



Department for Work and Pensions

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Social Security Administration Act 1992

Vinyl Chloride Monomer-Related Diseases

Report by the Industrial Injuries Advisory Council
in accordance with Section 171 of the
Social Security Administration Act 1992
reviewing the prescription of the
vinyl chloride monomer-related diseases.

*Presented to Parliament by the Secretary of State for Work and Pensions
by Command of Her Majesty
November 2005*



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INDUSTRIAL INJURIES ADVISORY COUNCIL

Secretary of State for Work and Pensions

Dear Secretary of State,

REVIEW OF VINYL CHLORIDE MONOMER-RELATED DISEASES

1. Our review has considered the research literature published before and since the Industrial Injuries Advisory Council (IIAC) Command Paper “Conditions due to Chemical Agents” published in 2002 (Cm 5395). This new review stems primarily from continuing uncertainty about the relationship of Raynaud’s phenomenon and scleroderma to osteolysis in vinyl chloride monomer (VCM)-exposed workers.

2. The existing regulations state that these three conditions must occur together in order for claimants to be eligible for prescription. We decided we needed to review, specifically, this narrow topic, to resolve a medical issue that has caused confusion in judicial decisions. We have concluded that the prescription for Prescribed Disease (PD) C24(b) should be amended so that osteolysis, VCM-related Raynaud’s phenomenon and VCM-related scleroderma are all prescribed independently. However, for reasons explained in the report we have recommended that, in claims related to Raynaud’s phenomenon, the claimant must have been employed in the prescribed occupation before 1 January 1984. We also emphasise that exposure to polyvinyl chloride (PVC) does not meet the terms of prescription.

3. We have taken this opportunity to consider prescription for VCM-related liver tumours, other than angiosarcoma, as we were aware of a growing research literature concerning this. However, there was insufficient evidence of excess risk for liver tumours other than angiosarcoma in VCM-exposed workers. We have therefore, not recommended prescription, but we will continue to monitor future research about this topic.

Yours sincerely

Professor A J Newman Taylor

Chairman

Date: November 2005

The Industrial Injuries Disablement Benefit Scheme

1. The Industrial Injuries Disablement Benefit (IIDB) scheme provides a benefit that can be paid to an employed earner because of an industrial accident or prescribed disease. The benefit is non-contributory and ‘no-fault’, and is paid in addition to other incapacity and disability benefits, although it is taken into account when determining the level of payment for income-related benefits. It is tax-free and administered by the Department for Work and Pensions.

The role of the Industrial Injuries Advisory Council

2. The Industrial Injuries Advisory Council (IIAC) is an independent statutory body set up in 1946 to advise the Secretary of State for Social Security on matters relating to the Industrial Injuries scheme. The major part of the Council’s time is spent considering whether the list of prescribed diseases for which benefit may be paid should be enlarged or amended.

The legal requirements for prescription

3. The Social Security Contributions and Benefits Act 1992 states that the Secretary of State may prescribe a disease where he is satisfied that the disease:

- a) ought to be treated, having regard to its causes and incidence and any other relevant considerations, as a risk of the occupation and not as a risk common to all persons; and
- b) is such that, in the absence of special circumstances, the attribution of particular cases to the nature of the employment can be established or presumed with reasonable certainty.

4. In other words, a disease may only be prescribed if there is a recognised risk to workers in an occupation, and the link between disease and occupation can be established or reasonably presumed in individual cases.

Historical background

5. The word acro-osteolysis is derived from Greek words *Akron* = extremity, *Osteon* = bone, *Lysis*= dissolution. Bone loss in the finger-tips due to exposure to vinyl chloride monomer (VCM) was first described in 1966 when the term acro-osteolysis was used to name the condition. It was a report of two cases, both of whom had accompanying skin changes (scleroderma). A further study of thirty-one cases of bone lysis in 1967 reported that most of the cases had both bone lysis and Raynaud’s phenomenon. Many papers have since been written documenting the association of bone lysis, scleroderma and Raynaud’s phenomenon. It seems to have been the frequency with which osteolysis was accompanied by scleroderma and Raynaud’s phenomenon that led to the term acro-osteolysis being extended beyond its original meaning, to become the name of a syndrome characterised by all three conditions. While this was convenient and may have had some clinical value it was an imprecise use of the term and has led to confusion.

6. In 1974 IIAC was asked by Ministers to consider the question of prescribing acro-osteolysis in relation to VCM poisoning. On the advice of the Council this reference was widened and in 1975 Ministers asked it to consider whether any condition resulting from exposure to VCM should be prescribed.

7. The Council made its original recommendations in relation to VCM in 1976 (Cmnd. 6620). In its report it stated that the word acro-osteolysis was initially used to name the unusual condition of the fingers of some men engaged in the cleaning of the inside of VCM polymerisation vessels. It said of acro-osteolysis that this was a term which was understood to describe a condition mainly affecting the fingers; that it encompassed a number of conditions; and in some reports it was not always evident which conditions were being discussed.

8. IIAC, at that time, preferred not to use the term acro-osteolysis but to look at each of the conditions that it encompassed as single entities. In this way the members found that there was sufficient evidence of a connection between VCM and osteolysis of the terminal phalanges of the fingers to recommend prescription. "Osteolysis of the terminal phalanges of the fingers" was made a prescribed disease (C24(b)) in 1977. In regard to Raynaud's phenomenon, the report recommended that it should not be prescribed as there was insufficient evidence at that time to show that the risk of developing the disease was greater than that among the general population. It found insufficient evidence that the skin changes were specific to VCM exposure.

**Background for
current review**

9. Osteolysis of the terminal phalanges is probably a late manifestation of pathological changes caused by VCM that affect the connective tissue of the skin, the small blood vessels of the digits and of the bones. While case studies of osteolysis associated with VCM exposure often report Raynaud's phenomenon, scleroderma, or both, surveys of factory workers at different PVC production sites (as carried out in the 1970s and earlier) indicate a greater proportion of workers with scleroderma and Raynaud's phenomenon without osteolysis, than would be expected in the general population.

10. In its review "Conditions due to Chemical Agents" (Cm 5395, 2002) IIAC chose to review osteolysis of the fingers, Raynaud's phenomenon and scleroderma in relation to VCM exposure, using the word 'acro-osteolysis' in its common medical usage as the syndrome of that name. In summarising the evidence the report stated that acro-osteolysis is characterised by the three conditions but did not clarify the extent to which the three conditions needed to occur together.

11. In December 2002 the Council approved regulations subsequently drawn up, in which Raynaud's phenomenon and scleroderma were prescribed in connection with lytic bone changes.

12. In July 2004 the Council's attention was drawn to the fact that an appeal tribunal had decided to diagnose Prescribed Disease (PD) C24(b) on the basis of Raynaud's phenomenon alone while, in a different case, the decision had been that Raynaud's phenomenon could not be diagnosed as Prescribed Disease (PD) C24(b) in the absence of bone lysis. Regardless of the judicial aspects, these conflicting decisions on diagnosis showed continuing medical uncertainty, reflected among IIAC members, as to whether Raynaud's phenomenon should be prescribed in its own right.

13. The membership of IIAC has changed since the completion of Cm 5395, except for the Chairman and one member, and the Council decided that the only way to clarify the position was to reassess the research evidence on the narrow aspect at issue and to conduct a fresh literature search. No new peer-reviewed papers were

found which had been published since the publication of Cm 5395, but the Council did take into account evidence in a published letter about Raynaud's phenomenon and scleroderma caused by VCM.

Evidence considered
VCM-related Raynaud's
phenomenon

14. IIAC has investigated in great detail whether Raynaud's phenomenon and scleroderma meet the requirements for prescription in their own right when arising from VCM exposure. The epidemiological evidence on which to base a definite answer is limited. It is easy to see why there has been ambiguity over this issue and we appreciated the need to provide clearer guidance than in our previous report to meet current needs in settling claims for the prescribed disease.

15. The research evidence considered by the Council encompassed all of the material published before and since the publication of Cm 5395. Further epidemiological evidence is unlikely ever to be available as the industrial practices which led to sufficient number of cases for such research have long since disappeared. Therefore, we have based our conclusions on scrutiny of case reports, epidemiological surveys and discourses on the pathology of the different conditions. This included recent literature that indicated that there is more than one pathological process to chronic Raynaud's phenomenon following VCM exposure.

16. The totality of the evidence has led the Council to conclude that an association exists between VCM exposure and Raynaud's phenomenon in the absence of osteolysis in the digits, and also between VCM exposure and scleroderma in the absence of osteolysis in the digits. The evidence indicates that the increased frequency of these conditions allows attribution to exposure to VCM in the individual case. There is consistent evidence that the inhalation of VCM in PVC production workers causes a characteristic clinical triad of osteolysis of the terminal phalanges, scleroderma and Raynaud's phenomenon, but not all three are invariably present together. Surveys of factory workforces have shown that among those exposed to VCM who do not have radiological evidence of osteolysis, the prevalence of Raynaud's phenomenon and scleroderma is greater than in the general population. In the circumstances, the Council believes it would be inappropriate to exclude from benefit those workers who have evidence of diseases clearly caused by VCM inhalation, but who do not have osteolysis of the terminal phalanges. The Council is unanimous in its view that the evidence indicated that the frequency of these conditions occurring in workers exposed to VCM is more than double that expected in the general population; that they may occur in the absence of osteolysis; and that they should be prescribed in addition to osteolysis in those exposed to VCM in the manufacture of PVC.

VCM-related liver
tumours

17. The Council was also made aware of a growing research literature concerning possible vinyl chloride monomer-related liver tumours, other than angiosarcoma. Following a literature search on the topic, the Council concluded that there was insufficient evidence that the risk of liver tumours, other than angiosarcoma, was more than doubled in any occupational group. However, the Council will continue to monitor the research literature should new evidence become available in the future.

**Occupational
considerations**

18. Once the association between VCM exposure and disease was clearly identified in the late 1960s, immediate changes to work practices were made to meet stringent new Health and Safety Executive (HSE) exposure limits. The change was

so rapid and so effective that the IIAC report of 1976, included the views of both employers' and employees' representatives that the levels of exposure in industry were usually substantially lower than those laid down in the Code of Practice; the levels set in the code were reduced still further during production of the report. Taking this into account and in the light of recent advice from the HSE, the Council considers that Raynaud's phenomenon should only be prescribed for workers who worked in the industry before 1 January 1984. This date is chosen as the cut-off as this was the year that HSE published figures to confirm that all production sites in the UK met the occupational exposure limits. After that date it would not be possible to attribute causation of Raynaud's phenomenon to VCM in an individual case on the balance of probabilities.

19 Angiosarcoma, liver fibrosis and scleroderma have a sufficiently low incidence in the general population that no occupational time limit need apply when these conditions occur in someone who has been exposed to VCM in the manufacture of PVC.

Recommendations

20. IIAC recommends that the description of Prescribed Disease (PD) C24 should be changed from that set out in current regulations. We believe that the term acro-osteolysis has proved too confusing as it refers both to a specific condition and to a syndrome the features of which may vary from one person to another. We recommend that the term is dropped and that osteolysis of the finger-tips, Raynaud's phenomenon and scleroderma are each prescribed independently.

21. We recommend that a person claiming for vinyl chloride monomer (VCM) – related Raynaud's phenomenon must have been in the prescribed employment before 1 January 1984 in order to meet the terms of prescription.

22. We underline that the disease PD C24 relates only to exposure to VCM, and that exposure to polyvinyl chloride (PVC) is not sufficient to qualify.

23. Regarding liver tumours other than angiosarcoma we do not recommend prescription on the basis of current evidence although we shall continue to keep the matter under review.

Conclusion

24. We appreciate that these recommendations will require a change in the regulations which were based on the 2002 report "Conditions due to Chemical Agents" (Cm 5395). However, we have now reached a clear and definite view on this issue and regulations that enact our recommendations would resolve the prevailing uncertainty and be the fairest way to proceed for the small number of workers affected.

Our recommendation is that the prescription for PD C24 should now be as follows:

Prescribed disease	Occupation
<p>C24 Exposure to vinyl chloride monomer causing:</p> <ul style="list-style-type: none"> a) Angiosarcoma of the liver, or b) Osteolysis of the terminal phalanges of the fingers, or c) Vinyl chloride monomer-related Raynaud’s phenomenon, or d) Vinyl chloride monomer-related sclerodermatous thickening of the skin, particularly but not exclusively of the hands, or e) Liver fibrosis 	<p>Work involving exposure to vinyl chloride monomer in the manufacture of polyvinyl chloride. (Where C24c occurs in the absence of C24a,b,d or e the occupational exposure must have occurred before 1 January 1984). (Exposure to polyvinyl chloride (PVC) is not a cause of the prescribed disease.)</p>



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