



**AMU INTERACTIONS WITH
PHARMACEUTICALS AND WHOLESALERS
(ESWATINI EXPERIENCE)**

PRESENTATION TO

*THE OIE SUB-REGIONAL WORKSHOP ON
THE DATABASE ON ANTIMICROBIAL
AGENTS INTENDED FOR USE IN ANIMALS
IN EASTERN & SOUTHERN AFRICA*

MOMBASA, KENYA

29 OCTOBER 2019

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PRESENTATION OUTLINE

- General Overview of Eswatini
- Department of Veterinary and Livestock Services (DVLS) and the Livestock Sector
- Regulation of Veterinary Medicinal Products
- VMP Supply Chain
- AMU Data Collection
- Data Compilation
- Data Collection Challenges





OVERVIEW OF KINGDOM OF ESWATINI



- Area – 17,364Km²
- Population – 1.3million



DVLS & LIVESTOCK SECTOR

- The Department of Veterinary and Livestock Services (DVLS) has the principal function & mandate in preservation of the country's territorial integrity with respect to animal and zoonotic disease invasion and spread
- The livestock production systems include, mainly;
 - Ruminants – Including mainly cattle (501 643) and goats (480 678) and to a lesser extent sheep (16 103), all in either communal or Title Deed Land systems
 - Beef is the main export commodity – in regional SADC markets and other international markets like the EU





DVLS & LIVESTOCK SECTOR

- Poultry Production (1 758 325 birds) – includes indigenous chicken (936 031), commercial broiler (435 030) and layer/egg (387 264) production. The commercial broiler and egg production is very intensive
 - Poultry products are the second main livestock export commodity (Broiler Day Old Chicks, Meat, Table eggs) to regional markets
- Porcine (40 689) – mainly intensive, but at small to medium scale

{Livestock figures sourced from Livestock Census, 2018:

<http://www.gov.sz/index.php/departments-sp-741563992/veterinary-livestock-production-services/80-agriculture/agriculture/1628-livestock-census-summary>}





REGULATION OF VMPS

- Regulation of Veterinary Drugs and Medicinal Products
 - Jurisdiction of Department of Veterinary and Livestock Services (DVLS), Ministry of Agriculture
 - Animal Disease Act 7, 1965 – Principal Act
 - Animal Disease (Amendment Act), 1990 – restriction of importation, distribution and usage of VMPS
 - Prohibition of use of Anabolic Hormones, Thyrostatic Substances & Growth Promoters Regulations, 2006
 - Regulation & Control of Veterinary Drugs and Medicinal Substances, 2012
 - Veterinary Public Health Act 17, 2013
 - Veterinary Public Health Regulations 2019 (Undergoing approval) – prohibition of Antibiotic use for growth promotion purposes





REGULATION OF VMPS

- Veterinary Public Health Act 17, 2013
 - Provides for National Residue Monitoring System of VMP residues in food of animal origin, mainly guided by the relevant EU Regulations for trade obligations
 - Provides for AMR inhibitory substances monitoring in food of animal origin
- Regulation of Human Medicines
 - Ministry of Health
 - Medicines and Related Substances Control Act 9, 2016 repealing Opium and Habit Forming Drugs Act, 1922
 - Regulations still at drafting stage





REGULATION OF VMPS



- Regulation and Control of Veterinary Drugs and Medicinal Substances Regulations No. 1, 2012
 - The Regulations provide for and/or specify:
 - The criteria for authorizing source of VMP that can be imported
 - The categorization/classification and listing of VMPS for authorization of usage and regulation of distribution (Compendium of Registered Veterinary Products)
 - The criteria for authorization of retailers and the category of products allowed for sale by retailer based on technical capacity
 - The Regulations also empower the DVLS to conduct Retailer Inspections, and impose sanctions as necessary
 - All VMP imports are regulated through a strict paper-based import permit control system regulated by the DVLS (started in 2007)
 - No local manufacturing is currently practiced and all imports are in “final or ready to use packs”





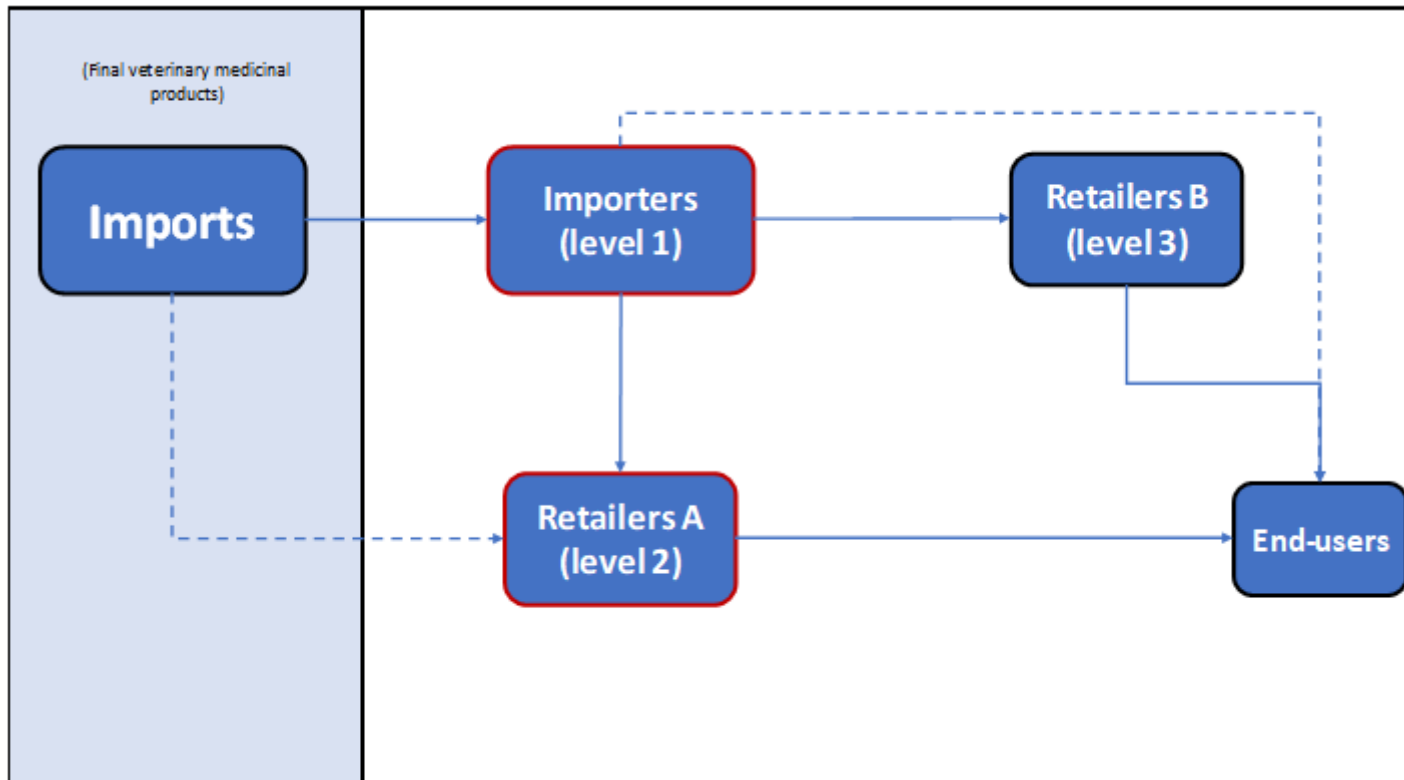
VMP SUPPLY CHAIN

- VMP Retailer supply chain is generally categorised into 3 group levels
 - **Level 1:** Source supplies exclusively through imports, distribute to other retailers & also sell to end users (9)
 - **Level 2:** Source supplies through imports and from Level 1 retailers as well; sell to end users (5)
 - **Level 3:** Source supplies from local retailers at Level 1; sell to end users (9)





VMP SUPPLY CHAIN



Courtesy: OIE Antimicrobial Use Team





AMU DATA COLLECTION



- Interaction with Retailers
 - Official request for Sales Data in writing by NFP for VMPs
 - Information requested for the last full calendar year in this format:

You are therefore, hereby, requested to submit all your antibiotic and/or antibiotic containing product sales data for the year 2017 tabulated as follows;

Format Example: *Note, Column (f) is only for importers also selling to other local retailers*

Product Trade Name (a)	Unit size (b)	Total Units/ Quantities sold in 2017 (c)	Source of Quantities sold (d + e = c)		Quantities sold to retailers*2 (f)
			Imported (d)	Local "Wholesaler"*1 (e)	
Mildox	50ml	150	100	50	
Hitet Gold	100ml	200	50	150	
Cosumix Plus	20g	500	450	50	

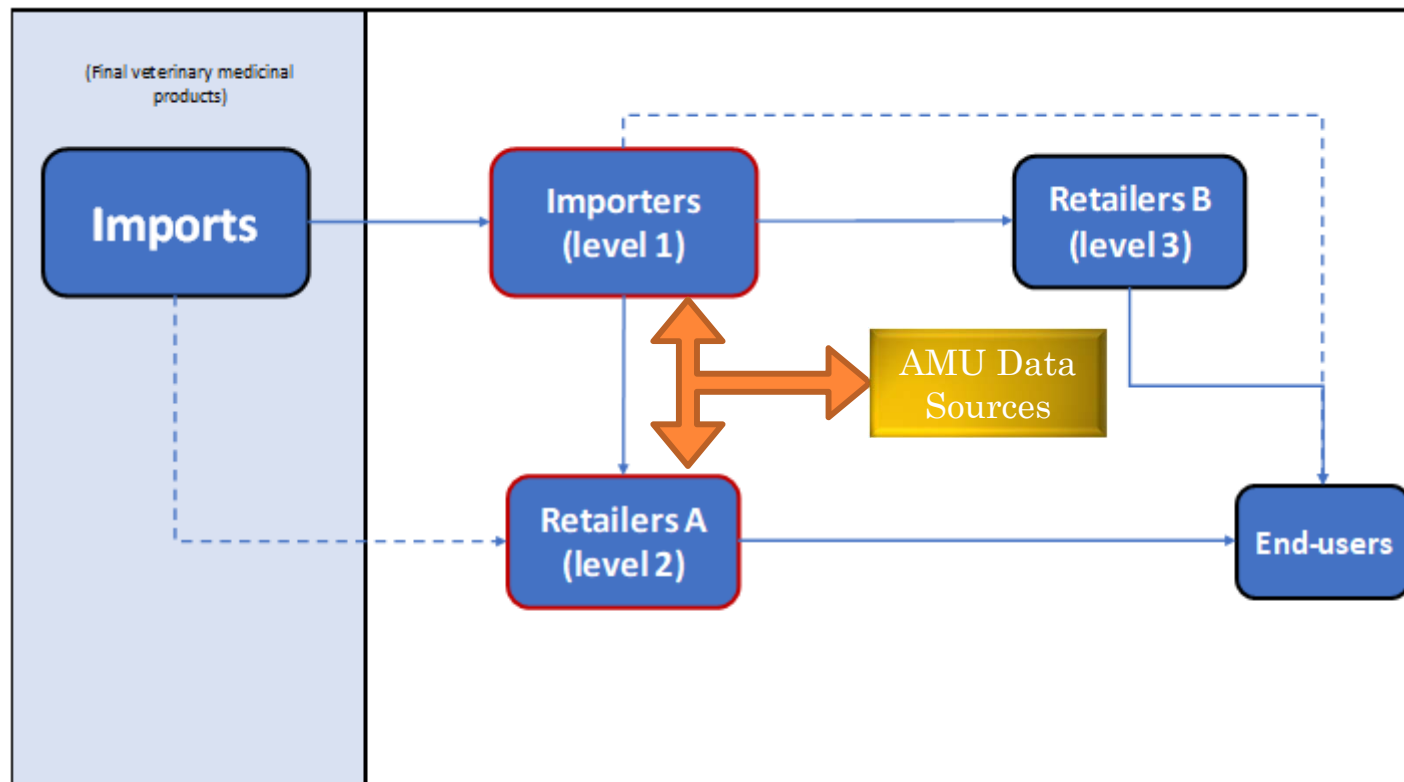
*1 On a separate sheet, indicate the supplier of each product locally purchased and quantities sourced from the supplier (e.g. 50 Mildox = 40 from Vulamasango + 10 from Zilwane Meds)

*2 On a separate sheet, all importers selling to other local retailers, indicate the distribution of each product sold (e.g. 500 Cosumix = 200 Public Sales + 100 TKZ Suppliers + 150 Bingo (PTY) Ltd + 50 Eyethu Logistics)



AMU DATA COLLECTION

- Source of data compiled and submitted to the OIE is from Level 1 & 2 Retailers, as Importers of final veterinary products and **sales** from retailers





AMU DATA COMPILATION

○ AMU Data Compilation

	A	B	C	D	E	F	G	H	I	J	K	L
1	Retailer	Product Trade Name	Package Size	Pack size (ml or g)	Packs Sold in 2017	Name of Active Ingredient	OIE Class of Antibiotic	Active Ingredient Concentration	Active Ingredient mass (g) per unit Volume (ml or g)	Amount Active Ingredient per pack in g	Total Amt of Active Ingredient sold in gams	Total amount of Active in Kg
72	Farm Servs	Terramycin eye powder	25g	25	0	Oxytetracycline	Tetracyclines	20mg/ml	0.02	0.5	0	0.00
73	Farm Servs	Terramycin LA	100ml	100	184	Oxytetracycline	Tetracyclines	200mg/ml	0.2	20	3680	3.68
74	Farm Servs	Terramycin LA	20ml	20	248	Oxytetracycline	Tetracyclines	200mg/ml	0.2	4	992	0.99
75	Farm Servs	Terramycin LA	500ml	500	6	Oxytetracycline	Tetracyclines	200mg/ml	0.2	100	600	0.60
76	Farm Servs	Tylovet 10%	100kg	100	60	tylosin	Macrolides	100g/kg	0.1	10	600	0.60
77	Farm Servs	Triple Sulfa	100g	100	146	Na Sulphamerazine	Sulfonamides	0.272g/g	0.272	27.2	3971.2	3.97
78	Farm Servs	Triple Sulfa	100g	100	146	Na Sulphamethazine	Sulfonamides	0.272g/g	0.272	27.2	3971.2	3.97
79	Farm Servs	Triple Sulfa	100g	100	146	Na Sulphathiazole	Sulfonamides	0.2985g/g	0.29859	29.859	4359.414	4.36
80	Farm Servs	Mastijet Forte	8g	8	1220	Tetracycline HCl	Tetracyclines	200mg/g	0.2	1.6	1952	1.95
81	Farm Servs	Mastijet Forte	8g	8	1220	Neomycin	Aminoglycosides	250mg/g	0.25	2	2440	2.44
82	Farm Servs	Mastijet Forte	8g	8	1220	Bacitracin	Polypeptides	2000IU	0.027028	0.216224	263.79328	0.26
83	Khuba	Alamycin LA	100ml	100	0	Oxytetracycline	Tetracyclines	200mg/ml	0.2	20	0	0.00
84	Khuba	Alamycin LA	500ml	500	0	Oxytetracycline	Tetracyclines	200mg/ml	0.2	100	0	0.00
85	Khuba	Coliprim	200ml	200	0	sulphachloropyridazine	Sulfonamides	10%	0.1	20	0	0.00
86	Khuba	Coliprim	200ml	200	0	trimethoprim	Sulfonamides	2%	0.02	4	0	0.00
87	Khuba	Cosumix Plus	200G	200	0	sulphachloropyridazine	Sulfonamides	100g/kg	0.1	20	0	0.00
88	Khuba	Cosumix Plus	200G	200	0	trimethoprim	Sulfonamides	20g/kg	0.02	4	0	0.00
89	Khuba	Cosumix Plus	20G	20	2428	sulphachloropyridazine	Sulfonamides	100g/kg	0.1	2	4856	4.86
90	Khuba	Cosumix Plus	20G	20	2428	trimethoprim	Sulfonamides	20g/kg	0.02	0.4	971.2	0.97
91	Khuba	Enroveto 20%	1L	1000	0	Enrofloxacin	Fluoroquinolones	200mg/ml	0.2	200	0	0.00
92	Khuba	ESB3	20G	20	0	sulphachloropyridazine	Sulfonamides	300g/kg	0.3	6	0	0.00



AMU DATA COMPILATION

○ AMU Data Compilation

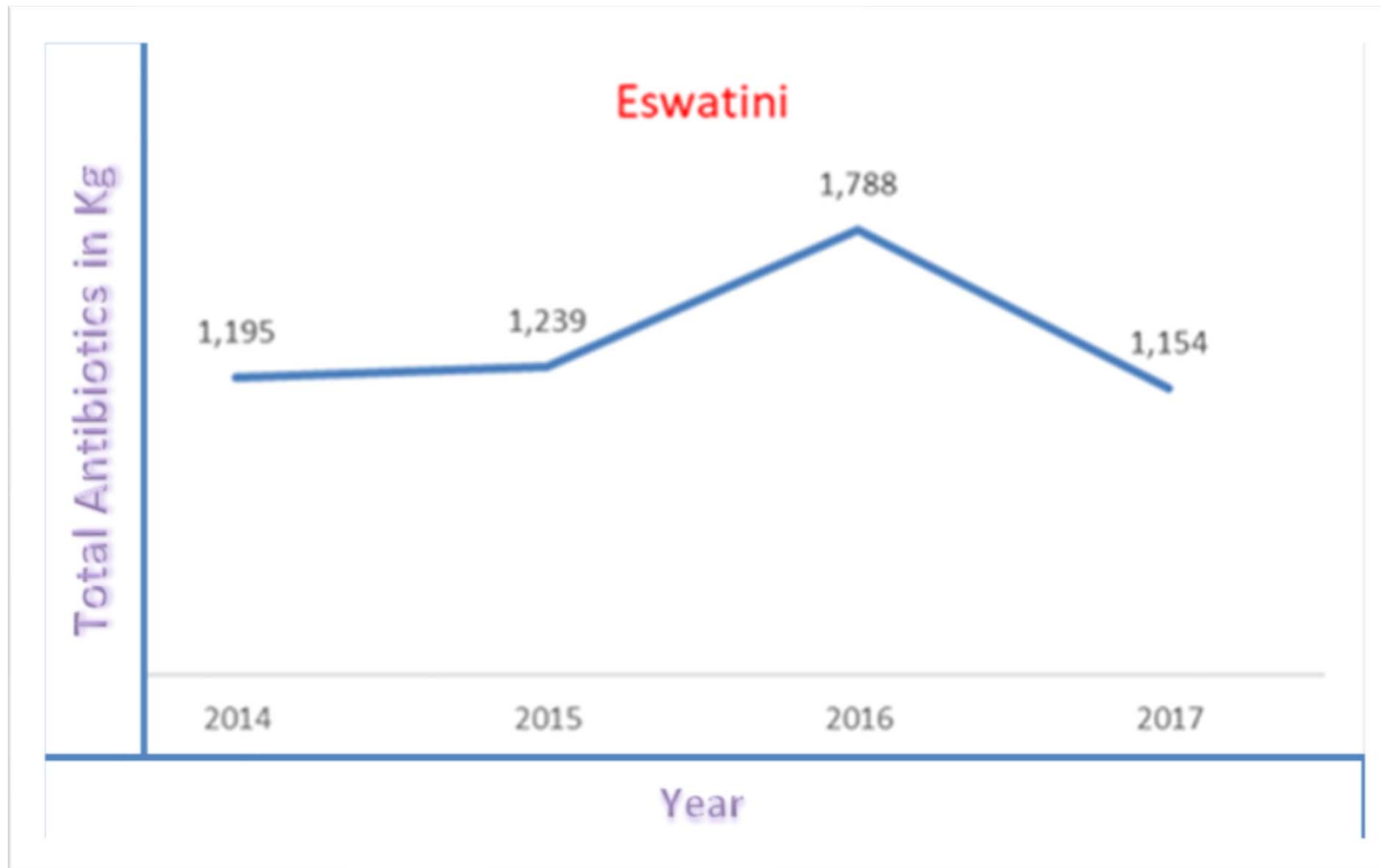
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290	TWK	Terramycin LA	20ml	20	41	Oxytetracycline	Tetracyclines	200mg/ml	0.2	4	164	0.16
291	V & H	Terramycin LA	100ml	100	111	Oxytetracycline	Tetracyclines	200mg/ml	0.2	20	2220	2.22
292	V & H	Terramycin LA	20ml	20	145	Oxytetracycline	Tetracyclines	200mg/ml	0.2	4	580	0.58
293	V & H	Terramycin LA	500ml	500	38	Oxytetracycline	Tetracyclines	200mg/ml	0.2	100	3800	3.80
294	Khuba	Terramycin LA	100ml	100	1420	Oxytetracycline	Tetracyclines	200mg/ml	0.2	20	28400	28.40
295	Khuba	Terramycin LA	20ml	20	1890	Oxytetracycline	Tetracyclines	200mg/ml	0.2	4	7560	7.56
296	Khuba	Terramycin LA	500ml	500	90	Oxytetracycline	Tetracyclines	200mg/ml	0.2	100	9000	9.00
297	Swaziphar	Terramycin LA	20ml	20	330	Oxytetracycline	Tetracyclines	200mg/ml	0.2	4	1320	1.32
298	Khuba	Tetra eye Powder	30G	30	0	Oxytetracycline	Tetracyclines	20mg/ml	0.02	0.6	0	0.00
299	Farm Servs	Ultratet	100ml	100	20	Oxytetracycline	Tetracyclines	125mg/ml	0.125	12.5	250	0.25
300	Farm Servs	Ultratet LA	100ml	100	17	Oxytetracycline	Tetracyclines	230mg/ml	0.23	23	391	0.39
301	Farm Servs	Ultratet LA	500ml	500	6	Oxytetracycline	Tetracyclines	230mg/ml	0.23	115	690	0.69
302							Tetracyclines					255.34
303												
304							Grand Total					1153.86





AMU DATA COMPILATION

- Eswatini AMU Data since 2014





AMU DATA COLLECTION CHALLENGES



○ Challenges

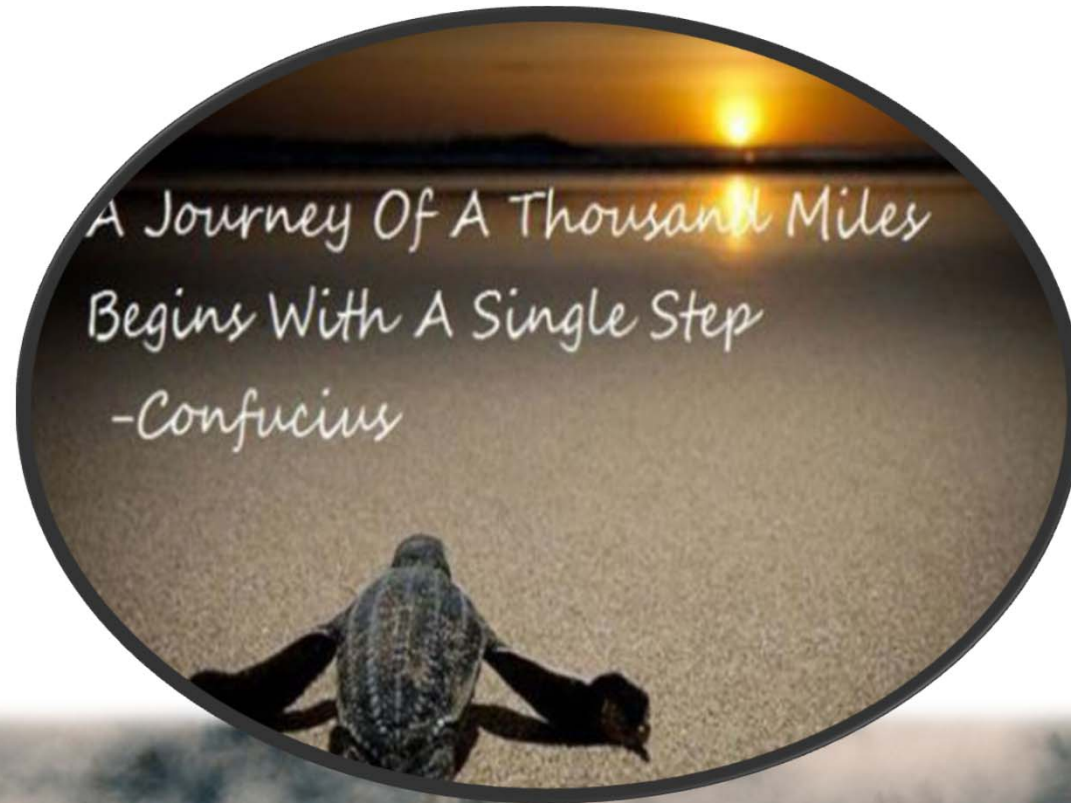
- Delayed feedback and submission by Retailers
- Data submitted in different formats – hard copies, Excel, Word, PDF
- Rarely, some product quantity discrepancies between two Level 2 and Level 1 Retailers who supplied one another & need for further engagements for reconciliation of data

○ Future Aspirations

- An Electronic Web-based VMP Database System
 - Publicly available list of authorized VMPs
 - E-permit system with retailer reconciliation module
 - Interphase with customs (ASYCUDA) system for accuracy of import data
 - Objective is easier and more accurate data collection



THANK YOU !



**It always seems
impossible until it's done.**

Nelson Mandela

