DAVA Systems' Issues raised by Industry

S.No.	Issues	Response
1.	Digital signature installation problem	Operational Problem at the client end. DAVA support teamwould provide necessary support whenever required.
2.	Recall Process	'Withdrawal Process' is available for Tertiary pack for exports. 'Recall Process' would be required with the implementation of system for domestic market.
3.	Requirement on human readable information	Already available in the Implementation Guidelines
4.	Movement and Distribution point details	These are part of implementation for Domestic Market.
5.	Unit price	Indication of Unit Price is optional.
6.	What is the exemption code format? Will it be different format for different target markets?	Details of Exception Codes are available in the 'Data Upload Guidelines'. These exemption code are fixed for all markets. Exemption code is required only in the TER file while uploading the Tertiary Data.
7.	What should the product image be of (actual product or unit pack)? Also the limit of 3 KB is too small for visibility	The earlier size limit of 3 KB has been increased to 10 KB.
8.	Do we need to affix 2 separate labels on US Pallets one covering US requirement and other covering DGFT Indiarequirement?	Separate barcode label as per DGFT notification need to be affixed in addition to the barcode labels as per importing countries' requirement, if any. At ports, the Indian Customs would scan the barcode labelled as per DGFT notification only.

9.	What if customers in US (for example) have different packaging hierarchy requirements (like using 7 as an indicator digit for GTINs of pallets) than what has been mandated by DAVA (rigid packaging level indicators like 5 for pallets and so on)	Separate barcode label as per DGFT notification need to be affixed which would use the indicator digit as mandated for DAVA system. The other country's labelling requirement to be followed in separate barcode label.
10.	Serial number uniqueness at product level instead of Manufacturer level, It creates practical problem in printing large serial numbers (say 20 char) on small packs.	Serial number uniqueness may be considered at GTIN level i.e. Manufacturer Code + Product Code.
11.	DAVA.gov.in portal links were not available intermittently or showing errors.	Temporary technical problems. Sorted out.
12.	Uploaded Data/Information are available on portal without secure access,it raises concerns about data security	Measures related to data security have been taken care.
13.	Registered Manufacturer login is not active	Being considered.
14.	Regulators should not define the GTIN indicator digit; it should be set by the manufacturer	Already explained at Sl.No. 9
15.	Exception should be granted on country-by- country basis, not a manufacturer-by-manufacturer basis or	As per Public Notice no. 3/2015-202- dated 21st April, 2016, exceptions are granted by Pharmexcil case to case basis to the manufacturer.

	product-by-product basis	
16.	Permit unique serial numbers for separate GTINs. Uniqueness, per GS1 standard and regulation, the traceability key should be identified by GTIN + Serial number not per Company.	Serial number uniqueness may be considered at GTIN level i.e. Manufacturer Code + Product Code.
17.	Allow automated upload of data	Yes. It can be done
18.	Remove the primary package serial number field	System is designed with assumptions of mandatory serialisation at primary level.
19.	Eliminate the requirement to upload product photos.	It is for value addition and optional and not mandatory
20.	Segregate the portal interface for exports and domestic product.	Not required.
21.	Allow pre-production files to be submitted in a way that permits batches to be split.	Data upload is after packaging and before dispatch.
22.	NIC should maintain development and simulation environments to support revisions to the DAVA portal.	Accepted. Necessary infrastructure is being put in place.
23.	NIC should establish a clear, predictable process for communicating revisions to the DAVA portal	Accepted Communication through SMS/ e-mail to registered user Intimation to user before expiry of DS is also being considered.
24.	The DAVA system should be designed based on global standards.	Following GS-1 India standards for labelling, UN location codes for country codes.

25.	Clarification is requested on the following scenarios: Bulk Pack/Semi-Finished Goods: Not considered a finished good or intended for commercial distribution Premix Goods: A blend of two or more ingredients in a semi-finished state. If bulk packaging is subject to requirements, how is the "tertiary package" defined? Goods Used for Trials: Placebo Goods: No active pharmaceutical ingredients, not considered a finished good Trial Samples: Not intended for commercial distribution	Policy matter.