#1 ) 80 milligram, qd	CIOMS FORM														RM											
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REACTION INFORMATION	SUSPECT ADVERSE REACTION REPORT																									
1. I. PARTICHE NATIONAL (Inst lated) PRIVACY   2. ADME OF SIRTH   2. AGE   3. SEX   3. WEIGHT   4.6 REACTION CRISET   4.6 REACTION	303FEOT ADVENSE REACTION REPORT																		_		_	_	_	_		
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1.PATIENT NATION   TO CONTROL						RFA	CTIC	או וא	NFOF	RMATION	d				•							•	•	•		
### TAST SESCRES READTON(S) (including primorit stacklass desc.)    Fair Note   Fair Note											_	4-6 RE	EACTI	ON C	ONSE	T	8-	12	СH	ECK	AL	L	- +0			
7.* 13 DECRETE REAL CENTRAL (Related product product serious Listed classifility Causality Causa	DOMINICA	AN REPUBLIC				Year	Unk		Male Unk								1									
Product   Santa   Causality	7 + 13 DESCRIBE REACTION(S) (in							<u> </u>						1	$\boxtimes$	PATI	ENT DI	ED								
Death (unknown cause) [Death]   TAGRISSO   Yes   No   Applicable   Related   NOCUMED PRESISTENT OF SIGNIFICATION   CONGENITAL   NOCUMED PRESISTENT OF SIGNIFICATION   CONGENITAL   NOCUMED PRESISTENT   NOCUMED PRESISTENT   CONGENITAL   NOCUMED PRESISTENT   NO	Event Verbatim [PREFERRED ]	TERM] (Relate		1	duct	Ser			ous	Listed							(		PRO	LONGE	ED II		ENT			
(Continued on Additional Information Page)    II. SUSPECT DRUG(S) (Include generic name)	Death (unknown cause) [Dea	ath]		TAC	TAGRISSO					No						HOSPITALISATION INVOLVED PERSISTENT										
THREATENING   CONCENTIAL ANCOMAIV																			DISA	ABILITY	OR					
(Continued on Additional Information Page)    II. SUSPECT DRUG(S) INFORMATION   III. SUSPECT DRUG(S) INFORMATION													LIFE THREATENING													
Continued on Additional Information Page																	۱ (				AL					
II. SUSPECT DRUG(S) (include generic name) #1 ) TAGRISSO (OSIMERTINIB) Tablet #1 ) TAGRISSO (OSIMERTINIB) Tablet #1 ) DAILY DOSE(S) #1 ) 80 milligram, qd #1 ) Oral use    Total use   Tot																										
14. SUSPECT DRUG(S) (include generic name)   20. DID REACTION   ARAPE AFTER STOPPING   TAGRISSO (OSIMERTINIB) Tablet   15. DAILY DOSE(S)   16. ROUTE(S) OF ADMINISTRATION									(Conti	inued on Add	dition	nal In	form	atio	n Pa	ige)	<u> </u>	_			_					
## ) TAGRISSO (OSIMERTINIB) Tablet    ABATE AFTER STOPPING ORDIGS				II.	SUS	PEC	T DF	RUG	i(S) II	NFORM <i>A</i>	TIC	NC					_				_					
#1 ) 80 milligram, qd			t																ABATE AFTER STOPPING							
#1 ) 80 milligram, qd	, , , , , , , , , , , , , , , , , , , ,										_															
#1 ) LUNG CANCER (Lung cancer)  #2   THERAPY DATES (from/fo)	15. DAILY DOSE(S) #1 ) 80 milligram, qd																		YES NO NA							
III. CONCOMITANT DRUG(S) AND HISTORY    III.	17. INDICATION(S) FOR USE							<u> </u>																		
#1 ) Unknown #1 ) Unknown #1 ) Unknown   #1 ) Unknown     YES   NO     NA	#1 ) LUNG CANCER (Lung cancer)																									
III. CONCOMITANT DRUG(S) AND HISTORY  22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)  23. OTHER RELEVANT HISTORY, (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates  Type of History / Notes Description Lung cancer (Lung cancer)  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES  III. CONCOMITANT DRUG(S) AND HISTORY  Ureal Reaction  25. REMARKS World Wide #: DO-ASTRAZENECA-202507CAM027715DO Study ID: PSP-23269 Case References: DO-AstraZeneca-CH-00922711A	18. THERAPY DATES(from/to)																	TYES THO MANA								
22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)  23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates  Type of History / Notes Description Unknown to Ongoing Indication Lung cancer (Lung cancer)  IV. MANUFACTURER INFORMATION  24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES	#1 ) Unknown #1							#1)	) Unknown																	
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24c. DATE RECEIVED BY MANUFACTURER  24d. REPORT SOURCE STUDY  LITERATURE  NAME AND ADDRESS WITHHELD.	24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT			NAM	E AND ADD	KES	S W	/IIHl	ΗEL	.U.															
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X INITIAL

FOLLOWUP:

Mfr. Control Number: 202507CAM027715DO

## **ADDITIONAL INFORMATION**

## 7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a male patient (age not provided).

Medical history and concomitant products were not reported.

On an unknown date, the patient started treatment with Tagrisso (osimertinib) 80 milligram everyday orally for lung cancer.

It was unknown if any action was taken with Tagrisso (osimertinib).

The patient died (preferred term: Death) on an unspecified date.

It was not known whether an autopsy was performed. The cause of death was death.

The reporter assessed the event as serious due to seriousness criteria of Death.

The reporter did not assess causality for death (unknown cause).

The company physician did not consider that there was a reasonable possibility of a causal relationship between Tagrisso and the following event: death (unknown cause).