

AHWP Comments for TC Advisors

- ▶ I apologize for not having the time to get input from all TC Advisors, but I believe they would agree with my opinions
- ▶ The work of AHWP continues to be necessary and important in supporting global convergence of effective and efficient medical device regulation
- ▶ AHWP truly represents multi-national and multi-sector cooperation to help assure patients have access to safe and effective products
- ▶ The AHWP Playbook is only a first step. There is more work to be done
- ▶ In my opinion what makes the Playbook unique is it represents a continuum of work building off the years of harmonization by GHTF
- ▶ The Playbook adds to the GHTF work by providing first level guidance on how to apply these best practices

AHWP Comments for TC Advisors

- ▶ We believe with the right focus and support the work, clarity, and guidance of the AHWP Playbook elements will be a real benefit to many countries
- ▶ It is exciting to see it presented at various international meetings such as The 1st MENA MedTech Regulatory Symposium
- ▶ Then to have a 2-day training on key aspects here in Thailand as part of the AHWP Annual meeting
- ▶ The Playbook is a first step in a long journey as we together create better documents and instructions to support the content



TC Advisor Comments on WG items

- ▶ I would like to highlight the importance of AHWP guidance to be useful for all parties (regulator and industry).
 - ▶ For example: I believe that WG1 discussion on the CSTD 10993 testing is good example of aligning policy and technical issues clarifying for all parties in AHWP
- ▶ We see good work plans with clear timelines and expectation. We commend the TC leadership and the WG for communicating these and working towards these goals in full transparency
- ▶ It seems that the AHWP engine has started and now it is time for AHWP leadership to take us on this journey
- ▶ As TC Advisors we are ready to be there for the adventure, and to see where it takes us
- ▶ You can count on our support, THANK YOU

Scott Sardeson RAC US/EU

3M Health Care

AHWP TC Industry Advisor

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Additional Challenge of Economics

Sample	GDP (PPP)
Cambodia	3,042
Vietnam	5,293
India	5,410
Philippines	6,533
Indonesia	9,559
China	11,904
Thailand	14,390
Thailand	14,393
Brazil	15,034
Mexico	16,453
Malaysia	23,298
Russian Federation	24,120
Korea Rep.	33,130
Japan	36,315
France	36,906
United States	53,000
Hong Kong SAR, China	53,203
Saudi Arabia	53,780
Singapore	78,744

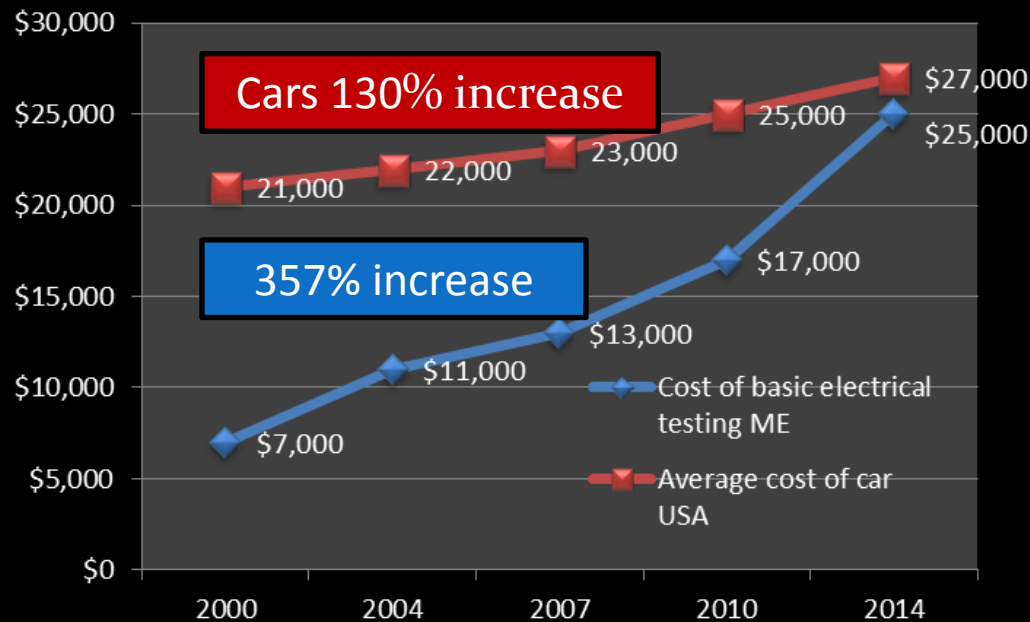
Fees that are standardized between international testing labs, can present 2X to 4X the burden to countries with lower GDP (PPP)

Weaker purchasing power presents a greater burden. 117 nations have half the purchasing power of countries that require expensive 3rd party testing .

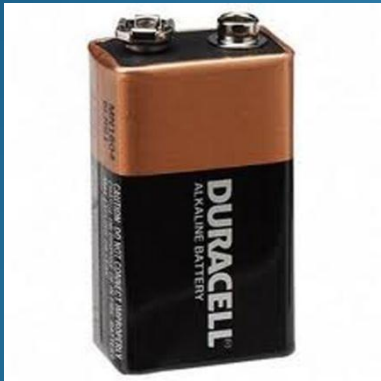
A \$25,000 test fee feels like \$50,000

Why Provide Alternatives

Costs related to application of standard IEC 60601-1



What to do?



+



= \$30,000
IEC 60601-1 test.

Class B Dental Device