DUPONT™ TYVEK® MEDICAL PACKAGING TRANSITION PROJECT (MPTP) FREQUENTLY ASKED QUESTIONS—NOVEMBER 22, 2013

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GENERAL

1. What is the DuPont Medical Packaging Transition Project (MPTP)?

This project is a plan to transition Tyvek® 1073B and Tyvek® 1059B to the latest flash-spinning technology and equipment. The project includes a systematic method for generating data to prove that the Tyvek® produced on the new lines is functionally equivalent in performance to the Tyvek® you purchase today, in an effort to help mitigate regulatory requalification.

There are three study components:

1. U.S. FDA Transition Protocol ("Transition Protocol")–a study plan involving production and testing of sterilized medical device packages that has been reviewed and accepted by the Center for Devices and Radiological Health (CDRH) at the U.S. FDA. Their letter of acceptance and the study plan are available on our website (www.Transition.Tyvek.com).

2. Phantom Protocol–additional testing of applications and technologies that are outside the scope of the Transition Protocol but have been requested by the industry to support risk assessments.

3. Product Stewardship–every DuPont product that is commercialized requires a formal DuPont Product Stewardship study to assess product risk and fitness for use.

2. What is included in the Phantom Protocol?

The Phantom Protocol includes things such as additional sterilization methods (steam, low-temperature oxidation and dry heat); package testing beyond 5-year aging; and studies of the effect of sterilization and aging on mechanical and microbial barrier properties. We are also conducting additional testing requested by the industry, including particle generation, printability and dimensional stability, to name a few. For a complete listing, visit our website (www.Transition.Tyvek.com).

3. What is included in Product Stewardship?

Every DuPont product that is commercialized requires a formal DuPont Product Stewardship study to assess product risk and fitness for use. For the MPTP, the study will include tests that are important to the medical device industry, including: cytotoxicity; bioburden; endotoxins; skin irritation and sensitization; U.S. and European Pharmacopeia/Food Contact; and extractables and leachables. Results will be published on our website (www.Transition.Tyvek.com).

4. Why is DuPont making this transition?

The transition of Tyvek® 1073B and Tyvek® 1059B to manufacturing lines using our latest flash-spinning technology will help ensure the continuity and flexibility of future supply.

5. Are Tyvek® Asuron™ and Tyvek® 2FS™ part of this transition?

No. Tyvek® Asuron™ and Tyvek® 2FS™ were commercialized on manufacturing lines that already use our latest flash-spinning technology, and, therefore, will not be part of the transition.

6. What is the purpose of controlled sales?

The purpose of controlled sales is to make Transition Protocol material available in advance of full commercialization to allow MDMs to conduct their internal risk assessments, including validating material for new or existing device packaging and/or conducting additional testing. It is **not** intended for packaging of existing commercial devices until applicable regulations in the country of sale are met.

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7. How do I get controlled sales material and can I specify that I want specific line/polymer combinations?

Controlled sales material is currently available through the SPMs. Because ALL line/polymer combinations represent the specification and miscellaneous properties published for Transition Protocol material, DuPont will fill orders from ALL line/polymer combinations randomly.

8. Is the controlled sales material available for purchase now? Are there specific requirements to allow one to purchase the material for testing purposes?

Controlled sales of Transition Protocol material to our direct customers (SPMs) began in July 2013. You should contact your SPMs to purchase controlled sales material.

9. Is there enough controlled sales material available to ensure that all MDM internal testing can be carried out?

Yes and we encourage all MDMs to use controlled sales material now to complete any additional testing as determined by their change control and risk assessments so that they are able to accept Transition Protocol material beginning in 1Q 2015. MDMs should discuss their plan and forecasted needs with their SPMs.

10. What can MDMs do now to prepare for full commercialization of Transition Protocol material?

MDMs should initiate their change management process, including risk assessments and associated documentation (considering applicable regulatory requirements) to ensure they are ready to accept Transition Protocol material when we commercialize in 1Q 2015. MDMs can use controlled sales material to complete any additional testing as determined by their risk assessments and should discuss their plan and forecasted needs with their SPMs.

11. Is the Transition Protocol material the same as what will be sold commercially?

Yes. Transition Protocol material used to create the packages for testing, sold for controlled sales and sold commercially after we receive affirmation from the regulatory bodies we have engaged, will all be made under the same manufacturing conditions.

12. Is commercial launch only contingent on U.S. FDA approval or other regulatory bodies also?

DuPont will begin transitioning to the newer manufacturing lines upon receipt of the letter from the U.S. FDA affirming functional equivalence, which is expected in 1Q 2015. It is important to note that a recommendation from the three-party committee in Japan was issued in November 2013 and a final report with results of functional equivalence is expected to be issued by CFDA-Jinan in January 2014.

13. Will customers receive styles from both the current and new lines during the transition?

Yes. The style names (i.e., 1073B and 1059B) will not change.

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14. Will customers know if material supplied after U.S. FDA approval is current or new material?

After receipt of the U.S. FDA letter affirming functional equivalence, which is expected in 1Q 2015, the Transition Protocol material will become interchangeable with current Tyvek®. Initially, we will fill orders using current and the new material to allow for an orderly changeover. Our direct customers will be able to determine which product they are receiving based on the product labeling.

15. If DuPont receives the U.S. FDA letter prior to 1Q 2015, will full commercialization also occur before 1Q 2015?

Based on the MPTP timeline, we anticipate receiving the U.S. FDA letter affirming functional equivalence in 1Q 2015. We do not anticipate receiving it any sooner.

16. When will we be given the specific date of when orders placed after that time will be filled by a mix of new and current material? Will we be able to place a significant last order of current material at that point?

We will announce to our direct customers and the industry at large when we fully commercialize the Transition Protocol material, which is anticipated 1Q 2015. You should take this time to complete your internal risk assessments and change control system requirements so you are prepared to accept Transition Protocol material and current Tyvek® product interchangeably.

17. When will DuPont shut down the older manufacturing lines?

We will begin transitioning to our newer lines upon receipt of the U.S. FDA letter affirming functional equivalence. We will discontinue manufacturing Tyvek® 1073B and Tyvek® 1059B on the older lines. We encourage you to use this time to complete your change control, risk assessments and necessary paperwork and be ready for the transition when we commercialize, which we estimate to be in 1Q 2015.

18. If I am not currently in the representative group of MDMs involved in Transition Protocol or Phantom Protocol testing, can I volunteer to be?

No, the test matrices have been finalized so we will not be able to accept any additional participants.

19. Are the MDMs who are participating in the MPTP representative of the entire spectrum of companies—from large to small and from all regions of the world?

The MDMs participating in the MPTP are from various regions around the world. Their packages represent a variety of different materials and configurations, collectively reflecting how Tyvek® is used in the industry.

20. Why are MDMs not identified on the list of companies participating in the MPTP?

To protect confidential information, we will not be publishing the list of MDMs participating in the MPTP.

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21. Can I see an actual copy of the Transition Protocol submitted to the U.S. FDA?

Since the document contains DuPont proprietary information, we cannot make it publicly available. Under confidentiality agreements, we will make details of the Transition Protocol available to companies participating in the MPTP.

22. Why are fewer packages made with Tyvek® 1059B included in the Transition Protocol?

Tyvek® 1073B is used in more applications globally and enables more complete matrix testing than Tyvek® 1059B. However, several of the more demanding applications for Tyvek® 1059B were added to demonstrate functional equivalence for this style. Any effects of radiation sterilization on Tyvek® 1059B will be identified through the data generated using Tyvek® 1073B, as the polymers used are identical.

23. How can the Transition Protocol be reflective of all the different packages that are possible?

When you look at all the types of packages that exist, they fall into three basic categories: 1) pouches & bags; 2) form-fill-seal applications; and 3) rigid trays & lids. Because every Transition Protocol package fits into one of these three categories, we are testing a representative cross-section of materials, package designs and manufacturers. It would be unrealistic and cost prohibitive to test every bottom web and/or coating combination in the industry.

24. Do MDMs need to do their own testing for configurations not covered in the Transition Protocol or the Phantom Protocol?

The intent of the MPTP is not to capture every possible material combination and sterilization method, but rather to show a broad cross-section of materials and sterilization methods used in the industry and prove the material produced using the latest flash-spinning technology is functionally equivalent to the current product. It's not practical to test every possible combination and sterilization method, which is why DuPont is using the principle of functional equivalence as the basis for this project.

25. What will be done when packages do not perform as expected?

Any package anomalies will be investigated for root-cause and the results of these investigations will be documented and reviewed with the U.S. FDA.

26. What about drug and other medicine or vaccine producers; are they covered in the Transition Protocol?

No. The Transition Protocol only includes medical devices regulated by the Center for Devices and Radiological Health (CDRH). Products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologic Evaluation and Research (CBER) are not included in the Transition Protocol. However, the Phantom Protocol includes combination products and pharmaceutical packaging applications.

Through the Phantom Protocol and Product Stewardship testing, we are generating data that drug companies typically reference on our current products.

Producers who market their products under pharmaceutical regulations should begin their change management process, including risk assessments, to prepare for full commercial launch.

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27. Will I know what package configurations and constructions are being tested for each Transition Protocol Test Matrix cell and any cells in the Phantom Protocol?

We have created the MPTP Cell Descriptor Selector Tool (available on our website at www.Transition.Tyvek.com) to provide MDMs with an easy way to view details about each cell, including package configurations and constructions, as well as sterilization information. Individual MDMs for each cell are not identified to protect proprietary and confidential information.

28. What if my company can't be ready for the transition by 1Q 2015?

We will assist you in developing a suitable plan. Please contact a member of our Global MDM Support Team to discuss your specific needs. You can find a listing of team members at www.Transition.Tyvek.com.

29. When will DuPont issue a formal change notification for the Transition?

In 1Q 2014, DuPont plans to send a Change Notification Letter to all SPMs with whom we have an executed Change Notification Agreement in place and to those companies with permission to reference information on Tyvek® 1073B and Tyvek® 1059B in our Device or Drug Master Files.

30. Will there be a cost difference between the current and the new material?

Pricing of controlled sales material we launched in July 2013 is the same as current commercial product. Going forward, pricing for all products will continue to be reviewed on an ongoing basis and adjusted based on a number of factors, including market dynamics, investment and cost to serve, among others.

31. Who can I talk to if I have more questions?

We have DuPont experts available in all regions to answer your questions. You can find contact information on our website (www.Transition.Tyvek.com).

32. How can I stay up to date with this ongoing process?

There are multiple ways for you to stay informed. You can visit the special section of our website (www.Transition.Tyvek.com); attend our global webcasts (or view them on-demand for up to a year); participate in one of our face-to-face seminars; or request an individual meeting with a member of our global team.

We encourage you to sign up to receive notifications when new information is posted. Signing up is easy; simply click on "Contact Us" in the upper right corner on our home page and complete the form.

REGULATORY

33. What role does the U.S. FDA play in the transition?

We engaged the Center for Devices and Radiological Health (CDRH) at the U.S. FDA to help mitigate regulatory requalification. CDRH provided input to the Transition Protocol design. Over the course of the protocol implementation, CDRH will review extensive data analysis by DuPont of independent third-party generated data to show that Tyvek® produced as a result of the transition does not represent a significant change in functional performance compared to current Tyvek®. If CDRH agrees with DuPont's analysis and conclusions, then it would issue guidance indicating that MDMs would not routinely be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot, change.

34. What guidance have you received from regulatory authorities outside the United States?

Europe

In Europe, the four largest Notified Bodies: BSI Assurance UK Ltd, SGS United Kingdom Limited, TÜV Rheinland® and TÜV SÜD Product Service GmbH issued guidance letters for European compliance. These four Notified Bodies received a copy of the U.S. FDA Transition Protocol Amendments and no issues have been reported.

For implementing the change, it is expected that manufacturers will have to review the change in Tyvek® and have documented records of their change review, including: review of risks, rationale for accepting the protocol conclusions for their application and/or identification of further testing required in accordance with their specific change assessment process, risk management process and sterilization standards. Published data from the Transition Protocol can be used in the MDM risk assessments. These records will need to be included in the respective medical device design files.

For Class Is, IIa and IIb devices: It is also expected that the Legal Manufacturers who hold CE Certification for Class Is, IIa and IIb will assess DuPont information within their specific change control process in accordance with sterilization standards and implement the change through their Quality System, which will be reviewed at the next scheduled Notified Body Audit.

For Class III devices: For Legal Manufacturers who hold CE Certification for Class III devices, it is expected that the impact of the change will be assessed, as well as the applicability of DuPont's information on the product, rationale for accepting the protocol conclusions for their application and/or identification of further testing required. This information should be submitted to the relevant Notified Body under a significant change notification. It is expected that the Notified Bodies will give consideration to the work carried out by DuPont in relation to the general aspects of the material equivalence when reviewing the significant change notification.

Japan

In Japan, a three-party meeting was held on September 25, 2013, with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceutical and Medical Device Agency (PMDA); the Association of Registered Certification Bodies (ARCB) under PAL; and the Japan Federation of Medical Device Association (JFMDA). Specification and miscellaneous properties of Transition Protocol materials were reviewed during the meeting. The recommendation from the three-party committee for Class II, III and IV medical devices is that MDMs should review their entries of record and assess if any information needs to be updated. If updates are required, MDMs simply need to submit a minor change notification (Keibi Henkou Todoke). This notification will **not** be audited or investigated by regulatory bodies; it is simply a report only. An example of the Japanese registration form of packaging material part, with English translation, is available on our website (www.Transition.Tyvek.com). The official Japanese guidance (Yakushokuki) describes the process of reporting partial changes made to medical devices under a minor change notification.

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China

In China, we are working with the China Food and Drug Administration (CFDA) Jinan Quality Supervision and Inspection Center for Medical Devices. CFDA-Jinan performed material property testing on current product as part one of a two-part study. In part two, they repeated the testing using Transition Protocol materials and control materials. Testing included: basis weight; Mullen burst; delamination; hydrostatic head; Gurley Hill porosity; microbial barrier; and tensile strength. Criteria were previously established for determining functional equivalence of specification and miscellaneous properties. The data looks good and is currently under review. A final report with results of functional equivalence is expected to be issued by CFDA-Jinan in January 2014. A summary of this final report will be posted on our website.

For more information

For additional information or to schedule a meeting with a DuPont representative, contact us through "Meet with DuPont Team Members" at www.Transition.Tyvek.com.

35. Have you taken into account the regulatory requirements of other countries such as Australia, Brazil, Canada and Korea?

We are working with authorities where the majority of medical devices are sold. The regulatory authorities we've engaged to date govern countries that account for greater than 90 percent of global single-use medical device sales.

If MDMs sell devices in a country other than those referenced here, they should contact their regulatory resources for that country to get change management guidance.

36. Does DuPont have a Drug and/or a Device Master File for Tyvek®, and will these files be updated or replaced after the transition?

DuPont has a Drug Master File and a Device Master File for Tyvek®. We will update both of these files, not open new ones. More information regarding the Transition Protocol material will be contained in the Device Master File than the Drug Master File because the U.S. FDA Transition Protocol is with CDRH.

37. What information will be included in your earliest submission to the U.S. FDA and what might delay the timing of your submission?

Independent third-party data will be submitted and includes: visual inspection; package integrity; seal strength; and microbial barrier after the following conditions: pre-sterilization, post-sterilization, 1, 3 and 5 year accelerated aging and 1 year real-time aging.

Our submission timing is currently on target; no delays are anticipated.

38. What are examples of language submitted in the Japanese regulatory files that would require re-submission?

The recommendation from the three-party committee for Class II, III and IV medical devices is that MDMs should review their entries of record and assess if any information needs to be updated. If updates are required, MDMs simply need to submit a minor change notification (Keibi Henkou Todoke). This notification will **not** be audited or investigated by regulatory bodies; it is simply a report only. An example of the Japanese registration form of packaging material part, with English translation, is available on our website at www.Transition.Tyvek.com.

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39. Has the U.S. FDA provided something in writing indicating MDMs will not need to submit 510(k) amendments? If so, how can we get a copy for our files?

We engaged the Center for Devices and Radiological Health (CDRH) at the U.S. FDA to help mitigate regulatory requalification. CDRH provided input to the Transition Protocol design. Over the course of the protocol implementation, CDRH will review extensive data analysis by DuPont of independent third-party generated data to show that Tyvek® produced as a result of the transition does not represent a significant change in functional performance compared to current Tyvek®. If CDRH agrees with DuPont's analysis and conclusions, then it would issue guidance indicating that MDMs would not routinely be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot, change. A copy of the letter from the U.S. FDA indicating their intent is currently posted on our website (www.Transition.Tyvek.com). A copy of the subsequent letter from the U.S. FDA affirming functional equivalence will be posted on our website when it is received.

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TECHNICAL

40. Will Tyvek® that is manufactured using the latest flash-spinning technology perform the same as current Tyvek®?

Data from developmental material testing and Transition Protocol material testing demonstrates evidence of functional equivalence. Sealing fingerprints, as well as material properties for styles produced on the newer lines vs. current material, are posted on our website (www.Transition.Tyvek.com).

41. Will there be any differences in the polymer used?

All polymers will continue to be virgin high-density polyethylene (HDPE). The HDPE being used was selected for specific attributes required to produce functionally equivalent Tyvek® styles.

42. How do you prevent cross contamination on the Tyvek® lines?

We have quality assurance measures and standard operating procedures in place to manage style and polymer transitions and prevent cross contamination.

43. Is distribution testing included in the Transition Protocol?

No. The Transition Protocol focuses on the sterile barrier performance of Tyvek® whereas transportation testing also tests the package design, pack-out configuration and protective packaging.

44. Why are steam, dry heat and/or low-temperature oxidative sterilization not included in the Transition Protocol?

The Transition Protocol is focused on the most commonly used sterilization methods, which include: ethylene oxide (EO), gamma irradiation and electron-beam. Steam, low-temperature oxidative and dry heat sterilization will be included in the Phantom Protocol.

45. Has DuPont performed any test that covers dry heat sterilization?

Dry heat sterilization is one of the sterilization methods included in the Phantom Protocol. The package configuration being tested is rigid trays with a lid of coated style 1073B.

46. The conditions for testing the effects of steam sterilization were listed as 127°C for 30 minutes. What could the effects be on the new Tyvek® if the exposure time is longer?

We are testing longer exposure times through Phantom Protocol cell testing. See the MPTP Cell Descriptor Selector Tool on our website (www.Transition.Tyvek.com) for details.

47. What data is available on the Transition Protocol material now that package testing for the Transition Protocol has begun?

Physical and mechanical property data for Tyvek® Transition Protocol material is posted on our website (www.Transition.Tyvek.com).

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48. What results will be publicly available after the completion of the MPTP testing? Will it be Tyvek® material data, packaging data or both?

We will be posting five Executive Summary Reports of MPTP package evaluation on our website (www.Transition.Tyvek.com), including:

- Report #1—Pre- and post-sterilization (T=0)
- Report #2—Accelerated aging (1, 3 and 5 years) and real-time aging (1 year)
- Report #3—Real-time aging (3 years) and accelerated aging (7 and 10 years)
- Report #4—Real-time aging (5 years)
- Report #5—Real-time aging (10 years)

In addition, we will post extensive Transition Protocol material data on our website as it becomes available.

49. Will you perform longer-term aging studies as part of the Transition Protocol, for example 10-year aging studies?

In the Phantom Protocol we will be generating 7- and 10-year accelerated aging data and 3-, 5-, and 10-year real-time aging data for a limited number of cells containing devices that currently have these extended expiry dates. In addition to these longer-term aging studies on packages, we will be generating 1-, 3-, 5-, 7- and 10-year accelerated **and** real-time aging data on Transition Protocol material.

50. What about Pharmacopeia and Food Contact Regulations?

While not an official part of the Transition Protocol, Tyvek® 1073B and Tyvek® 1059B produced on the newer assets will be Pharmacopeia and Food Contact compliant by meeting extractable testing and compositional requirements, as are the current commercial offerings. Test data required to meet these regulatory requirements will be generated as part of DuPont Product Stewardship testing.

51. What was the rationale behind choosing the accelerated aging conditions (i.e., 50°C ±4°C, and relative humidity of 23 ±7%)?

After surveying the industry, we chose 50°C because this is the least common denominator used in the industry today.

52. Why is dye penetration testing (ASTM F1929) being done, but no bubble leak testing (ASTM F2096)?

Dye penetration assesses the quality and integrity of the sealing interface between the (coated) Tyvek® and the film/tray. Bubble leak testing not only assesses this interface, but the adequacy of the package design and other materials of construction as well. The Transition Protocol is concerned with the seal integrity and not the package adequacy.

Bubble leak testing would require significantly more test method validation due to the wide range of coatings and packaging configurations being considered (e.g., a 1" x 4" pouch vs. 8" x 75" pouch). Additionally, ASTM precision and bias statements indicate ASTM F1929 provides higher confidence levels.

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53. Are all line/polymer combinations represented by the specification and miscellaneous properties published for Transition Protocol material?

Yes, all line/polymer combinations are represented.

54. We approve our validations to 3X EO cycles. Is it possible to perform 3X EO sterilization cycles on the new material?

There are several examples of package configurations being tested in the MPTP that are sterilized by 3X ethylene oxide (EO) cycles. You can conduct a search for these examples using the MPTP Cell Descriptor Selector Tool found on our website (www.Transition.Tyvek.com).

55. Are the FTIR and DSC reports available on the website?

All of the data shown during the October 2013 webcast, including the infrared spectrum "fingerprinting" via ATR-FTIR and the Differential Scanning Calorimetry (DSC), is posted on our website (www.Transition.Tyvek.com).

56. Do you have any test results for the mechanical strength of the new material vs. the current material?

We have posted a wealth of physical and mechanical property data for Transition Protocol material on our website at www.Transition.Tyvek.com. In addition, we have posted a data sheet showing a side-by-side comparison of the specification and miscellaneous properties of current DuPont™ Tyvek® vs. Transition Protocol material.

57. What type of printing processes were tested on Transition Protocol material?

As part of the additional data to be generated per industry requests, evaluations of flexographic and thermal printing on Transition Protocol material will be conducted in the Phantom Protocol. Results will be posted when available. It is also important to note that SPMs and MDMs participating in the MPTP have successfully printed Transition Protocol material using existing printing equipment and process conditions with no issues observed or reported.

58. Is there a table that you can provide which lists and compares all the parameters between current and new material?

Specification properties and miscellaneous properties of current Tyvek® and Transition Protocol material are shown side-by-side on data sheets that are available on our website (www.Transition.Tyvek.com).