



SAKELIGA
SELFSTANDIGE SAKEGEMEENSAP

Sakeliga: Comment on Zero BAC limit for South Africa – NRTAB

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Sakeliga**

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Key points to our written and verbal submission and policy recommendations:

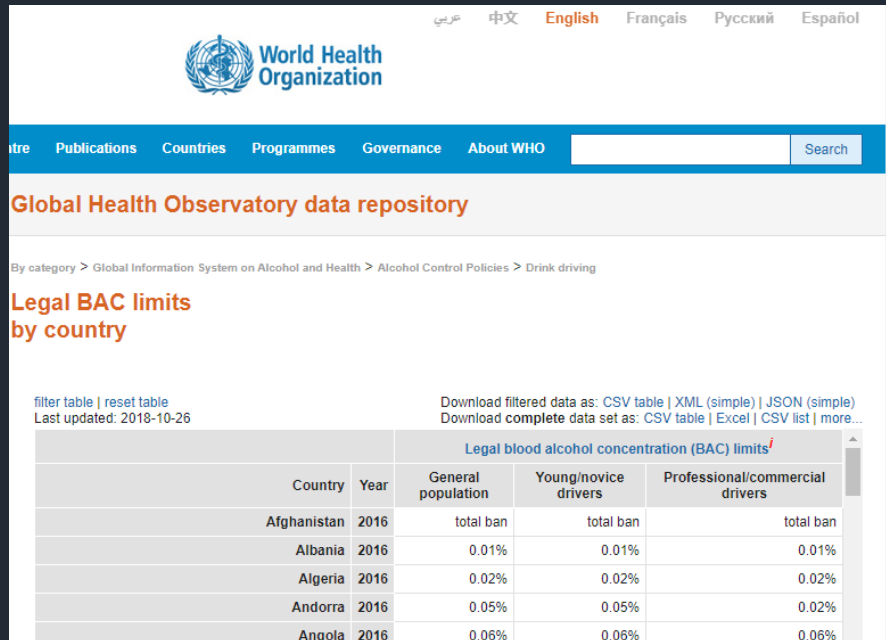
- Limited to the proposal for a 0% BAC Limit (clause 46 of the bill);
- Highlight concerns **about practicalities** (alcohol in foods, medicines) and the **cost of enforcement**;
- Give our consideration for maintaining the current limits (which does not preclude stricter enforcement of e.g. serious vehicular crimes);
- Point to some 'less restrictive policy options' available (international comparison of policies);
- We give reasons to maintain a legal limit vs a complete Zero BAC approach.



International comparison out of 194 countries

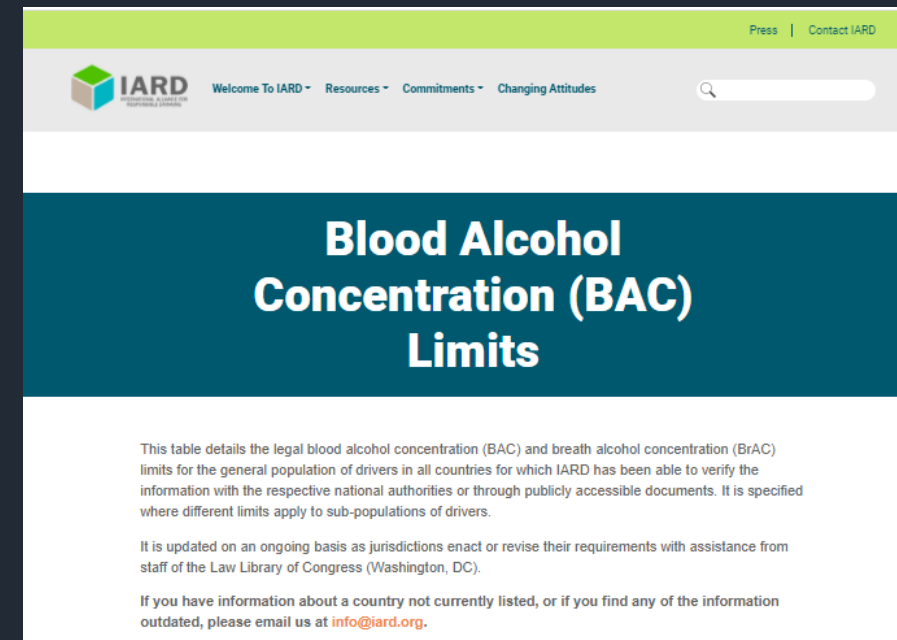
WHO, IARD datasets

Legal BAC limits on general population



The screenshot shows the WHO Global Health Observatory data repository page for "Legal BAC limits by country". The page includes a navigation menu with "Home", "Publications", "Countries", "Programmes", "Governance", and "About WHO". The main content area features a search bar and a "Global Health Observatory data repository" header. Below this, there is a breadcrumb trail: "By category > Global Information System on Alcohol and Health > Alcohol Control Policies > Drink driving". The title "Legal BAC limits by country" is prominently displayed. A table of data is provided, with options to "filter table", "reset table", and "Download filtered data as: CSV table | XML (simple) | JSON (simple)". The table lists countries and their legal BAC limits for the year 2016, categorized by "General population", "Young/novice drivers", and "Professional/commercial drivers".

Country	Year	Legal blood alcohol concentration (BAC) limits ⁱ		
		General population	Young/novice drivers	Professional/commercial drivers
Afghanistan	2016	total ban	total ban	total ban
Albania	2016	0.01%	0.01%	0.01%
Algeria	2016	0.02%	0.02%	0.02%
Andorra	2016	0.05%	0.05%	0.02%
Angola	2016	0.06%	0.06%	0.06%



The screenshot shows the IARD website page for "Blood Alcohol Concentration (BAC) Limits". The page features a green header with the IARD logo and navigation links: "Welcome To IARD", "Resources", "Commitments", and "Changing Attitudes". A search bar is located in the top right corner. The main content area has a dark teal background with the title "Blood Alcohol Concentration (BAC) Limits" in white. Below the title, there is a paragraph explaining that the table details legal BAC and BrAC limits for the general population of drivers in all countries for which IARD has been able to verify the information with the respective national authorities or through publicly accessible documents. It is specified where different limits apply to sub-populations of drivers. A second paragraph states that the information is updated on an ongoing basis as jurisdictions enact or revise their requirements with assistance from staff of the Law Library of Congress (Washington, DC). A final paragraph invites users to email info@iard.org if they have information about a country not currently listed or if they find any of the information outdated.



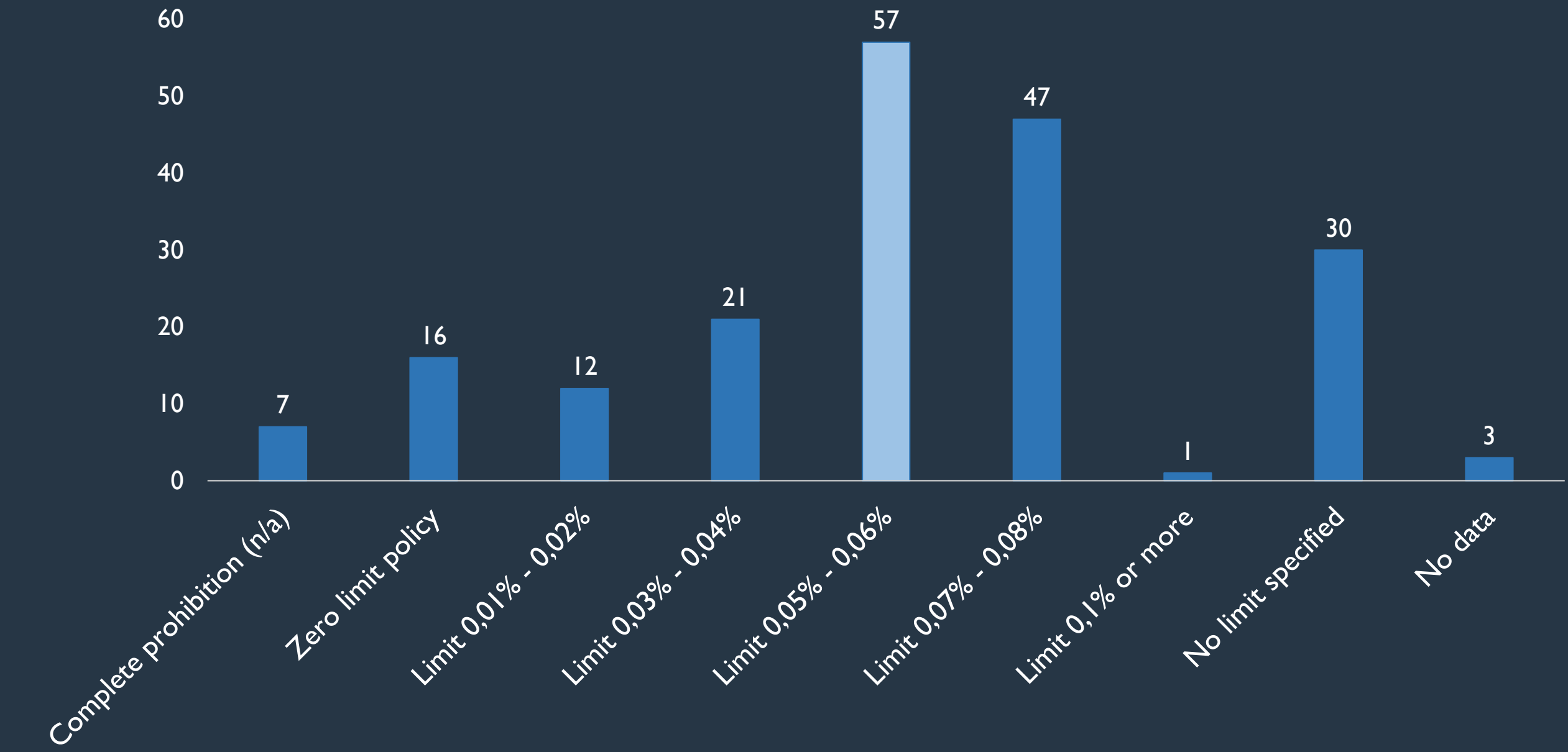
International comparison out of 194 countries

194	Countries / Regions
7	Complete prohibition (n/a)
16	Zero limit policy
12	Limit 0,01% - 0,02%
21	Limit 0,03% - 0,04%
57 (SA included)	Limit 0,05% - 0,06%
47	Limit 0,07% - 0,08%
1	Limit more than 0,1%
30	No limit specified
3	No data



Further breakdown: Comparison of legal limits 194 countries/regions with a legal BAC

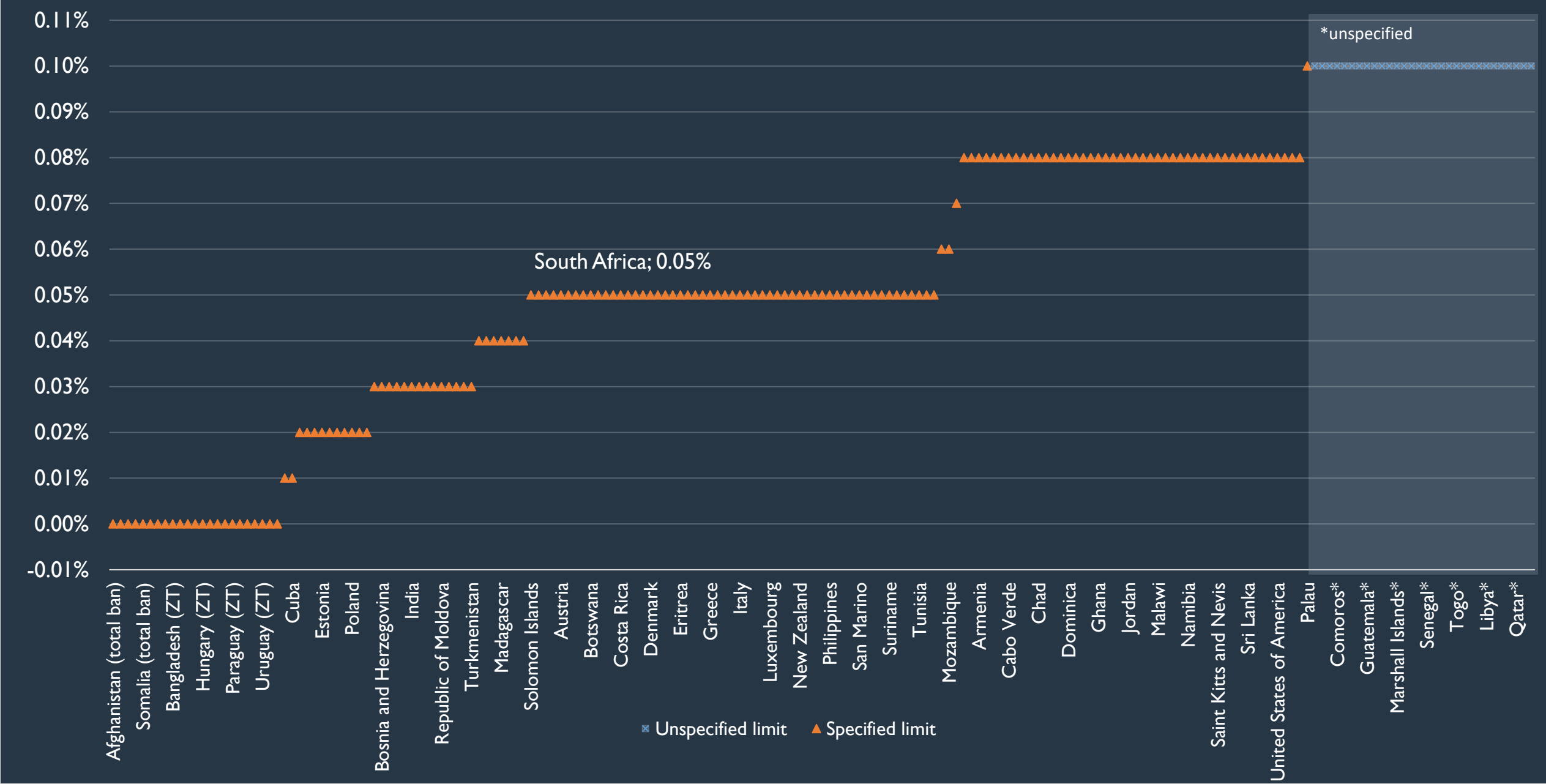
Note: Subset of 194 in total. Excl. 3 = no data, 30 = no set limit



191 Countries / regions comparison of levels of legal BAC limits

Note: Excl. 3 = no data, 30 = no set BAC limit shaded

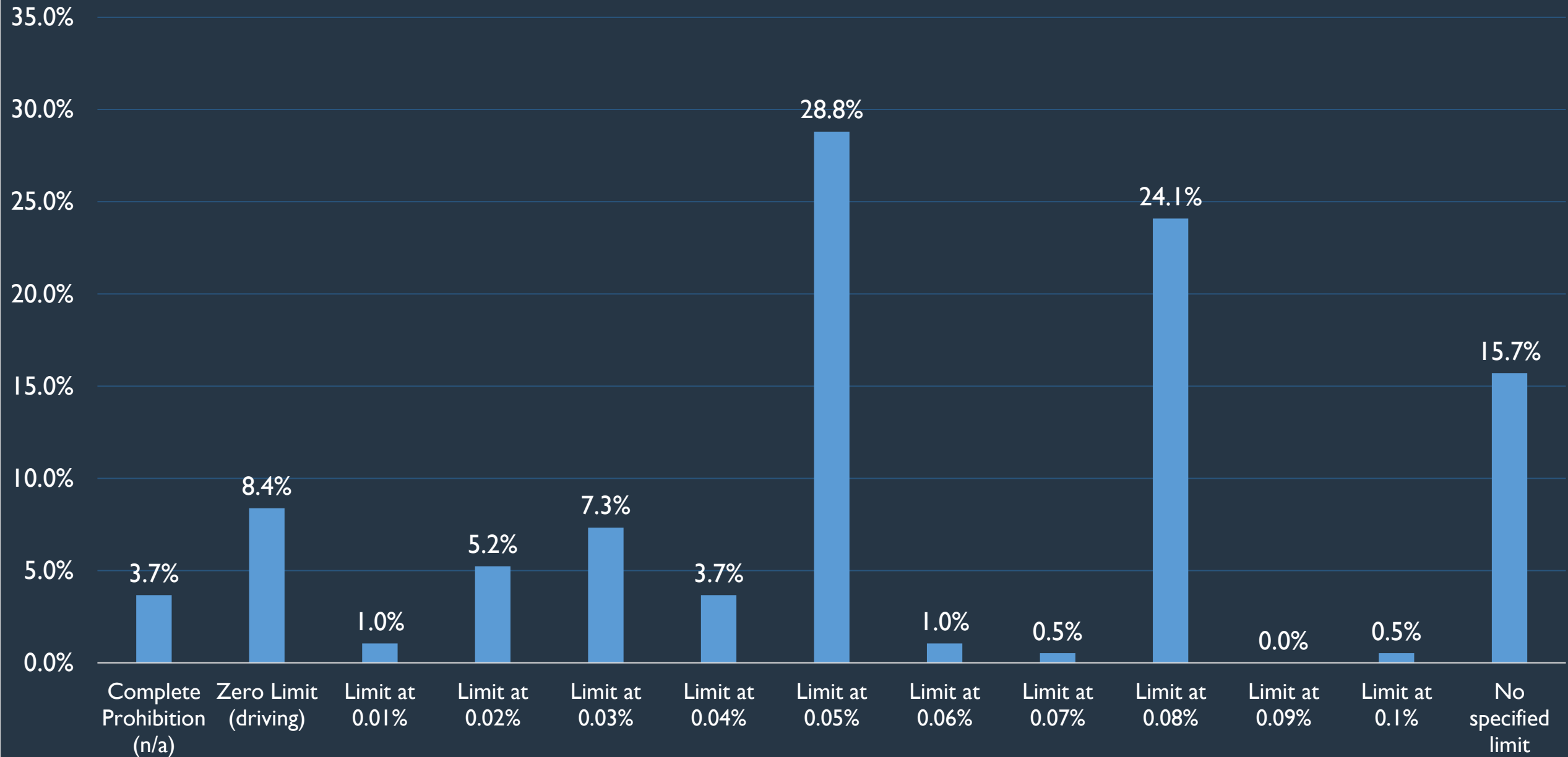
Source: WHO (2016), IARD datasets



% of 191 countries / regions that sets a legal BAC

Note: Subset of 194 in total. Excl. 3 = no data,

Source: WHO, IARD datasets



- Zero BAC limits: Only 16 out of 194 countries of regions
- SA's current BAC legal limit (general population is around midpoint)
- **Observation: There is plenty room to set stricter limits without immediately applying a zero limit.**



International comparison

- other approaches to 'drink driving' legislation



Graduated penalties and criminal sanction at higher BAC levels.



International comparison: Differentiated legal approaches -

'Decriminalisation' at lower BAC limits (e.g. warnings, fines) and criminal sanctions only at higher BAC limits :

- Romania: Graduated penalties. "BAC >0.80 incurs criminal sanctions" (IARD)
- E.g., Moldova, Norway, Panama, Paraguay: Penalties are graduated by BAC or BAC/BrAC (IARD)



International comparison:

- example of **Brazil** proves informative.



Example of Brazil

Relevant considerations e.g. Brazil's Zero Tolerance policy

- Zero tolerance policy, but with a small BAC limit (practicalities)
- Reasons: *“According to the Resolution, violation of article 165 of the Brazilian Traffic Code is established when the driver of a motor vehicle has a blood level with any concentration of alcohol or breath alcohol level higher than 0.05 miligrams per liter of air (amounts below that are within the margin of error of the equipment).”* Source: Library of Congress - <https://www.loc.gov/law/foreign-news/article/brazil-zero-tolerance-of-drunk-driving/>
- Note that equipment “margin for error” e.g. breathalysers, in Brazil's situation, it was apparently taken into consideration.



Example of Brazil

Relevant considerations e.g. Brazil's Zero Tolerance policy ("Dry Law")

- "Brazil has a 'dry law' indicating a nearly zero alcohol tolerance law regarding driving. The tolerated blood alcohol limit is 0.2g/l, to allow for alcoholic mouthwashes or certain medicines."

Source: <https://www.angloinfo.com/how-to/brazil/transport/driving/drinking-driving>



In our submission: Medicines with alcohol

- Andolex-C: “Contains alcohol 9% v/v”
- Bioplus syrup: “Alcohol 10,00% v/v”

Bioplus Syrup contains B-complex vitamins and caffeine to give you a go! Bioplus syrup also comes in 200 ml and 500 ml bottles. Reg. No. G2657 (Act 101/1965)

Bioplus® Syrup

Each 30 ml contains:

Caffeine 270 mg
Thiamine HCl (Vitamin B1) 16 mg
Riboflavin (Vitamin B2) 11 mg
Nicotinamide (Vitamin B3) 42 mg
Pyridoxine HCl (Vitamin B6) 9 mg
Cyanocobalamin (Vitamin B12) 26 µg
d- Pantothenol 11 mg
Calcium citrate 180 mg
Calcium gluconate 900 mg
Alcohol 10,00 % v/v
Preservatives
Methylhydroxybenzoate 0,09% m/v
Propylhydroxybenzoate 0,01% m/v
In a pleasant tasting glucose base.

Contains sugar:

Sucrose 7,20 g
Liquid glucose 8,70 g
Ref. No. G2657 (Act 101/1965)

Bioplus syrup is formulated with caffeine and B vitamins to provide you with both physical energy and mental vitality.

Source: <https://bioplus.co.za/syrup/> (date of last access: 2020/11/20)



PACKAGE INSERT

Andolex-C

Oral Rinse

SCHEDULING STATUS
B1

PROPRIETARY NAME AND DOSAGE FORM
ANDOLEX-C ORAL RINSE

COMPOSITION
Each 15 ml contains benzylamine hydrochloride 22.5 mg
Chlorhexidine gluconate 18 mg
9% v/v
Contains alcohol

Contains sugar: Sorbitol solution 3,75 g/15 ml
Other ingredients include polyvinyl alcohol, hydroxyethylcellulose, castor oil, propylene glycol, sodium benzoate, sodium citrate, sodium hydroxide, purified water.

PHARMACOLOGICAL CLASSIFICATION
A 16.4 Nonsteroid agent and local chemical antiseptic

PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Benzylamine hydrochloride has local analgesic and anti-inflammatory properties by stabilising the cellular membrane and inhibiting prostaglandin synthesis.
Chlorhexidine has antiseptic and disinfectant properties.

Pharmacokinetic properties
Benzylamine:
When administered as a local application, benzylamine has a low systemic absorption which reduces the potential of systemic side effects. Metabolism is mainly through oxidation, dealkylation and conjugation.
Chlorhexidine:
Minimal systemic absorption is observed. Chlorhexidine is poorly absorbed from the gastrointestinal tract and skin.

INDICATIONS
For the relief of minor infections and painful inflammatory conditions of the mouth and throat.
Chlorhexidine in ANDOLEX-C ORAL RINSE helps to reduce the development of plaque.

CONTRAINDICATIONS
Patients with known hypersensitivity to benzylamine, chlorhexidine or to any of the other ingredients of the formulation (see COMPOSITION).

ANDOLEX-C ORAL RINSE is not recommended in children under 6 years of age.

WARNINGS AND SPECIAL PRECAUTIONS
Do not swallow. If a burning or stinging sensation occurs, ANDOLEX-C ORAL RINSE can be diluted with water. Avoid contact with the eyes. Should it come in contact with the eyes, wash out thoroughly with water. Uninterrupted treatment should not exceed 7 days except under medical supervision.
Patients with the rare hereditary condition of sorbitol intolerance should not use ANDOLEX-C ORAL RINSE.
Contains sorbitol which may have an effect on blood sugar levels in patients with Diabetes Mellitus.
Effects on ability to drive and use machines
ANDOLEX-C ORAL RINSE has no or negligible influence on the ability to drive and use machines.

INTERACTIONS
Anionic agents in some toothpastes are incompatible with chlorhexidine. In order that the antiseptic effect of chlorhexidine is not reduced, it has been recommended that at least 30 minutes should be allowed to elapse between tooth brushing and rinsing with ANDOLEX-C ORAL RINSE.

PREGNANCY AND LACTATION
The safety of ANDOLEX-C ORAL RINSE in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
Adults:
Gargle
Gargle with 15 ml (approximately one tablespoon) for at least 30 seconds at 1½ to 3 hourly intervals, as needed. The solution should be expelled from the mouth after use and not swallowed.
Rinse for oral lesions:
15 ml (approximately one tablespoon) which should be held in the mouth and swished around for at least 30 seconds, with repeat use every 1½ to 3 hours throughout the day, as needed. The solution should be expelled from the mouth after use.
Spray:
5 to 10 sprays directly onto the painful or inflamed area and

How to clean and care for ANDOLEX-C spray:
Rinse the schalator sprayer and nozzle after every use to avoid sporadic blockages of the spray tube. Rinse the spray tube in warm, running water for at least 30 seconds and let the water run through the spray tube. This is very important as sometimes the small opening where the medicine comes out can become blocked. Shake off the excess water and leave the spray tube to dry completely.
Water: Blockage from medication build-up is more likely to occur if the spray tube is not allowed to dry thoroughly. The spray should be stored in an upright position.

SIDE EFFECTS
Immune system disorders
Less frequent: Hypersensitivity reactions including urticaria, rash, bronchospasm or laryngospasm and photo dermatitis.
Frequency unknown:
Serious allergic reaction (anaphylactic shock), signs of which may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and/or throat, and which may be potentially life-threatening.
Gastrointestinal disorders
Frequency unknown: Gastro-intestinal disturbances
General disorders and administrative site conditions
Less frequent: Oral tissue numbness and stinging sensation, dryness or thick, reversible discoloration of the tongue and teeth, transient disturbance of taste, oral desquamation, swelling of the parotid gland.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS.
Adverse effects have been reported following overdosage. Symptoms include nausea, vomiting, sore throat, and abdominal pain. Adverse central nervous system effects have been reported following overdosage. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety, and irritability. There is no specific antidote for benzylamine and should excessive quantities be ingested the treatment should be symptomatic and supportive.

IDENTIFICATION
A clear, colourless liquid with an odour of peppermint/rose.
PRESENTATION
Oral Rinse: Clear plastic bottles containing 200 ml and 2 l.
Spray: Clear glass or plastic PET bottles containing 30 ml.

STORAGE INSTRUCTIONS
Store in the carton, at or below 30 °C, in an upright position. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
31716-00743

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Hona Pharmaceuticals (Pty) Ltd
116 Riley Road, Bedfordview, 2007

DATE OF PUBLICATION OF THIS PACKAGE INSERT
Date of registration: 02 October 2002
Date of latest revision: 17 February 2017

FINAL PRODUCT MANUFACTURER
Pharma-C (Pty) Ltd, 50 Comrades Road Industria, Johannesburg, South Africa.
COUNTRY OF ORIGIN: South Africa

BOTSWANA Scheduling status: Oral Rinse: 4 Pharmacological classification: ATC: A01A D02 Other agents for local oral treatment ATC: A01A D03 - Anti-infectives for local oral treatment License number: BOT 9802/06
LESOTHO Scheduling status: Spray: 3 Pharmacological classification: ATC: A01A D02 Other agents for local oral treatment ATC: A01A D03 - Anti-infectives for local oral treatment License number: BOT 1402/06
NAMIBIA Scheduling status: N01 Pharmacological classification: ATC: A01A D02

Foods that contain alcohol

Only limited examples:

- Pure Vanilla, Almond & other “extracts”
- Foods that include cooking wines
- Some vinegars (small amounts)
- Some mustards (Dijon mustard) made with white wine.
- Some Soy sauces (e.g. Kikkoman soy sauce)

Source: <https://www.alcoholproblemsandsolutions.org/many-foods-contain-alcohol-discover-which-ones-do/>



Further info: Effect of small amounts of alcohol appears different from larger amounts.

NB: Point we wish to defer to medical experts for clarification:

“Alcohol produces both stimulant and sedating effects in humans. These two seemingly opposite effects are central to the understanding of much of the literature on alcohol use and misuse.”

- Chapter from Stimulant and sedative effects of alcohol – Springer link,
https://link.springer.com/chapter/10.1007%2F978-3-642-28720-6_135



Impact on law enforcement and policing resources?

Crime category	April 2017 to March 2018	April 2018 to March 2019
Illegal possession of firearms and ammunition	17 558	15 839
Drug-related crime	323 547	232 657
Driving under the influence of alcohol or drugs	86 160	82 912
Sexual offences as a result of police action	6 701	7 977
Total	433 966	339 385

Source: SAPS annual report 2018 / 2019



Impact on law enforcement and policing resources?

According to the SAPS annual report 2018 / 2019:

- FJ 2018 saw around 84 900 arrests for DUI and around 82 000 in FJ 2019.
 - 5,2% of all arrests in 2018 (FJ)
 - 5,4% of all arrests in 2019 (FJ)
- Zero limit is likely to increase arrests for DUI significantly (evidently even at minute BAC concentrations), arrests must be processed (lasting effects)
- If police / courts spend more resources on such enforcement, what would be the impact on other categories of crimes (e.g. enforcement of other crimes?)



Economic spill-over effects (raise a concern):

- Effective restriction on sales (even one drink) in some scenarios.
- Such effects on sales may compound across industries such as tourism, restaurants.
- Unsure about the size of effect – recommend seeking clarity on economic impact of a zero limit.
- Socio-Economic Impact Assessment



- Preference: Maintain current limits, does not exclude stronger enforcement
- **Proposal:** Do not apply a zero limit without considering:
 - More international comparison
 - Lessons from examples such as Brazil (e.g. equipment “margin for error”)
– practicalities
 - Differentiated legal approaches of other countries a “graduated” penalty perspectives.
 - Likely impact of “zero limit” to certain medicines, foods
 - Scientific questions on alcohol in small quantities – refer committee to medical experts and pharmacists.
 - Economic spillovers eg. cost of removing “one drink” from many businesses.
 - Impact on competing resources for policing increase in DUI arrests.



- Preference: Maintain current limits, (NB) does not exclude possibility of stronger enforcement
- **Proposal:** Do not apply a zero limit without considering:
 - More international comparison
 - Lessons from examples such as Brazil (e.g. equipment's "margin for error")
– practicalities of enforcement
 - Differentiated legal approaches of other countries a "graduated" penalty perspectives.
 - Likely impact of "zero limit" to certain medicines, foods
 - Scientific questions on alcohol in small quantities – refer committee to consider medical experts and pharmacists.
 - Clarify economic spillovers e.g. cost of removing "one drink" from many businesses.
 - Impact on competing public resources for policing increase in DUI arrests (especially at low BAC Levels).



Thank you.

