ASTRAZENECA PLC Form 6-K June 23, 2016

#### FORM 6-K

# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

For the month of June 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

	Indicate by	v check mark	whether the	e registrant	files or	will file	annual repo	rts under co	over of Form	20-F	or Form	40-	F.
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Form 20-F X Form 40-F \_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes \_\_\_\_ No X

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-\_\_\_\_\_

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AstraZeneca today confirmed that the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) has provided its interim recommendation on the use of FluMist® Quadrivalent Live Attenuated Influenza Vaccine (FluMist Quadrivalent) in the US for the 2016-2017 influenza season. The updated guidance states the vaccine should not be used in any setting, based on CDC vaccine effectiveness data from the last three influenza seasons in the US, which indicated FluMist Quadrivalent did not demonstrate statistically significant effectiveness in children 2-17 years of age.

The US CDC effectiveness data for 2015-2016 season contrast with studies by AstraZeneca as well as preliminary independent findings by public health authorities in other countries. These findings demonstrate FluMist Quadrivalent was 46-58% effective overall against the circulating influenza strains during the 2015-2016 season. As influenza vaccine effectiveness varies from season to season, it is evaluated in annual observational studies. The CDC states that when there is a good match between the strains in the vaccine and those that circulate during the influenza season, vaccines are typically 50-60% effective. AstraZeneca is working with the CDC to better understand its data to help ensure eligible patients continue to receive the vaccine in future seasons in the US.

The distribution and use of the vaccine in other countries are progressing as planned for the forthcoming influenza season, pending the annual release process from relevant regulatory authorities.

#### Financial considerations

The US Product Sales of FluMist Quadrivalent in FY 2015 amounted to \$206 million. The ACIP's updated recommendation is expected to result in very limited US demand in the second half of 2016 and consequently the Company will take an inventory write-down of approximately \$80 million in the second quarter of 2016. The Company maintains its financial guidance for 2016.

#### About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - oncology; respiratory and autoimmunity; and cardiovascular and metabolic disease. We are also active in infection, neuroscience and inflammatory diseases through collaborations with others. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

### About FluMist Quadrivalent Live Attenuated Influenza Vaccine

FluMist Quadrivalent is the only widely available quadrivalent live attenuated influenza vaccine (LAIV), which is administered as a nasal spray and contains four protective strains for the prevention of influenza.

FluMist Quadrivalent was originally approved in the US in 2003 and since then more than 116 million doses have been distributed around the world. Global Product Sales of Fluenz/FluMist Quadrivalent in FY 2015 amounted to \$290 million.

#### 1 UK:

https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/530756/Influenza\_vaccine\_effectiveness in primary care in children.pdf

- 2 Finland: http://www.nvm2016.is/sites/default/files/Nohynek NorVac influenzaLessonsNohynek short.pdf
- 3 US: http://www.cdc.gov/flu/about/qa/vaccineeffect.htm

#### **CONTACTS**

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

23 June 2016

-ENDS-

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 23 June 2016 By: /s/ Adrian Kemp

Name: Adrian Kemp Title: Company Secretary