swissmedic

Comparison of indication wording between Swissmedic, EMA and FDA – Labelling Analysis

Regulatory & Beyond, 16.11.2026

Tanja Colin, Head of Market Approval, Interpharma &
Matea Zosso, Senior Clinical Assessor, Swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

Background and approach

Background

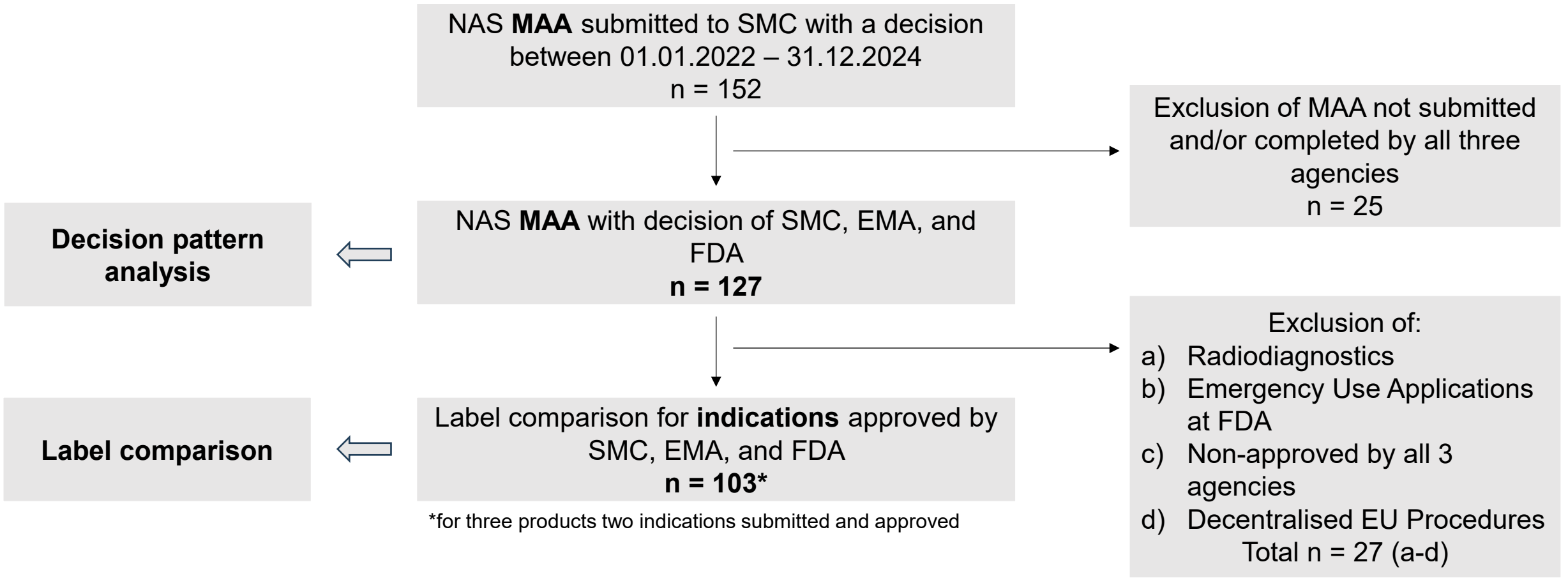
- Swissmedic and the industry have been successfully conducting a joint benchmarking study on the approval times of the FDA, EMA and SMC authorities for over 10 years*
- To date, a joint comparison of approved labels between FDA, EMA and SMC has not been performed
- A joint analysis was performed to evaluate the approved labels of the FDA, EMA and SMC for the period 2022-2024 after joint agreement on methods and evaluation criteria that builds shared confidence in the results

Approach

- The approval decisions for new active substances (NAS) applications submitted to SMC during 2022-2024 were evaluated for the three authorities
- The approved labels were compared and classified according to the extent of their differences
- In cases with major differences between the labels of the different authorities, it was investigated which authority was stricter
- Oncology and non-oncology products were evaluated separately

*Benchmarking study 2025

Method – Inclusion criteria for NAS applications



MAA = Marketing authorisation applications

Method – Label comparison: Classification and Strictness*

1. Label Differences: "How Similar are the labels?"

Classification of label	Criteria
Similar	Identical indication wording or only semantic differences
Minor difference	**small numerical difference** in the size of the patient population concerned
Major difference	**large numerical difference** in the size of the patient population concerned

*Based on publications: Rohr UP et al. Clin Transl Sci. 2023 Sep;16(9):1569-1581 and Perini M et al. Lancet Oncol. 2025 Feb;26(2):e103-e110.

2. Label Strictness: "Who is more strict?"

Strictness: Labels were ranked between the 3 agencies according to strictness

The label comparison was performed **by both parties independently** and results were compared. In case of divergent outcome of evaluation, the parties discussed the cases and agreed on a classification.

Results – Decision patterns NAS 2022-2024

Decision pattern analysis

NAS **MAA** submitted to SMC with a decision between 01.01.2022 – 31.12.2024
n = 152

Exclusion of MAA not submitted and/or completed by all three agencies
n = 25

NAS **MAA** with decision of SMC, EMA, and FDA
n = 127

MAA = Marketing authorisation applications

Results – Decision patterns NAS 2022-2024

Characteristic	Overall n = 127	ONC n = 37	Non-ONC n = 90
Decisions			
SMC- EMA- FDA-	1 (0.8%)	0 (0.0%)	1 (1.1%)
SMC- EMA- FDA+	5 (3.9%)	1 (2.7%)	4 (4.4%)
SMC- EMA+ FDA-	2 (1.6%)	1 (2.7%)	1 (1.1%)
SMC- EMA+ FDA+	7 (5.5%)*	3 (8.1%)	4 (4.4%)
SMC+ EMA- FDA-	0 (0.0%)	0 (0.0%)	0 (0.0%)
SMC+ EMA- FDA+	1 (0.8%)	1 (2.7%)	0 (0.0%)
SMC+ EMA+ FDA-	5 (3.9%)	0 (0.0%)	5 (5.6%)
SMC+ EMA+ FDA+	106 (83.5%)	31 (83.8%)	75 (83.3%)

Note: «Minus» = non-approval, i.e. rejections or withdrawals by applicant

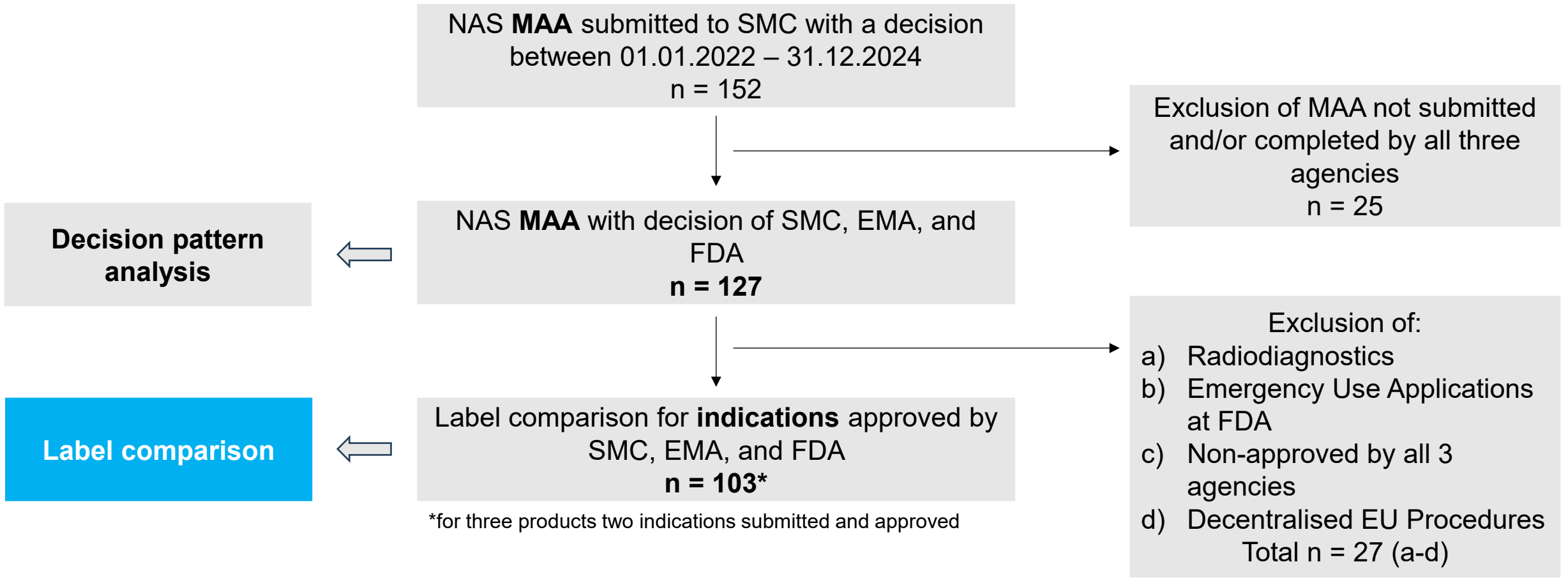
*post-analysis update based on DCO on 31.12.2025:

SMC- EMA+ FDA+: n=5 (3.9%)
→ 1 NAS after analysis period approved by SMC after resubmission
→ 1 NAS after analysis period suspended at EMA/withdrawn at FDA (↑ death rate with the product)

SMC+ EMA- FDA+: no change

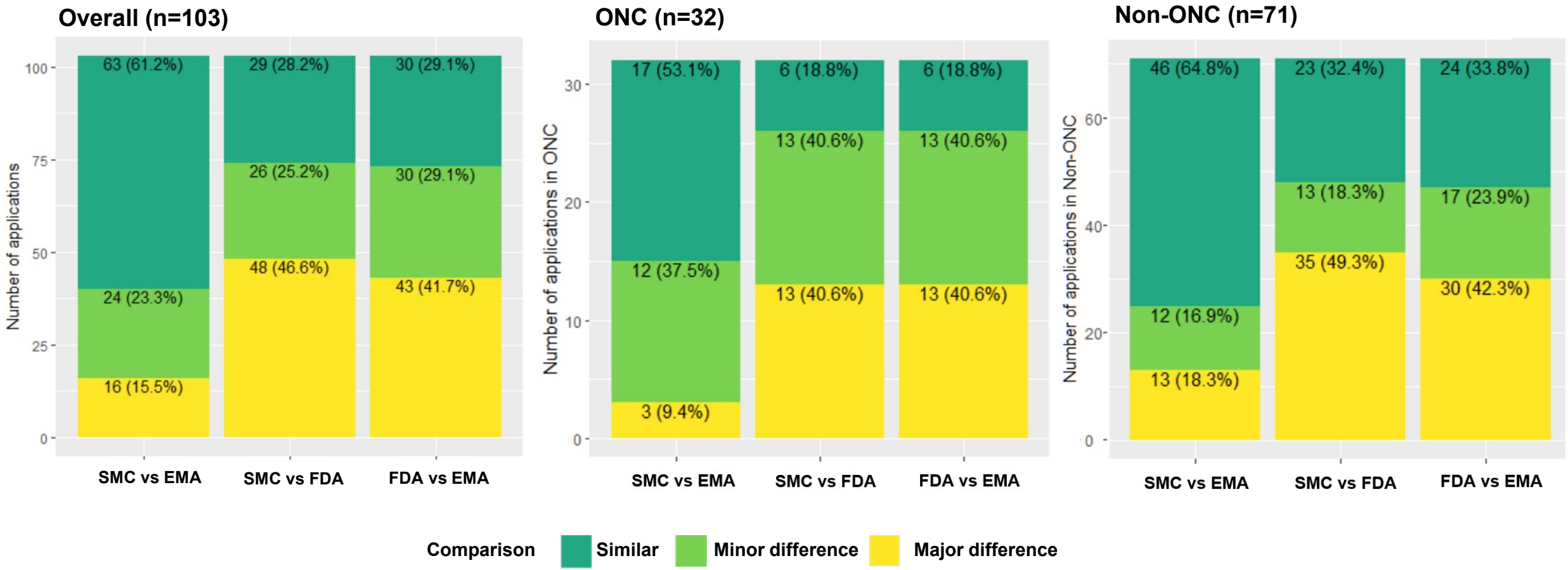
SMC+ EMA+ FDA-: no change

Results - Label comparison between agencies (NAS 2022-2024)

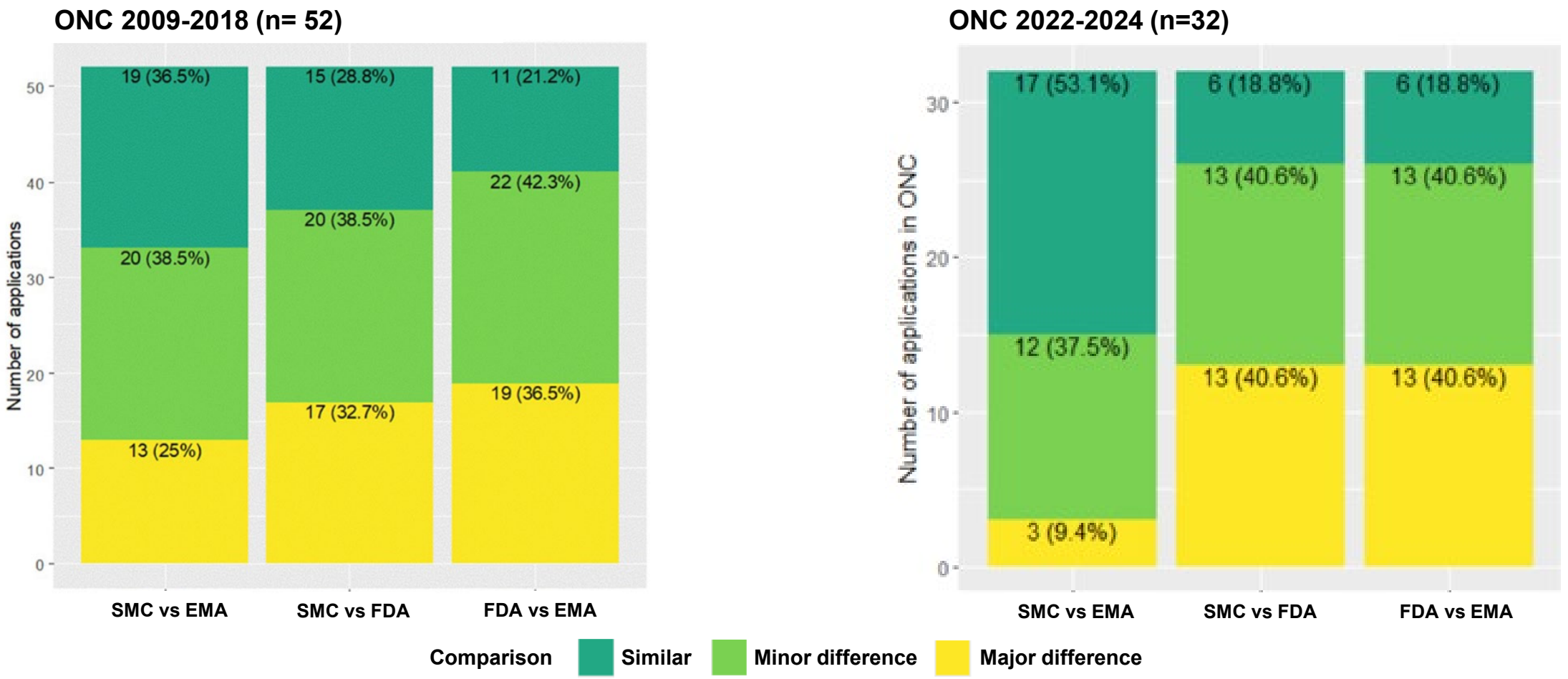


MAA = Marketing authorisation applications

Results - Label comparison between agencies (NAS 2022-2024)

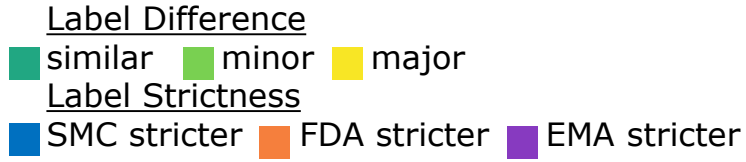


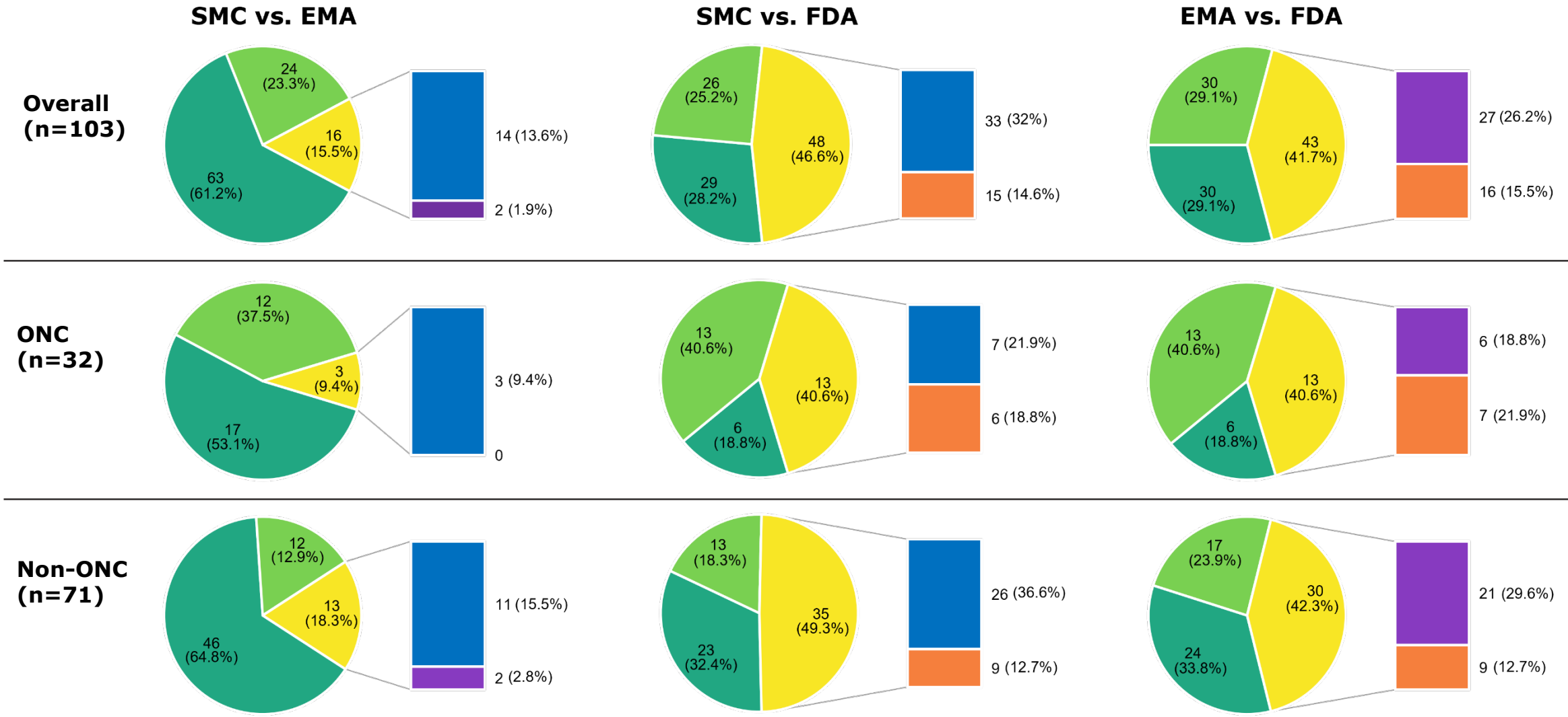
Historic Label comparison (ONC 2009-2018 vs 2022-2024)



Rohr UP et al. Clin Transl Sci. 2023 Sep;16(9):1569-1581

Strictness of major differences





% in parentheses always refer to the respective total n
Overall: n=103, ONC n=32, Non-ONC n=71

Summary

Decision Patterns

- Decision patterns were highly consistent between the three agencies Swissmedic, EMA and FDA.

Label Comparison

- For label comparison, the rate of major differences was low between EMA and Swissmedic.
- More cases of major differences were seen between the FDA and both the EMA and Swissmedic.
- For oncology labels with major differences, both the FDA and Swissmedic issued a stricter label in approximately half of the cases each.