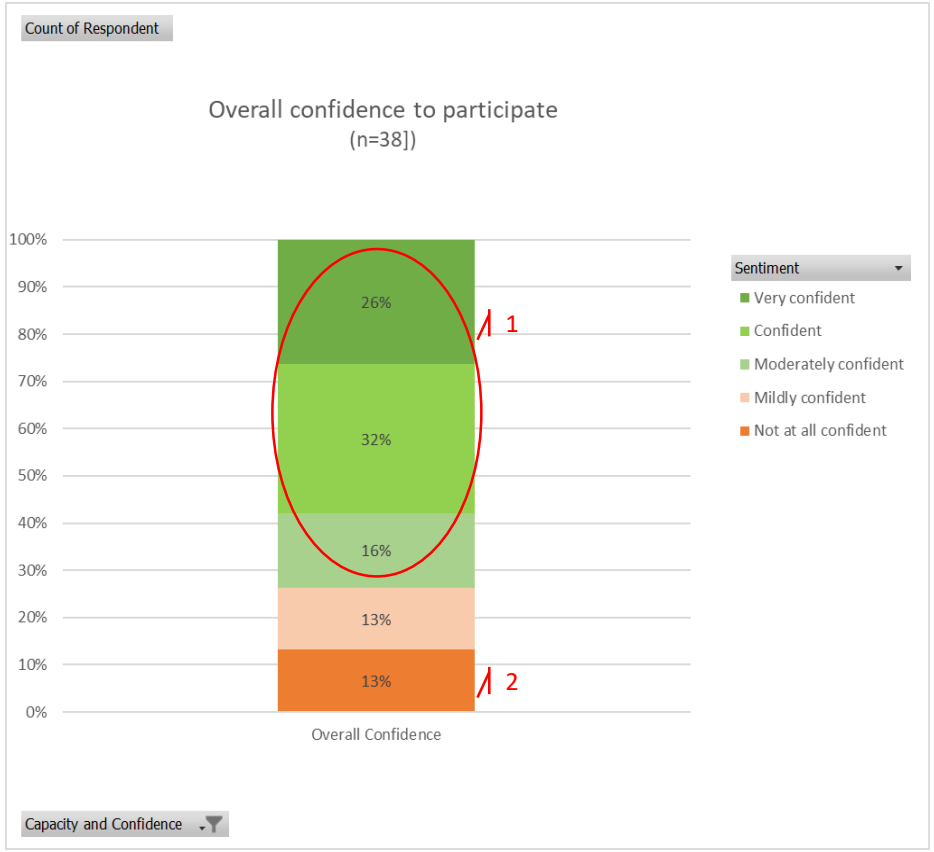
Overall, 53 percent of respondents indicated that they have a preferred implementation approach and 39 percent indicated that they had medicines which would require and exemption from a NMTF.



Q28 - Has your organisation identified a preferred approach to phase in a serialisation and/or traceability framework – for instance by medicine category or by medicine sponsor?
Q29 - Does your organisation handle medicines that would require exemptions from an NMTF?

13. Overall confidence to participate

Overall, respondents indicated a combined ‘Very confident/Confident/Moderately confident’ sentiment of 74 percent in answer to ‘how confident their organisations are to successfully participate in a NMTF’ [1]. Thirteen percent of respondents indicated that they were ‘not at all confident’ [2].



Q33 - Overall, how confident are you that your organisation would be able to successfully participate in a fully implemented NMTF?

END