

EWDTS

European Workplace Drug Testing Society

Proposal for the Registration and Batch Release testing of POCT-devices

9th EWDTS Symposium in Lisbon

- Wim Schielen



An increasing number of POCT devices for the on-site detection of the use of alcohol or illicit drugs appear on the market!



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- Reliable?
- Who says so? The producer? Independent validation?

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- Quality of Instructions for Use?
- What to do if a result is positive?

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High? So, reputation-damage for both parties, or even a law suit, or a request for compensation! Bad press?

Suppose one would want a minimum set of quality indicators (S_p , S_e , R_e , R_b , etc.), how to get them?

- Producer?
- Independent assessment?
- Who decides on the minimum set of quality indicators?
- What levels for the quality indicators are acceptable?

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How is this done in other area's?

Veterinary POCT Diagnostics

- Commercial sales
 - Registration/license (USDA/CFIA/FLI/ANSES...) + Batch Release testing

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 - Notification (Validation Dossier + Technical Insert) + Registration elsewhere

Veterinary POCT Diagnostics

More and more countries require an OIE registration and no specific national registration....

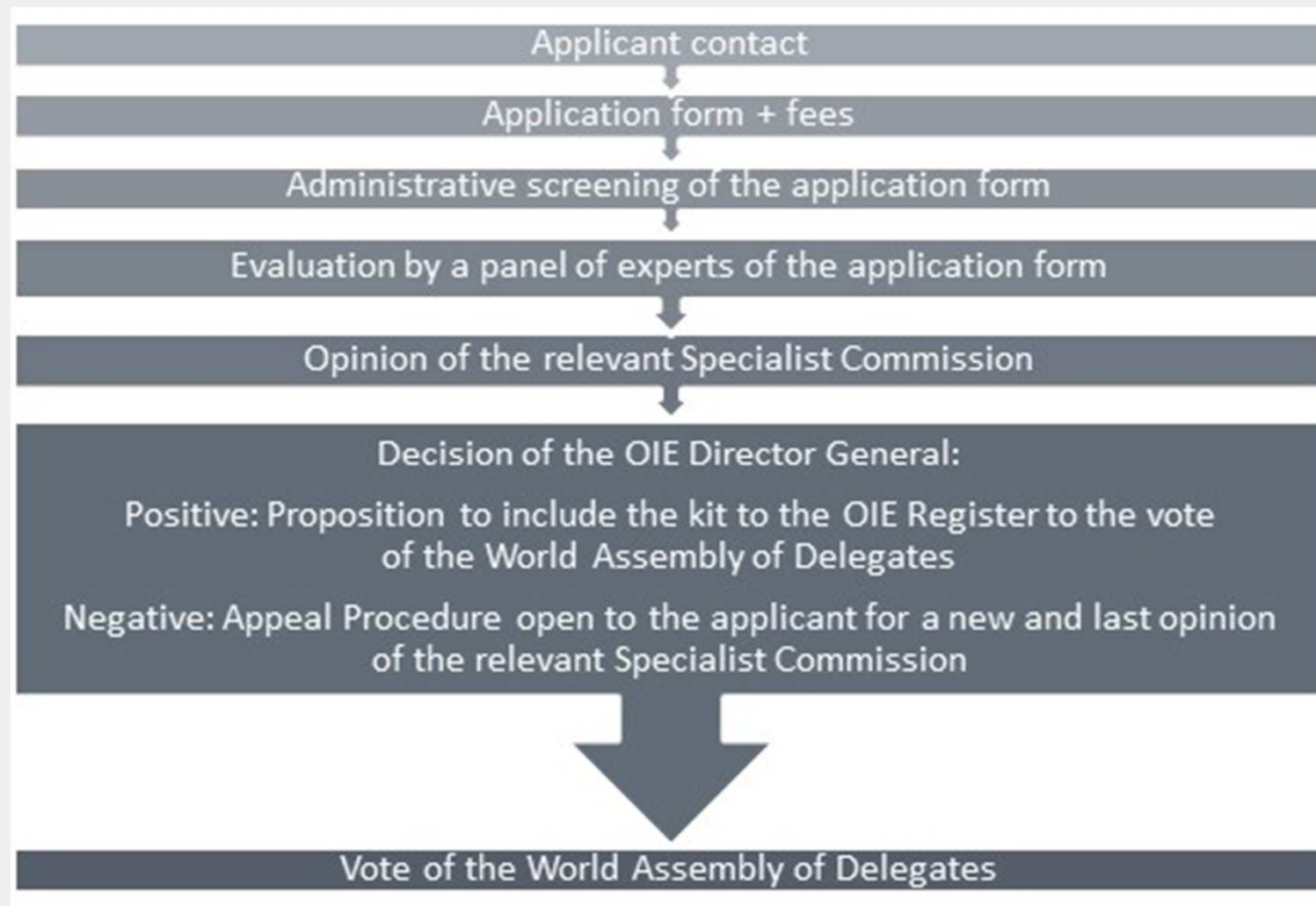
OIE is supra-national organization for control of animal disease – Organization International des Epizotes – World Organization for Animal Health, www.oie.int

Veterinary POCT Diagnostics

Registration at OIE is simple:

Why Registration of POCT devices?

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Registration of POCT devices provides...

- Independent check of
 - Fitness for purpose
 - Sensitivity in respect to the Guidelines CO-values
 - Specificity for the screening group
 - Manufacturing QC
 - Shelf life studies
 - Correctness of claims in the Instructions for Use
 - Correct labelling of product and device

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→ POCT device fulfills basic set of requirements

Batch Release testing of POCT devices provides...

- Independent check of Commercial lots in respect to:
 - Consistency of production lots compared to original registered product
- Claims are met for listed devices

Database of released lots/shelf life on website

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➔ Overview of POCT devices (lot) released for use in diagnostic procedures

Benefits of Device Registration and Batch Release testing of POCT devices? ^{# 24}

- User knows that the POCT product is safe to use and meets minimum criteria for proper use in diagnostic procedures.
- Much less dispute if confirmatory test differs from POCT test
- Devices that are registered have a good starting point for sales



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Open for discussion

Thank you for your attention!

