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

9th EWDTS Symposium in Lisbon

• Wim Schielen
Why Registration of POCT devices?

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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- Safe to use?
- Reliable?
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- Fit for purpose, eg fit for diagnostic procedures?
- Safe to use?
- Reliable?
- Who says so? The producer? Independent validation?
An increasing number of POCT devices for the on-site detection of the use of alcohol or illicit drugs appear on the market!

- Who buys them? For what purpose?
- Based on what criteria? Quality, price, cut-off? Independently assessed?
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- Quality of Instructions for Use?
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- Based on what criteria? Quality, price, cut-off? Independently assessed?
- Quality of Instructions for Use?
- What to do if a result is positive?
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Low? So, don’t bother... you win some, you lose some!

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 (Sp, Se, Re, Rb, 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
Veterinary POCT Diagnostics

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

- Notification (Validation Dossier + Technical Insert) + Registration elsewhere
Veterinary POCT Diagnostics

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

Veterinary POCT Diagnostics

Registration at OIE is simple:
Why Registration of POCT devices?

Veterinary POCT Diagnostics Registration at OIE is simple:

1. Applicant contact
2. Application form + fees
3. Administrative screening of the application form
4. Evaluation by a panel of experts of the application form
5. Opinion of the relevant Specialist Commission
6. Decision of the OIE Director General:
   - Positive: Proposition to include the kit to the OIE Register to the vote of the World Assembly of Delegates
   - Negative: Appeal Procedure open to the applicant for a new and last opinion of the relevant Specialist Commission
7. Vote of the World Assembly of Delegates
Why Registration of POCT devices?

Veterinary POCT Diagnostics Registration at OIE is simple:
Why Registration of POCT devices?

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
Why Batch Release testing of POCT devices?

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?

• 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
Benefits of Device Registration and Batch Release testing of POCT devices?

How to organize this Device Registration?
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EWDTs could install a committee to investigate the pros and cons of Device Registration and/or Batch Release testing......
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Open for discussion
Thank you for your attention!